



Oregon State University
Research Office

Office of Research Integrity
Human Research Protection Program
& Institutional Review Board

Policy and Procedure Manual

FWA00003920 ○ IRB00000122 ○ IORG0000084

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Table of Contents

1.	Human Research Protection Program	8
1.1	Institutional Policy	8
1.2	Institutional Authority	9
1.3	Mission	10
1.4	Ethical Principles	11
1.5	Regulatory Compliance	12
1.6	Federalwide Assurance (FWA)	12
1.7	Regulatory FLEXibility	12
1.8	Research Requiring IRB Review	13
1.9	Written policies and procedures	15
1.10	Organization of the Human Research Protection Program	16
1.10.1	Institutional Official	16
1.10.2	Associate Vice President for the Office of Research Integrity	17
1.10.3	Human Research Protection Program Administrator	17
1.10.4	Institutional Review Board	17
1.10.5	Executive Committee	18
1.10.6	Human Research Protection Program Staff	18
1.10.7	Unit Heads	18
1.10.8	Investigators	18
1.10.9	Other Related Units	19
1.10.9.1	<i>Research Conflict of Interest Program</i>	19
1.10.9.2	<i>Animal Program Office</i>	19
1.10.9.3	<i>Diving Safety and Small Boats</i>	19
1.10.9.4	<i>Export Control and International Compliance</i>	19
1.10.9.5	<i>Office for Commercialization & Corporate Development</i>	19
1.10.9.6	<i>Office for Sponsored Research Award Administration</i>	20
1.10.9.7	<i>Radiation Safety Committee</i>	20
1.10.9.8	<i>Biological Safety Committee</i>	20
1.10.9.9	<i>Chemical Safety Committee</i>	21
1.10.9.10	<i>Office of General Counsel</i>	21
1.10.10	Relationship Between Components	21
1.10.10.1	<i>Office of Research Integrity</i>	21
1.10.10.2	<i>Research Integrity and Environmental Health and Safety</i>	22
2	Investigator Responsibilities	22
2.1	Policy	22
2.2	Investigators	22
2.2.1	Procedures for Certifying Research Team Members	23
2.3	Responsibilities	24
2.4	Training for Investigators	25
2.4.1	Initial and Continuing Education	25
3	Quality Assurance/Quality Improvement Activities	25
3.1	Post-Approval Monitoring	26
3.1.1	Consent Monitoring	26
3.2	External Site Audits and Compliance Reviews	27
3.3	IRB Internal Compliance Reviews	27
3.4	Reporting and Disposition	27

4	Institutional Review Board.....	28
4.1	Policy.....	28
4.2	IRB Authority.....	28
4.3	Number of Boards.....	29
4.4	Board Composition.....	29
4.5	Board Membership.....	30
4.5.1	Appointment of Members to the IRB.....	31
4.5.2	Chair of the IRB.....	31
4.5.3	Vice Chair of the IRB.....	31
4.5.4	Alternate members.....	32
4.5.5	Subcommittees of the IRB.....	32
4.6	IRB Member Conflict of Interest.....	32
4.7	Duties of IRB Members.....	34
4.8	Attendance Requirements.....	34
4.9	Education for IRB Members.....	34
4.9.1	Orientation.....	35
4.9.2	Continuing Education.....	35
4.10	IRB Member Performance.....	35
4.11	Liability Coverage for IRB Members.....	36
4.12	Use of Consultants.....	36
4.13	Reporting and Investigation of Allegations of Undue Influence.....	37
5	Records and Documentation.....	37
5.1	Policy.....	37
5.1.1	IRB Records.....	37
5.2	IRB Study Files.....	38
5.3	IRB Minutes.....	38
5.4	IRB Minutes and Public Records Requests.....	40
5.5	IRB Membership Roster.....	40
5.6	Documentation of Exemptions.....	41
5.7	Documentation of Expedited Reviews.....	41
5.8	Access to IRB Records.....	42
5.9	Record Retention.....	42
6	IRB Review Process.....	44
6.1	Sponsored Research.....	44
6.1.1	Policy.....	44
6.1.2	Definitions.....	44
6.1.3	Responsibility.....	44
6.2	Conflict of Interest in Research.....	45
6.2.1	Policy.....	45
6.2.2	Definitions.....	45
6.2.3	Investigator Conflicts of Interest.....	46
6.2.3.1	<i>Evaluation of COI</i>	46
6.2.3.2	<i>Management of COI</i>	46
6.2.4	Recruitment Incentives.....	46
6.2.5	Institutional Conflict Of Interest.....	47
6.2.6	Identification of Institutional Conflict of Interest.....	47
6.2.7	Management of Conflict of Interest.....	47
6.2.7.1	<i>Decision making</i>	47
6.2.7.2	<i>Evaluation of risk</i>	47
6.2.7.3	<i>Potential actions</i>	47
6.3	Levels of Review.....	48

6.4	Exempt Studies	48
6.4.1	Authority to Grant Exemptions	49
6.4.2	Limitations on Exemptions	49
6.4.3	Categories of Exempt Research	49
6.4.3.1	Category 1.....	49
6.4.3.2	Category 2.....	49
6.4.3.3	Category 3.....	50
6.4.3.4	Category 4.....	50
6.4.3.5	Category 5.....	51
6.4.3.6	Category 6.....	51
6.4.3.7	Category 7.....	52
6.4.3.8	Category 8.....	52
6.4.4	FDA Exemptions	52
6.4.5	EPA Exemptions	52
6.4.6	Procedures for Exemption Determination	52
6.5	Expedited Review	53
6.5.1	Authority to Grant Approval.....	53
6.5.2	Categories of Research Eligible for Expedited Review	54
6.5.3	Expedited Review Procedures	56
6.5.4	Informing the IRB	57
6.6	Convened IRB Meetings	58
6.6.1	IRB Meeting Schedule	58
6.6.2	Preliminary Review	58
6.6.3	Primary and Secondary Reviewers.....	58
6.6.4	Pre-Meeting Distribution of Documents	59
6.6.5	Materials received by the IRB	59
6.6.6	Quorum	59
6.6.7	Meeting Procedures	60
6.6.8	Guests.....	61
6.7	Cooperative Research Projects	61
6.7.1	§46.114 Cooperative research.....	62
6.7.2	§56.114 Cooperative research.....	63
6.7.3	Research Funded by the NIH.....	63
6.7.4	Exempt Research.....	63
7	FDA-Regulated Research.....	64
7.1	Policy.....	64
7.2	Definitions	65
7.3	FDA Exemptions	65
7.4	Investigational New Drugs (INDs).....	65
7.4.1	Drugs and Biologics	66
7.4.2	Dietary Supplements.....	66
7.4.3	Food	67
7.4.4	Structure and Function vs. Disease Claim	67
7.4.4.1	<i>Studies Intended to Support a Health Claim</i>	68
7.4.5	Bioequivalence and Bioavailability Studies	68
7.4.6	IND Exemptions	69
7.4.7	IND Requirements.....	69
7.5	Investigational Device Exemptions (IDEs)	70
7.5.1	Medical Devices	70
7.5.2	Devices Exempted from IDE Requirements.....	70
7.5.3	Risk Determination.....	71
7.5.4	IDE and Related Requirements	71

7.6	Responsibilities	72
7.6.1	Investigator Responsibilities	72
7.6.2	IRB Responsibilities	74
7.6.3	Import and Export of Investigational Devices	75
8	Submission Types	75
8.1	Determination of Human Subjects Research	75
8.2	Determination of Engagement	76
8.3	§46.118 Determinations	76
8.4	Initial Application & Protocol	77
8.5	Continuing Review	77
8.5.1	Continuing review of research reviewed by the full board	77
8.5.1.1	<i>Approval Period</i>	77
8.5.1.2	<i>Continuing Review Process</i>	78
8.5.2	Research for which continuing review is not required	78
8.5.3	Continuing Review of Expedited Research	79
8.5.4	Lapse in IRB Approval	79
8.5.5	Period of Approval	79
8.5.5.1	<i>Review More Often Than Annually</i>	80
8.5.5.2	<i>Determination of Approval, Expiration, and Administrative Check-In Dates</i>	81
8.6	Project Modifications	81
8.6.1	Regulatory requirement	81
8.6.2	Policy	82
8.6.3	Modifications to Full Board Studies	82
8.6.3.1	<i>Minor Change</i>	82
8.6.3.2	<i>Full Board Review of Project Modifications</i>	82
8.6.4	Modifications to Expedited Studies	83
8.6.5	Modifications to Exempt Studies	83
8.6.6	Exceptions	83
8.6.6.1	<i>Policy</i>	83
8.6.6.2	<i>Definition</i>	83
8.6.6.3	<i>Procedure</i>	83
8.6.6.4	<i>Review</i>	84
8.7	Reportable Events	84
8.8	Significant New Findings	84
8.9	Final Reports	85
9	Review of Research	85
9.1	Criteria for IRB Approval of Research	85
9.1.1	Risk/Benefit Assessment	86
9.1.1.1	<i>Determination of Risk</i>	86
9.1.2	Scientific Merit	86
9.1.3	Equitable Selection of Subjects	87
9.1.4	Recruitment of Subjects	87
9.1.4.1	<i>Advertisements</i>	87
9.1.5	Compensation for Research Subjects	88
9.1.5.1	<i>Raffles and Lotteries</i>	89
9.1.6	Data and Safety Monitoring	89
9.1.7	Privacy and Confidentiality	90
9.1.8	Compliance with all Applicable State and Local Laws	91
9.2	Possible IRB Actions and Determinations	91
9.2.1	Human Subjects Research Determination	92
9.2.2	Engagement Determination	92
9.2.3	§.118 Determination	92

9.2.4	Acknowledge	93
9.2.5	Approve	93
9.2.6	Approved with Conditions	93
9.2.7	Defer for major revisions	94
9.2.8	Disapprove	95
9.2.9	Close	95
9.2.10	Suspend or Terminate	95
9.2.11	Investigator Hold	96
9.2.12	Protection of Currently Enrolled Participants	97
9.2.13	Administrative withdrawal or closure	97
9.3	Reporting IRB Actions	97
9.4	Appeal of IRB Decisions	98
10	Obtaining Informed Consent from Research Subjects	98
10.1	Policy	98
10.2	Definitions	99
10.3	Basic Requirements	99
10.4	Informed Consent Process	100
10.5	Basic Elements of Informed Consent	101
10.6	Documentation of Informed Consent	103
10.7	Posting of Clinical Trial Consent Form	104
10.8	Waiver of Informed Consent	105
10.8.1	Full Board and Expedited Studies	105
10.8.1.1	Screening, Recruiting, or Determining Eligibility	105
10.8.1.2	Broad Consent	105
10.8.2	FDA-Regulated Research	106
10.9	Waiver of Documentation of Informed Consent	106
10.9.1	Expedited and Full Board Research	106
10.10	Deception in Research	107
10.10.1	Applicability to Exemptions	108
11	Vulnerable Subjects in Research	108
11.1	Policy	108
11.2	Definitions	109
11.3	Involvement of Vulnerable Populations	110
11.4	Responsibilities	110
11.5	Procedures	111
11.6	Research Involving Pregnant Women, Human Fetuses and Neonates	111
11.6.1	Research Involving Pregnant Women or Fetuses	111
11.6.2	Research involving neonates	112
11.6.3	Research Involving, After Delivery, the Placenta, the Dead Fetus or Fetal Material	113
11.6.4	Research Not Otherwise Approvable	114
11.6.4.1	Research Not Funded by DHHS	114
11.6.4.2	Research Funded by DHHS	114
11.7	Research Involving Prisoners	114
11.7.1	Applicability	114
11.7.2	Purpose	115
11.7.3	Composition of the IRB	115
11.7.4	Review of Research Involving Prisoners	115
11.7.5	Incarceration of an Enrolled Subject	116
11.7.6	Additional Duties of the IRB	117
11.7.7	Certification to HHS	117
11.7.8	Waiver for Epidemiology Research with Prisoners	118

11.8	Research Involving Children	118
11.8.1	Parental Permission and Assent	120
11.8.1.1	<i>Parental Permission</i>	120
11.8.1.2	<i>Assent from Children</i>	120
11.8.1.3	<i>Assent Form</i>	121
11.8.1.4	<i>Children Who are Wards</i>	122
11.9	Persons with Impaired Decision-Making Capacity	122
11.9.1	IRB composition	123
11.9.2	Additional Safeguards	123
11.9.2.1	<i>Procedures for Determining Capacity to Consent</i>	123
11.9.3	Informed Consent and Assent	124

12 Unanticipated Problems, Serious or Continuing Noncompliance, and Any Suspension or Termination of IRB Approval 124

12.1	Regulatory Requirement	124
12.2	Unanticipated Problems & Adverse Events	124
12.2.1	Policy	124
12.2.2	Definitions	125
12.2.3	Additional definitions relevant to FDA-regulated research (Drugs)	126
12.2.4	Additional definitions relevant to FDA-regulated research (Devices)	126
12.2.5	Reporting	127
12.2.6	Submission of Reports	129
12.2.7	Procedures for Handling Anticipated Adverse Events	130
12.2.8	Procedures for Handling Reports of Possible Unanticipated Problems	130
12.2.8.1	<i>Reporting a Death, Serious Injury, or Significant Breach of Sensitive Information</i>	130
12.2.8.2	<i>Report Review by HRPP staff and Chair</i>	130
12.2.8.3	<i>Board Actions</i>	131
12.2.9	IND Safety Reports	133
12.2.10	IDE Reports	133
12.3	Protocol Deviations	133
12.3.1	Policy	133
12.3.2	Definitions	134
12.3.3	Deviations related to FDA-regulated device research	134
12.3.4	Reporting and Review	135
12.4	Concerns or Complaints about the Conduct of Research	135
12.5	Concerns or Complaints about the HRPP	136
12.6	Non-compliance	136
12.6.1	Policy	136
12.6.2	Definitions	136
12.6.3	Review of Potential Non-compliance	138
12.6.4	Review of Findings of Non-compliance	139
12.6.5	Actions	139
12.6.6	Request for Information	139
12.6.7	Vote on Specific Findings	140
12.6.8	Required Actions	140
12.6.9	Board Actions	140
12.6.10	Corrective Action Plans	141
12.7	Reporting to Regulatory Agencies and Institutional Officials	142
12.7.1	Scope	142
12.7.2	Procedures	142

13 Special Topics..... 144

13.1	National Institutes of Health Definitions and Requirements	144
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13.1.1.1	<i>ClinicalTrials.gov</i>	145
13.2	Certificates of Confidentiality.....	145
13.2.1	Definitions.....	145
13.2.2	Protections and Requirements.....	146
13.2.3	NIH Policy.....	146
13.2.4	NIH Certificate Policy Determination.....	147
13.2.5	Application Procedures for non-NIH Research.....	147
13.2.6	Review by Human Research Protection Program.....	147
13.3	Mandatory Reporting.....	148
13.3.1	Mandatory Reporting in International Settings.....	148
13.4	Title IX Sexual Harassment and Sexual Violence.....	149
13.5	Research Involving OSU Students and Employees as Subjects.....	150
13.6	Student Research.....	152
13.6.1	Human Subjects Research and Course Projects.....	152
13.6.1.1	<i>Responsibility of the Course Instructor</i>	152
13.6.2	Theses and Dissertations.....	152
13.7	Genetic and Genomic Studies.....	153
13.7.1	Data Sharing.....	153
13.8	Research Involving Coded Private Information or Biological Specimens.....	154
13.9	Case Reports Requiring IRB Review.....	155
13.9.1	Definitions.....	155
13.10	International Research.....	156
13.10.1	Monitoring of Approved International Research.....	157
13.10.2	Conducting Chart Reviews.....	157
13.10.2.1	<i>Authorization to conduct chart reviews</i>	157
13.10.2.2	<i>Determining review level</i>	157
13.10.2.3	<i>Non-exempt Chart Review and Consent</i>	158
14	Participant Outreach.....	158
14.1	Policy.....	158
15	Relevant References.....	159
16	HRPP Operations in Emergency Situations.....	159



Policy and Procedure Manual

Human Research Protection Program & Institutional Review Board

1. Human Research Protection Program

1.1 Institutional Policy

Oregon State University (OSU) fosters a research environment that promotes respect for the rights and welfare of individuals participating in research conducted by or under the auspices of OSU. In the review and conduct of research, actions by OSU will be guided by the principles of respect for persons, beneficence, and justice as set forth in *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, issued by the Office of the Secretary of the US Department of Health and Human Services (often referred to as the “Belmont Report”). The actions of OSU will also conform to all applicable federal, state, and local laws and regulations.

To conduct its responsibility effectively, OSU maintains an Institutional Review Board that reviews research protocols involving human subjects. The IRB is an autonomous administrative body established to protect the rights and welfare of human research subjects participating in research activities. The OSU IRB will review all research conducted by or under the auspices of OSU involving human subjects regardless of funding source, status, or performance site.

OSU has designated an Institutional Official (IO) who has overall responsibility for OSU’s IRB. The IO is legally authorized to represent the Institution, is the signatory official for the Federalwide Assurance (FWA), and assumes the obligations of the Institution’s Assurance. It is through the FWA that OSU commits to the U.S. Department of Health and Human Services (DHHS) that, for all research conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the policy applicable to such research, it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR 46, also referred to as the “Common Rule.” Additional federal agencies have codified the Common Rule in the relevant chapter and sections of the Code of Federal Regulations.

While the policies and procedures set forth in this document are primarily informed by the Common Rule, additional regulations, laws, or policies may apply, depending on the funding source, state laws, or the type or site of research. Similarly, for research that is not subject to the Common Rule, the policies and procedures may differ from those set forth in the regulation at 45 CFR 46. The Common Rule does not affect any state or local laws or regulations that may otherwise be applicable and that provide additional protections for human subjects, including tribal law passed by the official governing body of an American Indian or Alaska Native tribe and any applicable regulations set forth by the U.S. Food and Drug Administration.

No research involving human subjects may commence until all required Institutional approvals (including IRB) are obtained. The results from studies conducted without obtaining prior IRB approval cannot be represented as having such approval.

Representatives from the OSU administration may choose to review and disapprove the implementation of a research protocol that has been approved by the IRB. Those representatives may include the President and his or her designees, the Provost and his or her designees, the Senior Vice Provost for Academic Affairs, the Institutional Official, the Vice President for Research and his or her designees. However, no one at OSU shall approve or permit the implementation of any research protocol involving the use of human subjects that has not also been approved by the IRB.

All Institutional and non-Institutional performance sites for OSU, domestic or foreign, will be obligated by this policy to conform to ethical principles that are at least equivalent to those of this Institution or as may be determined by the head of the federal department or agency funding the research.

The purpose of this document is to implement this policy.

The policies and guidance put forth by the OSU Human Research Protection Program borrow extensively from the best practices of a variety of academic institutions, reflect the advice received from federal regulators, and are informed by input from leaders in research ethics. The information in this manual builds on ideas freely shared between institutions and exists because of the generosity and collegiality demonstrated by the community of professionals who work in the field of human research protections.

Version 4.3 of this manual has been revised to incorporate changes to the revised Common Rule, effective January 21, 2019.

Studies approved prior to January 21, 2019 will comply with the original Common Rule, as applicable. Studies approved on or after January 21, 2019 will comply with the revised Common Rule, as applicable.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
04-24-2015	05-15-2015	03-17-2016	03-17-2016
None	N/A	06-23-2016	06-23-2016
06-29-2017 12-14-2017	12-15-2017	12-21-2017	12-21-2017
01-29-2018	02-21-2018	02-22-2018	02-22-2018
11-13-2018	11-20-2018	12-26-2018	01-20-2019

1.2 Institutional Authority

Research under the auspices of the Institution includes research:

- Conducted at this Institution
- Conducted by or under the direction of any employee or agent of this Institution (including students) in connection with his or her Institutional responsibilities
- Conducted by or under the direction of any employee or agent (including students) of this Institution using any property or facility of this Institution, and/or
- Involving the use of this Institution's non-public information to identify or contact human subjects

Agents include all individuals performing institutionally designated activities or exercising Institutionally delegated authority or responsibility. Determinations of whether or not an employee is acting as an agent of the Institution will be made in accordance with the OSU Conflict of Commitment Policy.

The policies and operating procedures in this document serve as the governing procedures for the conduct and review of all human subjects research conducted under the auspices of OSU. The authority to carry out these procedures as described comes from the President of the University via the Institutional Official.

Oregon State University faculty, staff and students engage in activities associated with innovative and high impact research, instruction and outreach/engagement, and are at the forefront of many new discoveries. The activities bear with them certain ethical and legal responsibilities. The University Administration is committed to the highest standards of integrity and resolves that such activities undertaken by OSU faculty, staff, and students should be conducted in accordance with strict ethical principles and in compliance with Institutional policies, federal and state laws and regulations, and other applicable requirements.

Adherence to high standards provides a framework for (i) achieving full compliance with applicable ethical, regulatory and University requirements and (ii) promoting an organizational culture that encourages ethical conduct and a commitment to compliance. Areas in which integrity is critical to success include, but are not limited to: human subject research; animal care and use; biosafety; chemical safety; radiation safety; occupational safety; export controls; conflicts of interest; diving safety; small boat safety; handling of hazardous, controlled or regulated substances; material transfers; environmental protection; and research misconduct.

The University, through its compliance committees and authorized officials, will issue and promulgate Institutional policies and procedures to ensure the appropriate and responsible conduct of all applicable activities at Oregon State University.

-Oregon State University President Edward J. Ray (May 2011)

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
04-24-2015	05-15-2015	03-17-2016	03-17-2016
None	N/A	06-23-2016	06-23-2016

1.3 Mission

The Human Research Protection Program supports OSU’s commitment to research by collaborating with investigators to protect the rights and welfare of human subjects who participate in studies. The program achieves this by promoting the ethical principles of respect for persons, beneficence, and justice; and by assisting the OSU community in taking a “participant first”¹ approach to ensuring compliance with the standards set forth in the Common Rule.

¹ President Obama’s Precision Medicine Initiative: Data Security Policy Principles and Framework, May 25, 2016. “Strive to build a system that participants trust. This means having a “participant first” orientation when identifying and addressing data security risks. Participants are the foundational stakeholders of all research activities.”

https://www.whitehouse.gov/sites/whitehouse.gov/files/documents/PMI_Security_Principles_Framework_v2.pdf

The HRPP includes formal and informal mechanisms to carry out the following functional responsibilities:

Institutional Review Board(s)

- a. Review applications to conduct research with human subjects
- b. Ensure that research plans meet the federally mandated criteria for approval and are in compliance with state laws and local policies

HRPP Office

- a. Manage the review process of proposed research with human subjects
- b. Act as IRB Chair’s designees for determinations of exemption
- c. Support IRB members and coordinate board meetings
- d. Provide outreach and education to the OSU research community
- e. Monitor, evaluate, and continually improve the protection of research subjects
- f. Develop guidance and policies relative to best practices
- g. Implement approved policies
- h. To ease the regulatory burden on researchers by taking advantage of flexibility in the federal regulations when appropriate
- i. When appropriate, intervene in research and respond directly to concerns of research subjects
- j. Manage resources dedicated by IO to carry out the above listed actions

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
04-24-2015	05-15-2015	03-17-2016	03-17-2016
None	N/A	06-23-2016	06-23-2016
12-15-2017	12-15-2017	12-21-2017	12-21-2017
11-13-2018	11-20-2018	12-26-2018	01-20-2019

1.4 Ethical Principles

OSU is committed to conducting research with the highest regard for the rights and welfare of human subjects. It upholds and adheres to the principles of *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research* by the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research (1979). These principles are:

- a) Respect for Persons, which is ensured by obtaining informed consent, consideration of privacy, confidentiality, and additional protections for vulnerable populations.
- b) Beneficence, which is ensured by maximizing possible benefits and minimizing possible risks to all human subjects.
- c) Justice, the equitable selection of subjects.

OSU's HRPP, in partnership with its research community, is responsible for ensuring the ethical treatment of all human subjects in research conducted under its auspices.

Revision Dates			
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11-12-2010	N/A	07-18-2014	07-18-2014
04-24-2015	05-15-2015	03-17-2016	03-17-2016
None	N/A	06-23-2016	06-23-2016

1.5 Regulatory Compliance

The HRPP is responsible for ensuring compliance with applicable federal regulations, state law and Institutional policies. All human subjects research at OSU that is funded by a federal agency must be conducted in accordance with this policy and the regulations found in the Common Rule and 21 CFR 50 and 56 when applicable.

Unregulated research must also be conducted in accordance with this policy.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
04-24-2015	05-15-2015	03-17-2016	03-17-2016
06-23-2016	06-23-2017	06-23-2016	06-23-2016
12-20-2017	N/A	12-21-2017	12-21-2017

1.6 Federalwide Assurance (FWA)

The IRB operates under the authority of its current Federalwide Assurance (00003920) and one registered IRB (IORG0000084).

In its FWA, OSU has previously opted to limit the application of the Assurance to research funded by federal agencies that have adopted the Common Rule. Under the revised Common Rule, the option document that the federal regulations will be applied to all studies has been omitted from the Assurance process.

1.7 Regulatory FLEXibility

Regulatory **FLEX**ibility- As of May 2021, the OSU HRPP ceased using the "FLEX initiative" review process for human subjects research applications. Studies that were reviewed using the FLEX process are allowed to continue currently approved activities until the expiration date is reached. Revisions and renewals will not be accepted for FLEX studies, but rather the PI must submit a new application and the study will be re-reviewed using the current Exempt, Expedited or Full Board review process.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
03-17-2016	N/A	03-17-2016	03-17-2016
None	N/A	06-23-2016	06-23-2016
07-27-2016	N/A	07-29-2016	07-29-2016

11-13-2018	11-20-2018	12-26-2018	01-20-2019
5-21-2022	2-14-2023	3-16-2023	3-16-2023

1.8 Research Requiring IRB Review

The OSU IRB covers all research involving human subjects that is under the auspices of the Institution, regardless of funding or the source of funding.

Research. The Common Rule defines research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.

For the purposes of this policy, a **systematic investigation** is an activity that involves a prospective study plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a study question.

Designed to develop or contribute means that the investigator intends to disseminate results to those outside of the University. Methods of dissemination may include, but are not limited to, websites, social networks, social media, poster presentations, conferences, library placement, or publications. Examples that would not be seen as dissemination outside of the University include presentation to a department in fulfillment of a university requirement; sharing results with the sponsor or a collaborator; or student presentations to a class or campus organization.

Investigations designed to develop or contribute to **generalizable knowledge** are those designed to draw general conclusions that may be applied to populations outside of the specific study population, used to inform policy, or be analyzed for predictive value.

Examples of activities that do not meet this definition of research and are therefore not subject to IRB review include²:

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

² These examples are not intended to constitute the implementation of a “burden reducing provision” from the revised Common Rule (2018-19). According to the pre-amble to the revised Common Rule, this language does not represent a change in regulatory thinking. OSU did not previously review studies in these categories and has included this language strictly for the purposes of clarification.

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

(5) Student projects intended to provide an educational experience, when the project is intended to fulfill a course or degree requirement and is not designed to contribute to generalizable knowledge. The intended benefit is to the student. Resulting presentations or publications designed to document the educational experience only.

Research subject to FDA regulations. Research, as defined by FDA regulations, means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Federal Food, Drug, and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations. [21 CFR 50.3(c), 21 CFR 56.102(c)]

Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act means any use of a drug other than the use of an approved drug in the course of medical practice. [21 CFR 312.3(b)]

Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act means any activity that evaluates the safety or effectiveness of a device. [21 CFR 812.2(a)]

Any activity in which results are being submitted to or held for inspection by FDA as part of an application for a research or marketing permit is considered to be FDA-regulated research. [21 CFR 50.3(c), 21 CFR 56.102(c)]

Human Subject (Common Rule). A human subject is defined by the Common Rule as a living individual about whom an investigator conducting research (i) obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

- **Intervention** means both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- **Interaction** means communication or interpersonal contact between investigator and subject.
- **Private** information means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

- **Identifiable private information** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- **Identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Human Subject (FDA). For research covered by FDA regulations (21 CFR 50 and 56), a human subject means an individual who is or becomes a participant in a clinical investigation, either as a recipient of the test article or as a control. A subject may be in normal health or may have a medical condition or disease. In the case of a medical device, a human subject/participant also includes any individual on whose tissue specimen an investigational device is used or tested. If tissue is used to test an investigational device, the tissue donor is a human subject.

Test Article. A test article is a drug, device, or other article including a biological product that is the object of a clinical investigation involving human subjects or their specimens.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
04-24-2015	05-15-2015	03-17-2016	03-17-2016
None	N/A	06-23-2016	06-23-2016
11-8-2017	12-15-2017	12-21-2017	12-21-2017
01-29-2018	02-21-2018	02-22-2018	02-22-2018
11-13-2018	11-20-2018	12-26-2018	01-20-2019

1.9 Written policies and procedures

This document details the policies and regulations governing research with human subjects, regardless of funding source, and the requirements for submitting research proposals for review by the OSU IRB. This is not a static document. The policies and procedures are continuously reviewed and revised to ensure alignment with the regulations and nationally recognized best practices.

Non-substantive changes to this manual can be made by the Administrator without review or approval by the Executive Committee of the IRB or the Institutional Official.

This manual will be available on the HRPP website and will serve as the mechanism for keeping the Institution’s research community apprised of new information that may affect the IRB, including laws, regulations, policies, procedures, and emerging ethical and scientific issues.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
12-17-2015	12-18-2015	03-17-2016	03-17-2016
None	N/A	06-23-2016	06-23-2016
07-27-2016	N/A	07-29-2016	07-29-2016

1.10 Organization of the Human Research Protection Program

The HRPP consists of various individuals, boards, and committees. The HRPP Office is a unit within the Office of Research Integrity. The officials, individuals, and administrative units outlined below have primary responsibilities for implementing the HRPP.

1.10.1 Institutional Official

Role of the Institutional Official (IO)

- The Institutional Official (IO) is the individual who is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Assurance;
- The IO is responsible for ensuring that the Human Research Protection Program (HRPP) functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. The IO represents the institution named in the Federalwide Assurance (FWA);
- The IO should be an individual of sufficient rank who has the authority to ensure that all obligations of the HRPP are carried out effectively and efficiently. This person is usually the President, Chancellor, Director General, Chief Executive Officer, or Chief Operating Officer for the legal entity that constitutes the institution conducting research. The IO should be at a level of responsibility sufficient to allow authorization of necessary administrative or legal action should that be required. Thus, department chairs, division directors or other officials who only have authority over one portion of the institution would generally not be an appropriate IO. Similarly, OHRP recommends that the IO not be the chair or member of any IRB designated under the FWA.

General administrative obligations and responsibilities of the IO

- Signatory authority for the FWA;
- Completing recommended Assurance training for the IO;
- Designating one or more Institutional Review Boards (IRBs) that will review research covered by the institution's FWA;
- "Setting the tone" by promoting an institutional culture of respect and conscience, so that the ethical conduct of human subjects research is supported at the highest levels of the organization;
- Ensuring that the IRB functions independently and that its chair and members have direct access to the IO for appeal if they experience undue influence or if they have concerns about the function of the IRB;
- Ensuring that adequate resources, including funds, space, and personnel are provided to support the operation of the HRPP;
- Appointing, suspending or terminating the IRB membership of any individual;
- Appointing, suspending, or terminating the IRB chair or co-chair;
- Reviewing and signing memoranda of understanding and cooperative agreements between the institution and other organizations, including those that establish reliance on IRBs of record for collaborative research (e.g., IRB Authorization Agreements,);
- In accordance with 45 CFR 46.108, the IO will ensure that the IRB has adequate meeting space and sufficient staff to support the IRB's review and record keeping duties. The resources provided for the IRB and HRPP office will be reviewed during the annual budget review process;
- By written memo, the IO may delegate certain responsibilities and authorities to appropriately trained individuals.

1.10.2 Associate Vice President for the Office of Research Integrity

The Associate Vice President for the Office of Research Integrity has administrative oversight of the Human Research Protection Program. In this role, the AVP will support the IO in carrying out the administrative obligations outlined for that position.

The IO may delegate certain responsibilities and authorities to the AVP, such as acting as the institutional signatory when a matter does not involve federal funding or other federal components.

1.10.3 Human Research Protection Program Administrator

The Administrator for the Human Research Protection Program reports to the Associate Vice President for the Office of Research Integrity. The Administrator is responsible for administering a Program that is committed to facilitating ethical research as demonstrated by adherence to best practices and innovative approaches to engaging the research community. This includes:

- Developing, managing and evaluating policies and procedures that ensure compliance with applicable state laws and federal regulations governing research. This includes monitoring changes in regulations and policies that relate to human research protection
- Overseeing all aspects of the human research protection program, including the HRPP office and the institutional review board(s)
- Day-to-day responsibility for the operation of the HRPP office, including supervision of HRPP staff
- Advising the IO on key matters regarding research at OSU
- Implementing the Institution's policies, as they relate to the conduct of research with human subjects
- Submitting, implementing and maintaining an approved FWA with the Office of Human Research Protection (OHRP)
- Developing and implementing needed improvements and ensuring follow-up of actions, as appropriate, for the purpose of managing risk in the research program
- Developing training requirements for IRB members, HRPP staff, and investigators
- Serving as the primary contact at OSU for OHRP and other federal regulatory agencies
- Working closely with the IRB Chair(s) on the development of policy and procedures for review and approval by the IO
- Working closely with the IRB Chair(s) in the preparation of, and follow up to, each convened meeting
- Providing regulatory guidance to the IRB Chair(s) and members

1.10.4 Institutional Review Board

OSU has at least one IRB that is responsible for the protection of rights and welfare of human research subjects at OSU.

Throughout this document, there will be references to "the IRB" and "IRB Chair" singular rather plural, as the number of registered Boards and Chairs may change, but all Boards and Chairs share a single charge.

1.10.5 Executive Committee

The IRB will have a Chair and a Vice Chair who will work closely with the Administrator to carry out the mission of the HRPP. These members of the IRB leadership will serve on the Executive Committee.

1.10.6 Human Research Protection Program Staff

HRPP staff are responsible for all aspects processing proposals involving human subjects. This responsibility includes the initial review of documents and screening of research proposals prior to its review by the IRB, as well as serving as liaisons between the investigators and the IRB. HRPP staff review the IRB minutes for accuracy and ensures proper documentation of discussions, including controverted issues and actions taken by the IRB during its convened meetings.

HRPP staff are responsible for providing administrative and clerical support to the IRB Chair and HRPP Administrator as well as scheduling and coordinating all IRB functions. HRPP staff are also responsible for record retention related to the program. HRPP staff are responsible for maintaining complete IRB files, records of all research protocols, IRB correspondence (including e-mails), as well as Research Credentialing records of investigators and research staff.

HRPP staff who have passed the exam to become Certified IRB Professionals (CIP), and who are otherwise appropriately qualified, may be appointed to the IRB for the purposes of conducting reviews of minimal risk studies.

The HRPP staff are required to complete the relevant CITI courses in the Protection of Human Research Subjects. Staff members will be provided with sufficient training opportunities to maintain their required certification (CIP) or other relevant certification(s).

1.10.7 Unit Heads

School Directors, Department Heads, Department Chairs, and Directors of Centers and Institutes (“Unit Heads”) are responsible for ensuring that each Principal Investigator (PI) is qualified by training and experience to conduct the proposed research.

Unit Heads are responsible for ensuring that investigators have the resources required to conduct the research in a way that will protect the rights and welfare of participants. Such resources include but are not necessarily limited to adequate personnel, space, equipment and time to minimize the risk to research subjects and to facilitate the responsible conduct of research.

1.10.8 Investigators

The investigator has the ultimate responsibility for protecting the human subjects who participate in their research studies. The investigator is expected to abide by the highest ethical standards in the conduct and oversight of research and for developing a protocol that incorporates the principles of the Belmont Report. Investigators are expected to conduct research in accordance with the approved research protocol and to oversee all aspects of the research by providing training for and supervision of all study team members.

In addition to complying with all the policies and standards of the governing regulatory bodies, the investigator must comply with Institutional and administrative requirements for conducting research. The investigator is responsible for obtaining all required approvals prior to initiating research.

1.10.9 Other Related Units

1.10.9.1 Research Conflict of Interest Program

The OSU policy for Conflict of Interest promotes objectivity in research by establishing expectations and disclosure requirements to ensure that the design, conduct and reporting of research will not be biased by a Significant Financial Interest of an individual. Communication between the HRPP and the RCOI Program is facilitated through five mechanisms:

- Applications that are received by the HRPP that include a disclosure of a conflict of interest are forwarded to the COI Administrator or Officer for review. The study file is accessible to COIC while under review and after it has been approved. IRB approval may be issued prior to a determination from the COIC if the HRPP has reviewed the relevant details and finds that the matter is appropriately managed within the protocol and, if applicable, the consent process.
- The HRPP Administrator is alerted to disclosures made in the COI system when they involve, or appear to involve, research with human subjects. Any resulting management plan is accessible to the HRPP and IRB members.
- COI Administrator or Officer provides regular reports of all managed conflicts. The HRPP Administrator makes this report available to all HRPP staff and maintains a mechanism for reviewing the report against new submissions.
- At the discretion of the Vice President for Research, a representative from the HRPP will serve as a non-voting member of the COIC.
- At the discretion of the Vice President for Research, a representative from the RCOI Program will serve as a non-voting member of the IRB.

1.10.9.2 Animal Program Office

In the event that a research protocol involves both human and animal subjects, the Administrators for the HRPP and the Animal Program Office will work together to ensure that information regarding the reviews is shared between committees.

1.10.9.3 Diving Safety and Small Boats

In the event that a research protocol involves human subjects and scientific diving operations or small boat use, the HRPP Administrator and the Scientific Diving and Small Boat Safety Officer will work together to ensure that information regarding reviews is shared between committees.

1.10.9.4 Export Control and International Compliance

HRPP staff will notify the Export Control and International Compliance Officer when a research submission involves an international component, work in, or personnel from an embargoed country, or classified research.

1.10.9.5 Office for Commercialization & Corporate Development

The Office for Commercialization & Corporate Development (OCCD) supports research development and commercialization of University intellectual property. Applications that are received by the HRPP which include the transfer of biological materials to or from OSU are referred to the OCCD for consultation regarding the potential need for a Material Transfer Agreement (MTA). Similarly, researchers will be referred to the HRPP if they indicate to OCCD that they plan to conduct research involving human subjects.

1.10.9.6 Office for Sponsored Research Award Administration

The OSRAA staff review and approve all research proposals and agreements with external sponsors. This Institutional review ensures that all terms of the award are in compliance with Institutional policies.

When the grant or contract agreement includes human research activities that will be conducted by investigators who are not employees or agents of OSU, a subcontract is executed between OSU and the collaborating Institution. The subcontract includes the requirement for the collaborating Institution to assure compliance with federal regulations for the protection of human subjects in research and to provide certification and documentation of current and ongoing IRB approval upon execution of the subcontract, and annual certification thereafter, during the life of the sub-award. The collaborating Institution must also ensure that study team members involved in human subjects research are in compliance with the NIH policy on education in the protection of human research subjects and provide documentation of their education to OSU.

For all externally funded research, the HRPP Office will include OSRAA on notices of exemption, approval, expiration, suspension, termination, or closure sent to Investigators.

1.10.9.7 Radiation Safety Committee

All research and teaching activities at OSU that require the possession and/or use of radioisotopes or radiation-emitting machines are governed by the provisions of a license and/or regulations issued by the State of Oregon. The Radiation Safety Program provides for these uses under the applicable laws and regulations of federal, state, and local agencies. Furthermore, the Program ensures that no risk from ionizing radiation shall be incurred except where justified by benefits from the activity and that radiation exposure shall be as low as reasonably achievable. The Radiation Safety Committee (RSC) must specifically authorize all uses of ionizing radiation and the authorized user has primary responsibility for all safety aspects of work under the program. This includes familiarity with and adherence to all regulations, personnel training, and the conduct of safe operations with the assistance of Radiation Safety.

Applications that are received by the HRPP which include the use of radiation are forwarded to the RSC for simultaneous review. HRPP will release the approved documents to the PI once RSC approval is also granted.

1.10.9.8 Biological Safety Committee

In recognition of the necessity for conducting research utilizing potentially hazardous biological materials in a safe and secure manner, the Institutional Biosafety Committee (IBC) reviews biohazardous work conducted for any purpose by OSU personnel or in any OSU facility. The IBC has full authority to impose containment requirements or procedural safeguards, audit programs, and inspect facilities to ensure that biohazards are handled, used, and disposed of in a safe and compliant manner.

Applications that are received by the HRPP which include the collection and/or use of biological samples are forwarded to the Biosafety Officer for review. In cases where the biosafety review is relevant to participant safety, IRB approval of a study involving biological materials will not be issued until and unless it is first approved by the IBC and/or the Biosafety Officer.

1.10.9.9 Chemical Safety Committee

Applications that are received by the HRPP which include the use of chemicals are forwarded to the Chemical Safety Officer (CSO) for simultaneous review. In turn, the CSO will send the HRPP the approval documentation issued by the Chemical Safety Committee and indicate whether or not the protocol submitted for IRB review is consistent with the application materials reviewed and approved by the committee. In cases where the chemical review is relevant to participant safety, IRB approval of a study involving the use of chemicals will not be issued until and unless any required approval from the Chemical Safety Committee has been obtained.

1.10.9.10 Office of General Counsel

The OSU IRB relies on the Institution's Office of General Counsel for the interpretations of Oregon State law, and the state laws of any other jurisdiction where research is conducted, as they apply to human subjects research.

1.10.10 Relationship Between Components

The IRB functions independently of, but in coordination with, other Institutional compliance committees. The IRB, however, makes independent determinations about whether to approve or disapprove a protocol based upon whether or not human subjects are adequately protected.

1.10.10.1 Office of Research Integrity

Under the direction of the Vice President for Research, and in accordance with University policies, procedures, and guidelines, the Associate Vice President for Research (AVPR) provides advice to senior management, staff, and employees to maximize compliance with statutory and regulatory requirements; regularly reviews compliance programs to identify areas of risk and works with senior administration to secure solutions that will manage or eliminate threats to research integrity; works with administrative units across campus to harmonize policies between ORI and other areas impacting the OSU research community; and collaborates with senior management and campus compliance areas to organize and provide a coordinated education and outreach program to promote the responsible conduct of research.

The AVPR provides leadership and coordination for the administration, support, monitoring, and assessment of a range of research compliance functions, including: the Institutional Review Board, Animal Care and Use Committee, Conflict of Interest Committee, Scientific Diving and Small Boat use for research, the Export Control and International Compliance Office, and the Biosafety Committee.

This position also provides the Research Office interface and linkage to the Environmental Health and Safety programs. The AVPR provides leadership to ORI by establishing and maintaining research compliance systems; embracing the vision and goals for research integrity and assuring those are aligned with those of the University; communicating the vision and goals to staff; developing a highly cohesive compliance work team; and enabling staff to perform effectively.

While the AVPR has a critical role for overseeing the compliance programs and for coordinating activities of the compliance groups broadly across campus, administrators and officers for each of the compliance units will have direct and unimpeded access to the Institutional Official (IO) at their discretion.

1.10.10.2 Research Integrity and Environmental Health and Safety

Administrators and Safety Officers from each of the ORI and EH&S units meet periodically. The group focuses on policy harmonization across units and works to identify areas of risk and vulnerability related to the conduct of research at OSU.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
01-30-2015	N/A	-	-
04-24-2015	05-15-2015	-	-
12-17-2015	12-18-2015	03-17-2016	03-17-2016
None	N/A	06-23-2016	06-23-2016
06-24-2016	07-14-2016	07-29-2016	07-29-2016
11-16-2017 12-14-2017	12-15-2017	12-21-2017	12-21-2017
02-01-2018	02-21-2018	02-22-2018	02-22-2018
11-13-2018	11-20-2018	12-26-2018	01-20-2019
12-22-2022	2-14-2023	3-16-2023	3-16-2023

2 Investigator Responsibilities

2.1 Policy

Principal Investigators are ultimately responsible for the conduct of research. Principal Investigators may delegate research responsibility. However, investigators must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibility.

The following procedures describe the investigator responsibilities in the conduct of research involving human participants.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010		07-18-2014	07-18-2014
04-13-2016		04-13-2016	04-13-2016
None	N/A	06-23-2016	06-23-2016

2.2 Investigators

Principal Investigators

OSU unclassified employees with the following appointments may serve as a Principal Investigator (PI), if they are otherwise sufficiently qualified to conduct and oversee the research:

- Academic Teaching and Research Faculty
- Previously tenured faculty members who have relinquished tenure and who hold academic wage appointments (not to exceed three years past the date of tenure relinquishment.)

- Non-teaching Administrative and Professional Faculty. Exceptions may be made for Research Associates who are no longer Postdoctoral Scholars (trainees), so long as they are otherwise sufficiently qualified to conduct and oversee the research.
- USGS and ODFW Leaders in the Cooperative Fish and Wildlife Research Unit

OSU unclassified employees with the following appointments are not permitted to serve as the PI on a study involving human subjects:

- Unclassified hourly
- Academic wage appointment other than those associated with tenure relinquishment.

The following additional classifications are not permitted to serve as the PI on a study involving human subjects:

- Classified employees
- Temporary Support Staff
- Training and Student Appointments: Student, Graduate Assistant, Postdoctoral Scholar, Clinical Fellow
- Unpaid: Affiliate, Courtesy, Emeritus, Postdoctoral Fellow, Graduate Fellow, and Visiting Faculty not paid by OSU

The HRPP recognizes one Principal Investigator (PI) for each study. The PI is ultimately responsible for the conduct of the entire study and all study team members.

Protocols that require skills beyond those held by the PI must be modified to meet the investigator's skills or have one or more additional qualified faculty as Co-investigator(s).

Research Team

Any individuals who will consent subjects, interact with enrolled subjects, or have access to individually identifiable data should be listed as study team members. When this is not a reasonable requirement for enhancing the protection of human subjects, or the individuals are not considered to be key personnel, the IRB may permit the PI to follow the procedures below.

2.2.1 Procedures for Certifying Research Team Members

There are circumstances under which listing individuals as study team members on an IRB application is not a reasonable requirement for enhancing the protection of human subjects. Examples of such circumstances can include:

- Individual researchers will be identified in the field;
- The study involves community based participatory research and one or more study activities are conducted by lay individuals and/or study participants;
- Individuals conducting one or more study activities but who are not considered to be key personnel, will not contribute to the scientific development of the project or assist with data analysis, and for whom an OSU campus is not their primary location.

While these individuals need not be listed on the application to the IRB or elsewhere, the PI is required to train, oversee, and certify these individuals as qualified members of the team. The protocol must include the following:

- A description of who these individuals will be (e.g., community members, regional high school teachers, Extension Agents, etc.)
- A description of the responsibilities and activities that these individuals will perform
- A detailed plan for training, oversight, and procedures for ensuring protocol adherence

A list of certified study team members must be submitted to the HRPP Office at the time of continuing review for studies requiring full board review.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
11-24-2015	11-24-2015	03-03-2016	03-03-2016
04-13-2016		04-13-2016	04-13-2016
None	N/A	06-23-2016	06-23-2016
12-15-2017	12-15-2017	12-21-2017	12-21-2017
12-22-2022	2-14-2023	3-16-2023	3-16-2023

2.3 Responsibilities

In order to satisfy the requirements of this policy, investigators who conduct research involving human subjects must attest:

- That the information contained in the application is accurate and complete;
- That research involving humans, including recruitment, will not begin until IRB approval has been granted;
- To the scientific merit and importance of this study;
- To the competency and availability of the study team member(s) to conduct the project;
- That facilities, equipment, and personnel are adequate to conduct the research.

Furthermore, investigators must agree to:

- Comply with all HRPP and IRB policies, decisions, conditions, and requirements;
- Accept responsibility for every aspect of the conduct of this study;
- Adhere to all aspects of the protocol, once approved;
- Obtain approval prior to amending or altering the study, when required by this policy;
- Report in accord with this policy, any adverse event(s) and/or unanticipated problem(s);
- Inform the HRPP if PI or another member of the study team leaves OSU or otherwise changes institutional affiliations;
- Notify the HRPP office immediately of the development of any potential conflict of interest not already disclosed and, when applicable, report to an external IRB if OSU has entered into a reliance agreement with an external IRB.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
01-30-2015	11-24-2015	04-13-2016	04-13-2016
None	N/A	06-23-2016	06-23-2016
07-27-2016	N/A	N/A	07-29-2016
12-15-2017	12-15-2017	12-21-2017	12-21-2017

12-22-2022	2-14-2023	3-16-2023	3-16-2023
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2.4 Training for Investigators

The OSU HRPP is committed to providing training and an on-going educational process for investigators and members of their research team related to ethical concerns and regulatory and Institutional requirements for the protection of human subjects.

2.4.1 Initial and Continuing Education

The research community has a responsibility to ensure that the treatment of human subjects in research meets the highest ethical standards. Recognizing this responsibility, the National Institutes of Health (NIH) requires NIH funding recipients to certify training in the ethical use of humans in research. Endorsing the goals of such training, the OSU HRPP requires education in the protection of human research participants for all researchers conducting research involving human subjects, not just those receiving NIH funding.

OSU study team members must complete the CITI course.

External (non-OSU) study team members have two training options:

- a) CITI Course, or
- b) Provide an electronic copy of the certificate of education found acceptable by the IRB at their home Institution.

All study team members involved in FDA-regulated research and/or NIH-funded clinical trials must complete one of the Good Clinical Practice (GCP) modules offered by CITI.

If a non-OSU study team member is unable to complete, or provide proof of completion, of the above described training (for reasons such as illiteracy, inability to use or access the internet, or CITI training is not offered in the individual's native language), they may contact the HRPP Office for additional options.

Approval of research projects will not be issued until documentation of training has been received by the HRPP for all study team members. Beginning January 2017, OSU will require that training be renewed every three years.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
04-24-2015	11-24-2015	04-13-2016	04-13-2016
None	N/A	06-23-2016	06-23-2016
09-13-2016 11-08-2016 11-16-2017	12-15-2017	12-21-2017	12-21-2017

3 Quality Assurance/Quality Improvement Activities

The objective of the Quality Assurance / Quality Improvement Activities are to support investigators in the conduct of their research while maintaining and improving the effectiveness of human research protections, and compliance with Institutional policies and procedures.

3.1 Post-Approval Monitoring

Directed (“for cause”) audits and periodic (not “for cause”) compliance reviews may be conducted to assess investigator compliance with Institutional policies and procedures. Directed audits of IRB-approved research studies are in response to identified concerns. Periodic compliance reviews may be conducted using a systematic method to review IRB-approved research. The results will be reported to the Administrator, IRB Chair, and IO. At the Chair’s discretion, or IO’s direction, results may be reported at a convened meeting of the Board.

Activities of auditors during directed audits and periodic compliance reviews may include, but are not limited to:

- a) Requesting progress reports from researchers;
- b) Examining investigator-held research records;
- c) Contacting research subjects;
- d) Observing research sites where research involving human research subjects and/or the informed consent process is being conducted;
- e) Auditing advertisements and other recruiting materials as deemed appropriate by the IRB;
- f) Reviewing projects to verify from sources other than the researcher that no unapproved changes have occurred since previous review;
- g) Monitoring conflict of interest concerns to assure the consent documents include the appropriate information and disclosures;
- h) Conducting other monitoring or auditing activities as deemed appropriate by the IRB.

3.1.1 Consent Monitoring

In reviewing the adequacy of informed consent procedures for proposed research, the IRB may on occasion determine that monitoring of the consent process by an impartial observer (consent monitor) is required in order to confirm that the process is being carried out appropriately or to reduce the possibility of coercion or undue influence.

Such monitoring may be particularly warranted where the research presents significant risks to subjects, or if subjects are likely to have difficulty understanding the information to be provided. Monitoring may also be appropriate as a corrective action where the IRB has identified problems associated with a particular investigator or a research project.

If the IRB determines that consent monitoring is required, the IRB Chair and the Administrator will develop a monitoring plan and submit it to the Board for approval. The consent monitoring may be conducted by HRPP staff, IRB members or another party, either affiliated or not with the Institution. The PI will be notified of the IRB’s determination and the reasons for the determination. Arrangements will be made with the PI for the monitoring of the consent process for a specified number of subjects. When observing the consent process, the monitor will verify the following:

- informed consent process was appropriately completed and documented,
- subject had sufficient time to consider study participation,
- consent process did not involve coercion or undue influence,
- information was accurate and conveyed in understandable language, and
- subject appeared to understand the information and gave their voluntary consent.

Following the monitoring, a report of the findings will be submitted to the IRB Chair, who will determine whether and what action will be taken. At the Chair’s discretion, the results may also be reported at a convened meeting of the Board.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
04-24-2015	11-24-2015	04-13-2016	04-13-2016
None	N/A	06-23-2016	06-23-2016

3.2 External Site Audits and Compliance Reviews

External directed audits and periodic compliance reviews may be conducted at external sites, where OSU’s IRB serves as the “IRB of Record,” to assess compliance with HRPP policies and procedures.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
04-24-2015	11-24-2015	04-13-2016	04-13-2016
None	N/A	06-23-2016	06-23-2016
07-27-2016	N/A	N/A	07-29-2016

3.3 IRB Internal Compliance Reviews

A periodic review of the IRB may be conducted by parties internal or external to OSU, but not affiliated with the IRB through membership, reporting lines, or appointment authority. The results of the review will be reported to the Administrator, Chair(s), and the IO. The reviewer(s) will be sufficiently knowledgeable of HRPP and IRB processes and procedures to assess whether the approved policies have been followed and reviews are being conducted by members and staff without inappropriate influence from investigators or university administration.

The Administrator will review the results of internal compliance reviews with the IRB Chair and the Institutional Official. If any deficiencies are noted in the review, a corrective action plan will be developed and implemented by the Administrator and Chair, and overseen by the IO.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
04-24-2015	11-24-2015	04-13-2016	04-13-2016
None	N/A	06-23-2016	06-23-2016
06-24-2016	07-14-2016	7-29-2016	7-29-2016

3.4 Reporting and Disposition

The results of all quality assurance activities are reported to the Administrator, the IRB Chair, and the IO. Non-compliance will be handled according the procedures articulated in later sections.

If an auditor or reviewer finds that subjects in a research project have been exposed to unexpected harm, the reviewer will report such findings to the Administrator, the IRB Chair, and

the IO within 24 hours.

In the event that evidence of scientific or scholarly misconduct is found during an audit or investigation, that information will be reported in accordance with the OSU Policy on Scientific and Scholarly Misconduct.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
04-24-2015	11-24-2015	04-13-2016	04-13-2016
None	N/A	06-23-2016	06-23-2016

4 Institutional Review Board

4.1 Policy

All human subjects research conducted under the auspices of the Institution must be reviewed and approved (or acknowledged if exempt) by the IRB prior to the initiation of the research. The IRB will review proposed research involving human subjects for ethical considerations, scientific merit, and adherence to applicable federal regulations and HRPP policies. The results from studies conducted without obtaining IRB approval may not be represented as having IRB approval.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
04-24-2015	11-24-2015	06-23-2016	06-23-2016
7-27-2016	N/A	N/A	07-29-2016

4.2 IRB Authority

The IRB derives its authority from the Federal Regulations and from OSU Institutional policy. Under the Common Rule, the IRB has the authority to:

- a) Approve, require modifications to secure approval, or disapprove all research activities overseen and conducted under the auspices of the IRB;
- b) Suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants;
- c) Observe, or have a third party observe, the consent process; and
- d) Observe, or have a third party observe, the conduct of the research.

Under the FDA regulations, the IRB has the authority to act as above and the additional authority to:

- a) Require progress reports from the investigators and oversee the conduct of the study; and
- b) Place restrictions on a study

Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of the Institution. However, approval from those officials is not sufficient for the initiation of research activities and does not override disapproval from the IRB.

Institution officials may strengthen requirements and/or conditions, or add other modifications to secure Institutional approval or approval by another committee, or may disallow continuation of the research project, or of components of the project involving human subjects research. If the Institution requires changes to previously approved research proposals and/or consent forms, these documents must be re-reviewed and approved by the IRB before initiating those changes or modifications.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
04-24-2015	11-24-2015	06-23-2016	06-23-2016

4.3 Number of Boards

The HRPP Administrator and the IRB Chair will review the activity of the IRB on at least an annual basis and make recommendations to the IO regarding any changes in the number of boards needed for the Institution.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
04-18-2016	11-24-2015	06-23-2016	06-23-2016
07-27-2016	N/A	07-29-2016	07-29-2016

4.4 Board Composition

The IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the Institution.

The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

The IRB shall be able to ascertain the acceptability of proposed research in terms of Institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.

If the IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific³ areas.

³ Scientist/Non-scientist: Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist, while members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist. In

The IRB shall include at least one member who is not otherwise affiliated⁴ with the Institution and who is not part of the immediate family of a person who is affiliated with the Institution.

The IRB reviewing FDA-regulated research shall include at least one physician member. That member must be present when the Board is reviewing FDA-regulated articles (drugs and devices).

No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

One member may satisfy more than one membership category.

The IRB Chair and the Administrator shall continuously review the membership and composition of the IRB to determine if they continue to meet regulatory and Institutional requirements. Recommendations on IRB membership will be made to the IO.

When multiple boards are constituted, members from one board may serve as expedited reviewers for another board, as needed.

The roster of members will be made available on the HRPP website.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
04-24-2015	11-24-2015	06-23-2016	06-23-2016
11-08-2017	12-15-2017	12-21-2017	12-21-2017
01-29-2018	02-21-2018	02-22-2018	02-22-2018
11-16-2018	11-20-2018	12-26-2018	01-20-2019
03-10-2021	05-18-2021	06-23-2021	06-23-2021

4.5 Board Membership

The structure and composition of the IRB must be appropriate to the amount and nature of the research that is reviewed. Every effort is made to have member representation that has an understanding of the areas of specialty that encompasses most of the research performed at OSU.

addition, the IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews.

⁴ Affiliated: An employee or agent of the organization registering the IRB (or a member of that person's immediate family) is considered affiliated. Affiliated members include, but are not limited to, individuals who are: part-time employees; current students; members of any governing panel or board of the Institution; paid or unpaid consultants; healthcare providers holding credentials to practice at the Institution; and volunteers working at the Institution on business unrelated to the IRB. An individual that has no affiliation with the organization registering the IRB, other than as an IRB member, is considered unaffiliated with the entity operating the IRB. Unaffiliated members may include people whose only association with the Institution is that of a patient, subject, or former student at that Institution. Paying unaffiliated members for their services would not make the member "otherwise affiliated" as stated in the regulations, or cause the member to have a conflicting interest.

In addition, the IRB will include members who are knowledgeable about and experienced working with vulnerable populations that typically participate in OSU research.

4.5.1 Appointment of Members to the IRB

All member appointments are made by the IO for a renewable three-year period of service. Any change in appointment, including reappointment or removal, requires written notification from the IO. Members may resign prior to the end of their appointment by written notification to the Administrator, Chair, or IO.

The HRPP Administrator, Vice Chair, or Chair may identify a need for a new, replacement, or alternate member. Anyone can nominate candidates or express interest in membership by contacting the Administrator. Department Chairs or Heads may also forward nominations to the Institutional Official, the Administrator, or the IRB Chair. OSU faculty may also indicate their interest in serving on the Board by contacting the HRPP Administrator.

The Administrator or Chair will present recommendations for new members, reappointments, and removals, to the IO.

4.5.2 Chair of the IRB

The IRB Chair should be a highly respected individual, from within the Institution, fully capable of managing the Board, and the matters brought before it with fairness and impartiality. The task of making the IRB a respected part of the Institutional community will fall primarily on the shoulders of the Chair. The IRB must be perceived to be fair, impartial and immune to pressure by the Institution's administration, the investigators whose protocols are brought before it, and other professional and nonprofessional sources.

The IRB Chair is responsible for conducting the meetings in a manner that promotes respectful dialogue with a focus on the protection of human subjects. The IRB Chair may designate the Administrator or other IRB members to perform duties, as appropriate, for review, signature authority, and other IRB functions.

The IRB Chair advises the Administrator and IO about any concerns related to member performance and competence.

If a Chair is not acting in accordance with the IRB's mission, policies or procedures, has an undue number of absences, or not fulfilling the responsibilities of the Chair, he/she may be removed by and at the discretion of the IO.

4.5.3 Vice Chair of the IRB

The Vice Chair serves as the Chair of an IRB in the absence of the Chair and has the same qualifications, authority, and duties as Chair. In addition, the Vice Chair is responsible for the organization and presentation of continuing education offered to IRB members at full board meetings.

4.5.4 Alternate members

The appointment and function of alternate members is the same as that for primary members, and the alternate's expertise and perspective are comparable to those of the primary member. The role of the alternate member is to serve as a voting member of the IRB when the regular member is unavailable to attend a convened meeting or may attend according to a pre-arranged schedule (e.g., every other meeting). When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member received or would have received.

In most circumstances, the IRB roster identifies the primary member(s) for whom each alternate member may substitute. The alternate member will not be counted as a voting member unless the primary member is absent. The IRB minutes will document when an alternate member replaces a primary member. Certain individuals may be an alternate for any member. For example, all members of one Board are listed as alternates for the other Board(s) in case they are needed as a result of volume or expertise.

4.5.5 Subcommittees of the IRB

The IRB Chair, in consultation with the Administrator, may designate one or more IRB subcommittees to perform duties, as appropriate, to review and undertake IRB functions, and to make recommendations to the IRB. The number and composition of the IRB Subcommittee members shall depend on the authority delegated by the IRB Chair to such IRB Subcommittee (e.g., limited to making recommendations versus decision-making authority).

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
04-24-2015	11-24-2015	06-23-2016	06-23-2016
02-09-2018	02-21-2018	02-22-2018	02-22-2018
05-31-2018	11-20-2018	12-26-2018	01-20-2019
05-16-2019	05-18-2021	06-23-2021	06-23-2021

4.6 IRB Member Conflict of Interest⁵

Relevant regulation(s): §46.107(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

No regular, alternate, or ex officio member may participate in the review of any research project in which the member has a conflict of interest (COI), except to provide information as requested by the Chair or other members present. It is the responsibility of each IRB voting and non-voting member to disclose any COI in a study submitted for review and recuse him/herself from the deliberations and vote.

OSU IRB members and consultants are responsible for disclosing to the Board any actual, potential, or perceived conflicts of interest (COI) concerning protocols reviewed by the IRB.

⁵ Policy approved by the IRB March 2, 2010.

The Chair will ask the Board if any member present has a potential conflict of interest with any investigator or protocol that is under consideration on the day's agenda. This COI query by the Chair will be recorded in the minutes, along with any declarations of COI made by the members/consultants.

In the event that a member believes that she or he cannot provide an independent review, that member will leave the meeting room prior to final deliberation on that protocol. They will not vote on the outcome of the review, nor will they comment on the protocol unless relevant information is requested by a Board member. Members and consultants with conflicts of interest will leave the meeting room prior to the Board's final deliberation and vote. If quorum is lost as a result, the protocol will be tabled until the next convened meeting of the Board. Their exit and re-entrance will be recorded in the minutes as a recusal.

If any member discloses a conflicting interest but indicates that they are able to provide an independent review, Board members will discuss the conflict and make a determination regarding the need for recusal. If there is disagreement on the need for recusal, the issue will be put to a vote. All members, including the member with the potential conflict may participate in the vote.

An IRB member or consultant may be considered to have a conflicting interest requiring recusal when they, or member of their family⁶, has any of the following:

- a) Substantive involvement in the design, conduct, or reporting of the research
- b) Direct supervisory line or mentorship of member of the study team
- c) Ownership interest, stock options, or other financial interest related to the research
- d) Agreement to receive compensation related to the research
- e) Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement
- f) Board or executive relationship related to the research
- g) Any other reason for which the member/consultant believes that he or she cannot provide an independent review or which may lend itself to the perception of a conflicted interest. Reasons may include personal or professional relationships, minor consultation on study design.

IRB members are responsible for self-identifying any conflicting interests to the HRPP Office before conducting review using the expedited procedure, so as to remove themselves' from involvement in the review of the research.

Review assignments are made by the HRPP staff, in collaboration with the Administrator or Chair as needed. Per FDA guidance, in no cases may a researcher select the reviewer for their submission.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
03-18-2016	N/A	06-23-2016	06-23-2016

⁶ "Family member" is defined as anyone having a relationship to a person as a spouse or domestic partner; the parent, child, or sibling of the individual or domestic partner; or any person for whom the individual has a legal support obligation.

4.7 Duties of IRB Members

Members of the IRB or their designated alternates are expected to:

- Attend and participate in the majority of the convened IRB meetings;
- Review all materials provided in each meeting packet in advance of the convened meetings they attend;
- Review all materials relevant to study proposals assigned to them for an expedited review;
- Review and promptly inform the HRPP staff of corrections or additions to convened board meeting minutes;
- Treat the research proposals, protocols, and supporting data confidentially
- Report any concerns about the HRPP to the Administrator, Chair, or IO. If these individuals are not the appropriate recipients of the concerns, IRB members are encouraged to report concerns through one of the follow avenues:
 - University Ombuds: <http://oregonstate.edu/ombuds/>
 - Office of University Compliance: <http://leadership.oregonstate.edu/compliance/reporting>
 - Anonymous third party hotline provider, EthicsPoint: <https://secure.ethicspoint.com/domain/media/en/gui/41096/index.html>

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
01-30-2015	N/A	06-23-2016	06-23-2016

4.8 Attendance Requirements

Members should attend all meetings for which they are scheduled. If a member is unable to attend a scheduled meeting, they should inform the HRPP office. If the inability to attend will be prolonged, a request for an alternate to be assigned may be submitted to the Chair or the Administrator.

If an IRB member is to be absent for an extended period of time, such as for a sabbatical, he or she must notify the IRB at least 30 days in advance so that an appropriate temporary replacement can be obtained. If the member has a designated alternate, the alternate can serve during the primary member's absence.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
04-25-2015	11-24-2015	06-23-2016	06-23-2016

4.9 Education for IRB Members

A vital component of a comprehensive human research protection program is an education program for IRB members. OSU is committed to providing training and an on-going educational process for IRB members and the staff of the HRPP office, related to ethical concerns and regulatory and Institutional requirements for the protection of human subjects.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective

11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016

4.9.1 Orientation

Before voting or assuming the role of a Primary Reviewer, new members will:

- a. Meet with the HRPP Administrator and/or the IRB Chair. The Chair will always be encouraged to participate in this orientation session. That session will include:
 - i. Discuss workload, expectations, meeting preparation
 - ii. Tour of the HRPP website, which includes links to:
 - Belmont Report and Nuremberg Code
 - OSU Policies and Procedures for the Protection of Human Subjects
 - Federal regulations relevant to the IRB
 - Guidance documents relevant to the IRB
 - Reviewer worksheets and related instructions
 - iii. Review member's CV, areas of expertise, and existing conflicts of interest
 - iv. Providing IRB Member Handbook
- b. Complete the relevant modules in the CITI Course
- c. Attend at least two convened meetings
- d. Participate in mock review and reviewer worksheet completion with HRPP staff
- e. Shadow the reviews of at least three board members. Whenever possible, the first review will be completed in person with HRPP staff and primary reviewer; the second will be conducted in person or via email based on the preference and needs of the new member

New members will count towards quorum once added to the federal roster, but must abstain from voting until their onboarding requirements have been completed.

4.9.2 Continuing Education

To ensure that oversight of human research is ethically grounded and the decisions made by the IRB are consistent with current regulatory and policy requirements, training is continuous for IRB members throughout their service on the IRB. Educational activities may include, but are not limited to:

- Continuing education during IRB meetings which may include new information that might impact the IRB, including laws, regulations, policies, procedures, and emerging ethical and scientific issues
- Executive Committee meetings, at least quarterly
- Annual retreats, which may include speakers and mock reviews
- Announcements in meetings and/or via email related to current events
- Unlimited access to the HRPP office resource library
- Placemats displaying regulatory information are provided for each member to use during meetings
- Other training opportunities will be considered by the IO, including attendance at the annual PRIM&R conference or regional conferences on human research protections

4.10 IRB Member Performance

Members who are not acting in accordance with the HRPP's mission or policies and procedures or who have an undue number of absences may be removed at the discretion of the IO. The Chair and Administrator provide informal, but continuous, feedback to everyone involved in the Program. The

Administrator conducts formal evaluations annually of each Program staff member. These evaluations are informed, in part, by feedback received from Board members and researchers.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
11-20-2018	11-20-2018	12-26-2018	01-20-2019

4.11 Liability Coverage for IRB Members

The Institution’s insurance coverage applies to employees and any other person authorized to act on behalf of the Institution or acts or omissions within the scope of their employment or authorized activity.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016

4.12 Use of Consultants

When necessary, the IRB Chair or the Administrator may solicit individuals from the Board, the Institution, or elsewhere with competence in special areas to assist in the review of issues or protocols, which require appropriate scientific or scholarly expertise beyond or in addition to the primary and/or secondary reviewer’s expertise. The need for a consultant may be identified by HRPP staff or any member of the Board for protocols reviewed by an exempt, expedited, or full board procedure. The HRPP office will ensure that all relevant materials are provided to the consultant for review.

Written statements from consultants will be retained as part of the study file. Key information provided by consultants at meetings will be documented in the minutes.

Consultants are asked to disclose any conflicts of interest that they may have with the study prior to providing a review.

If the study requires full board review, reviews provided by consultants will be presented to the Board for consideration either in person or in writing. If in attendance, these individuals may participate in the discussion of the protocol but not the vote, unless the consultant is also a member of the Board.

Ad hoc or informal consultations requested by individual members (rather than the full board) will be requested in a manner that protects the researcher’s confidentiality and is in compliance with the HRPP policy on conflicts of interest.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
04-24-2015	12-18-2015	06-23-2016	06-23-2016
10-26-2016	12-15-2017	12-21-2017	12-21-2017

4.13 Reporting and Investigation of Allegations of Undue Influence

If an IRB Chair, member, or staff person feels that the IRB has been unduly influenced by *any* party, they may report any concerns to the Administrator, Chair, or IO. If these individuals are not the appropriate recipients of the concerns, IRB members are encouraged to report concerns through one of the following avenues:

- University Ombuds: <http://oregonstate.edu/ombuds/>
- Office of University Compliance: <http://leadership.oregonstate.edu/compliance/reporting>
- Anonymous third party hotline provider, EthicsPoint: <https://secure.ethicspoint.com/domain/media/en/gui/41096/index.html>

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
04-24-2015	12-18-2015	06-23-2016	06-23-2016

5 Records and Documentation

5.1 Policy

IRB shall prepare and maintain adequate documentation of the IRB's activities. All records must be accessible for inspection and copying by authorized representatives of the FDA, OHRP, sponsors, and other authorized entities at reasonable times and in a reasonable manner.

OSU IRB documents are not signed by the Chairperson or designee. Federal regulations do not require signatures on approval documents (*see FDA Factsheet FAQ 1998*). Therefore, the OSU IRB documents meet the regulatory requirements for notifications.

5.1.1 IRB Records

IRB records include, but are not limited to:

- a) Written operating procedures
- b) IRB membership rosters
- c) Records of research investigators, IRB members, and HRPP staff that have fulfilled the Institution's ethics/compliance training requirements
- d) IRB correspondence (other than protocol related)
- e) IRB Study Files
- f) Documentation of Emergency Exemption from Prospective IRB Approval (21 CFR 56.104(c))
- g) Documentation of Exceptions from Informed Consent Requirements for Emergency Use of a Test Article (21 CFR 50.23)
- h) Documentation of exemptions
- i) Documentation of convened IRB meetings minutes
- j) Documentation of review by another Institution's IRB when appropriate
- k) Documentation of cooperative review agreements, e.g. Memoranda of Understanding (MOUs) and authorization or reliance agreements
- l) Federalwide Assurances
- m) Protocol violations submitted to the IRB
- n) Quality assurance reviews

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016

5.2 IRB Study Files

The IRB will maintain a separate file for each research application (protocol) that it receives for review. Protocols will be assigned a unique identification number and entered into the IRB tracking system.

Study files include (as applicable), but are not necessarily limited to:

- a) Documents submitted as part of an initial application
- b) Documents submitted as part of post-approval, such as project modification, continuing review applications, or reportable events
- c) Approved consent forms
- d) Reviewer worksheets from IRB members (if exempt or expedited)
 - Note:** Review forms are to be used as a guide for full board studies and not indicative of final determinations.
- e) Documentation of information provided by consultants or as part of scientific reviews
- f) Documentation of the level of review (e.g., exempt, expedited, full board)
- g) Documentation of any determinations required by the regulations and protocol-specific findings supporting those determinations, including: waivers, risk level, and subparts
- h) Documentation of all IRB actions, determinations, and stipulations
- i) Documentation of study expiration and related notification to the PI
- j) Correspondence pertaining to appeals
- k) Study related correspondence between the IRB and the study team
- l) Any reports of prior device investigations
- m) Documentation of audits, investigations, or reports of external site visits
- n) Documentation of study-specific QA/QI activities
- o) Documents submitted as part of a study closure

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
04-24-2015	12-18-2015	06-23-2016	06-23-2016
06-24-2016	07-14-2016	07-29-2016	07-29-2016
12-22-2022	2-14-2023	3-16-2023	3-16-2023

5.3 IRB Minutes

It is the responsibility of the HRPP staff present to take minutes of the meeting. If the meeting is audio recorded, that recording will be destroyed after the minutes for that meeting are acknowledged. Only the final version of the minutes from a single meeting will be retained.

Minutes are distributed for member comment within one week of the meeting. The Chair or Vice Chair must provide their acknowledgement of the content. Proceedings must be written and available for review by the next regularly scheduled IRB meeting date. There is no regulatory requirement to vote on

or formally approve minutes. Once acknowledged by the members at a subsequent IRB meeting, the minutes must not be altered by anyone, including a higher Institutional authority.

A copy of the minutes for each IRB meeting will be provided to the IO as part of the materials for the following meeting.

Minutes of IRB meetings must contain sufficient detail to show each of the items below, as applicable:

a) Attendance

- i. Names of members present
- ii. Names of members, or alternate members, who are participating through videoconference or teleconference and documentation that those attending through videoconferencing or teleconferencing received all pertinent material prior to the meeting and were able to actively and equally participate in all discussions
- iii. Names of alternates attending in lieu of specified (named) absent members. (Alternates may substitute for specific absent members only as designated on the official IRB membership roster)
- iv. Names of consultants present
- v. Name of investigators present
- vi. Names of guests present

Note: The initial attendance list shall include those members present at the meeting. The minutes will indicate, by name, those members who enter or leave the meeting. The vote on each action will reflect those members present for the vote on that item. Members who recuse themselves because of conflict of interest are listed by name and the reason documented.

- b) The presence of a quorum throughout the meeting, including the presence of one member whose primary concern is in a non-scientific area
- c) Business Items discussed
- d) Continuing Education
- e) Actions taken, including separate deliberations, actions, and votes for each protocol undergoing review
- f) Basis or justification for these actions including required changes in research
- g) Votes on these actions
- h) Summary of controverted issues and their resolution
- i) Approval period for initial and continuing approved protocols, including identification of research that warrants review more often than annually and the basis for that determination
- j) Risk level of initial and continuing approved protocols
- k) Review of Plans for Data and Safety Monitoring
- l) Review of post approval submissions, e.g. amendments; reports of unanticipated problems, deviations, non-compliance; suspensions/terminations; etc
- m) Data and Safety Monitoring Board (DSMB) summary
- n) Protocol-specific documentation that the research meets the required criteria [45 CFR 46.116(d)] when approving a consent procedure that does not include or that alters some or all of the required elements of informed consent, or when waiving the requirement to obtain an informed consent

- o) Protocol-specific documentation that the research meets the required criteria [45 CFR 46.117(c)] when the requirements for documentation of consent are waived
- p) Documentation that actions or determinations are in compliance with 45CFR46 subparts, as applicable
- q) Documentation of any additional safeguards needed to enhance the protection of subjects considered to be vulnerable
- r) The rationale for significant risk/non-significant risk device determinations
- s) Identification of any research for which there is need for verification from sources other than the investigator that no material changes are made in the research.
- t) Notation that members are directed to review the list of research approved since the last meeting utilizing exempt and expedited procedures. The list will be included in the agenda packet for all board members, monthly or (if canceled) at the next convened meeting
- u) An indication that, when an IRB member has a conflicting interest with the research under review, the IRB member was not present during the deliberations or voting on the proposal, and that the quorum was maintained.
- v) Determinations of conflict of interest and plan for addressing the COI
- w) Key information provided by consultants will be documented in the minutes or in a report provided by the consultant

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
04-24-2015	12-18-2015	06-23-2016	06-23-2016
10-3-2019	05-18-2021	06-23-2021	06-23-2021

5.4 IRB Minutes and Public Records Requests

IRB meeting minutes are subject to the Oregon Public Records Rule. Rules regarding public records requests made to OSU are available in OSU’s Oregon Administrative Rules, at 576-004-0000 through 576-004-00020. All requests should be made directly to the Office of General Counsel. The procedures are available on the OSU website and Requests for OSU public records may be made by e-mail to this address: publicrecords@oregonstate.edu.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
04-24-2015	12-18-2015	N/A	12-18-2015

5.5 IRB Membership Roster

A list of IRB members must be maintained; and must sufficiently describe each member's areas of expertise. The list must contain the following information about members, but may include additional details:

- a) Name
- b) Gender
- c) Earned degrees

- d) Affiliated or non-affiliated status (neither the member nor an immediate family member of the member may be affiliated with the Institution)
- e) Department or other relationship with the institution
- f) Status as scientist (physician-scientist, other scientist, non-scientist or social behavioral scientist).
- g) Representative capacities of each IRB member; which IRB member is a prisoner representative (as required by Subpart C), and which IRB members are knowledgeable about or experienced in working with children, pregnant women, cognitively impaired individuals, and other vulnerable populations locally involved in research.
- h) Role on the IRB (Chair, Co-Chair, etc.)
- i) Voting status (*ex officio* members are non-voting members)
- j) For alternate members, the primary member or class of members for whom the member could substitute, as applicable

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
01-30-2015	N/A	06-23-2016	06-23-2016
11-08-2017	12-15-2017	12-21-2017	12-21-2017
01-29-2018	02-21-2018	02-22-2018	02-22-2018
05-31-2018	11-20-2018	12-26-2018	01-20-2019
03-10-2021	05-18-2021	06-23-2021	06-23-2021

5.6 Documentation of Exemptions

Documentation of verified exemptions consists of the reviewer’s citation of a specific exemption category and written concurrence that the activity described in the investigator’s request for satisfies the conditions of the cited exemption category. Exempt determinations are included in the agenda packet monthly (or at the next convened IRB meeting, in the event that a meeting is cancelled) and any discussion is documented in the minutes.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016

5.7 Documentation of Expedited Reviews

IRB records for initial review by the expedited procedure must include: the specific permissible category; that the activity described by the investigator satisfies all of the criteria for approval under expedited review; the approval period and any determinations required by the regulations including protocol-specific findings supporting those determinations. If continuing review of expedited research is required, rationale must be documented.

Studies approved by expedited review are included in the agenda packet monthly (or at the next convened IRB meeting, in the event that a meeting is cancelled) and any discussion is documented in the minutes.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
11-13-2018	11-20-2018	12-26-2018	01-20-2019

5.8 Access to IRB Records

The IRB has policies and procedures to protect the confidentiality of research information:

- a) When unattended, all paper IRB records are kept secure in locked cabinets or locked rooms;
- b) Ordinarily, access to all IRB records is limited to the IRB Chair, IRB members, ORI administrators, officers, and staff, authorized Institutional Official, ancillary compliance units when relevant, and officials of Federal and state regulatory agencies (OHRP, FDA). Research investigators are provided reasonable access to files related to their research. Appropriate accreditation bodies are provided access and may recommend additional procedures for maintaining security of IRB records. All other access to IRB records is limited to those who have legitimate need for them, as determined by the IO;
- c) Records are accessible for inspection and copying by authorized representatives of Federal regulatory agencies during regular business hours;
- d) HRPP staff will provide copies of records for authorized personnel if requested;
- e) All other access to IRB study files is prohibited.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
03-18-2016	N/A	06-23-2016	06-23-2016

5.9 Record Retention

All records described in this policy shall be accessible for inspection and copying by authorized representatives of the IRB, by authorized representatives of the federal funding agency, if any, and any federal oversight body with relevant authority.

Records retained by the IRB. Records document the review of research proposals that involve the use of human subjects. Reviews may be made by the entire review board (IRB), by selected members, the board's chair, or by HRPP staff. Records will be retained for three years post-study termination and may include, but are not limited to; approved protocols and consent forms; samples and/or approved test instruments; copies of grant proposals (as applicable, but not required after 1/18/2018); review summaries; and related memoranda and correspondence.

IRB minutes are retained permanently. The electronic (born-digital) version is considered the record copy.

Determination forms and requests for an approval in principle will be retained for at least three years and will only be stored electronically.

In accordance with **45 CFR 46.115** and **21 CFR 56.115**, the IRB shall also prepare and maintain adequate documentation of IRB activities, including the following:

- Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
- Minutes of IRB meetings.
- Records of continuing review activities.
- Copies of all correspondence between the IRB and the investigators.
- A list of IRB members in the same detail as described in 45 CFR 46.103(b)(3).
- Written procedures for the IRB in the same detail as described in 45 CFR 46.103(b)(4) and 45 CFR 46.103(b)(5), 21 CFR 56.108(a) and (b).
- Statements of significant new findings provided to subjects, as required by 45 CFR 46.116(b)(5) and 21 CFR 50.25.

Records retained by the Principal Investigator. The principal investigator shall have primary responsibility for storing their research records in a secure and audit accessible manner for a minimum of three years post-study termination, including signed consent forms and completed surveys, research notebooks, as well as digital records or other media form. These records may be stored electronically, so long as the plan for storage and corresponding secure destruction of any paper records is described in the IRB-approved protocol. Exceptions to the length or manner of storage may be considered if requested by the target population, site of research, external collaborators, or funding source.

For FDA-regulated research. In accordance with **21 CFR 312 (drugs)**, an investigator or sponsor shall retain the records and reports for 2 years after a marketing application is approved for the drug; or, if an application is not approved for the drug, until 2 years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified.

In accordance with **21 CFR 812 (devices)**, an investigator or sponsor shall maintain the records required by this subpart during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.

Departing faculty. In the event of exigent circumstances where the investigator cannot retain research records, or if the investigator intends to leave their position at the university, the investigator and their Department Head or Dean (not the IRB) should identify the successor responsible for maintaining those Institutional records, and for determining whether the original records or verified copies shall be retained by the university. In the event a researcher leaving their position at the university removes the original research data from the university, they must leave a verified copy and agree to provide access to the university to the original data, as well as to other individuals or entities having a legitimate need for access.

Relevant references:

- 45 CFR 46.115 IRB Records
- 21 CFR 56.115 IRB Records
- 21 CFR 312 Investigational New Drug Application

- 21 CFR 812 Investigational Device Exemptions

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
04-26-2016	N/A	06-23-2016	06-23-2016
12-15-2017	12-15-2017	12-21-2017	12-21-2017
01-29-2018	02-21-2018	02-22-2018	02-22-2018
11-20-2018	11-20-2018	12-26-2018	01-20-2019

6 IRB Review Process

6.1 Sponsored Research

6.1.1 Policy

It is OSU's policy that any sponsored research conducted under the auspices of the Institution is conducted in accordance with federal guidelines and ethical standards.

The following describes the procedures required to ensure that all sponsored research meets this requirement.

6.1.2 Definitions

Sponsor. Sponsor means the company, Institution, individual donor, or organization responsible for the initiation, management, or financing of a research study.

Sponsored research. Sponsored research means research funded by external entities through a grant or contract that involves a specified statement of work (e.g., the research proposal) with a related transfer of value to the sponsor, including clinical trials involving investigational drugs, devices or biologics.

6.1.3 Responsibility

Per the revised Common Rule (2018) section 46.103, IRBs are no longer required to review and document concordance between grant proposals and study protocol.

The IRB will forward a copy of all relevant notices to the Office of Sponsored Research and Award Administration for any externally sponsored research, regardless of funding source. Relevant notices include, but may not be limited to, initial or continuing approval or exemption; suspension, termination, and closures; approvals in principle; and project modifications involving a change in funding.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
03-04-2015	12-18-2015	06-23-2016	06-23-2016
12-12-2017	12-15-2017	12-21-2017	12-21-2017
01-29-2018	02-21-2018	02-22-2018	02-22-2018
11-13-2018	11-20-2018	12-26-2018	01-20-2019

12-22-2022	2-14-2023	3-16-2023	3-16-2023
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6.2 Conflict of Interest in Research

6.2.1 Policy

It is the IRB’s policy to preserve public trust in the integrity and quality of research at the Institution by minimizing actual or perceived conflict of interest in the conduct of research.

The following describe the procedures by which this responsibility is carried out.

6.2.2 Definitions

Conflict of Interest. A non-research interest, such as an interest in the source(s) of funding, materials, equipment, data, research subjects, or site of research related to this study. These interests may be financial but extend to personal and other non-financial interests. These interests are exclusive of the costs of conducting the research.

Examples of potential conflicts of interest in research involving human subjects may include, but are not limited to:

- An investigator or family member participates in research on a technology, process or product owned by a business in which the faculty member holds a financial interest. Any interest should be disclosed to the IRB, regardless of whether it meets the threshold of a “significant financial interest,” as defined by the Public Health Service (PHS).
- An investigator or family member has a financial or other business interest in an entity that is supplying funding, materials, products, equipment, research subjects, or the site of data collection for the current research project.
- An investigator or family member serves on the Board of Directors of a business that is supplying funding, materials, products, equipment, research subjects, or the site of data collection for the current research project.
- An investigator receives consulting income from an entity that is funding the current research project.
- An investigator participates in research on a technology, process or product developed for which the investigator has intellectual property rights (e.g., copyrights, trademarks, patents, or trade secrets) or receives royalties.

Non-financial Conflict of Interest. Non-financial conflict of interest may exist when an individual serves dual roles, such as health care provider and investigator. Other interests such as publication, promotion or tenure, can also become conflicts of interest that may affect an individual's judgment. Membership in oversight committees, such as the IRB, as well as positions of authority may pose potential conflicts of interest. Any position that includes responsibilities for the review and approval of research projects or contracts other than his/her own may potentially affect the design of, decisions made and/or action taken surrounding a specific study. Non-financial conflicts may also include familial relationships with a source, site, or collaborator.

Investigator. For the purposes of this policy, “investigator” refers to any member of the study team or a member of their immediate family.

Equity Interest. Stock, stock options or ownership interest as determined through reference to public prices or other reasonable measures of fair market value during the time the investigator is carrying out the study and for 1 year following completion of the study.

Immediate Family Member. Immediate family member is defined as anyone having a relationship to a person as a spouse or domestic partner; or the dependent children of the spouse or domestic partner.

6.2.3 Investigator Conflicts of Interest

These procedures apply to both financial and non-financial conflicts of interest and promote objectivity in research to ensure conflict of interests do not adversely affect the protection of participants.

For clinical studies involving the use of new human drugs and biological products or medical devices, certifications and disclosure requirements are defined in Food and Drug Administration (FDA) regulations, Title 21 CFR Part 54.

Conflicts of interest should be eliminated when possible and effectively disclosed and managed when they cannot be eliminated.

The research application asks protocol-specific questions regarding conflict of interest for all study team members and their immediate family members. Applications that are received by the IRB which include a disclosure of a conflict of interest are forwarded to the COI Administrator for review. The study file is accessible to COI Committee while under review and after it has been approved. IRB approval may be issued prior to a determination from the COI Committee if the IRB has reviewed the relevant details and finds that the matter is appropriately managed within the protocol and, if applicable, the consent process.

6.2.3.1 Evaluation of COI

At initial review of the research protocol and COI disclosure, the IRB also determines whether the financial or non-financial interest affects the protections of research participants.

6.2.3.2 Management of COI

The IRB will determine if the rights and welfare of human research participants will be better protected by one or more of the following:

1. Disclosure to subjects through the consent process
2. Modification of the research protocol or safety monitoring plan
3. Monitoring of research by independent reviewers
4. Disqualification of the conflicted party from participation in all or a portion of the research
5. Appointment of a non-conflicted Principal Investigator
6. Prohibition of the conduct of the research at OSU

6.2.4 Recruitment Incentives

Payment arrangements among sponsors, organizations, investigators, and those referring research participants may place participants at risk of coercion or undue influence or cause inequitable selection. Payment in exchange for referrals of prospective participants from researchers (physicians) (“finder’s fees”) is not permitted. Similarly, payments designed to accelerate recruitment that is tied to the rate or timing of enrollment (“bonus payments”) are also not permitted.

6.2.5 Institutional Conflict Of Interest

The policy of the IRB is to ensure that the welfare of human subjects and the integrity of research will not be compromised, or appear to be compromised, by competing Institutional interests or obligations.

Although the HRPP policy has separated OSU Foundation functions from the University functions, circumstances may exist in which separation of function is not sufficient to avoid the appearance of Institutional conflict of interest.

6.2.6 Identification of Institutional Conflict of Interest

The Conflict of Interest Committee will make all disclosures and management plans accessible to the HRPP Administrator and Chair. If the Administrator and Chair determine that the I-COI is related to the research, information about the I-COI will be disclosed to all IRB members for consideration regarding the impact on new or ongoing studies.

6.2.7 Management of Conflict of Interest

6.2.7.1 Decision making

A key aspect in decision-making is to analyze when it would be appropriate and in the public interest to accept and manage a COI, rather than require that the COI be eliminated prior to the initiation of research. In some cases, the benefits of conducting a proposed research activity at the Institution will be potentially high, and the risks will be low. In other cases, the scientific advantages of conducting the research may be speculative and the risks may be great. In these latter instances, the conflict should be avoided by disapproving the research application.

6.2.7.2 Evaluation of risk

Each case should be evaluated based upon the following:

- a) The nature of the science;
- b) The nature of the interest;
- c) How closely the interest is related to the research;
- d) The degree of risk that the research poses to human participants; and
- e) The degree to which the interest may be affected by the research.

6.2.7.3 Potential actions

Potential actions to be considered include any (or a combination) of the following as appropriate to minimize risks to subjects and maximize transparency:

- a) Public disclosure of the financial interest;
- b) Not conducting proposed research at that Institution, or halting it if it has commenced;
- c) Reducing or otherwise modifying the financial (equity or royalty) stake involved;
- d) Increasing the segregation between the decision-making regarding the financial and the research activities;
- e) Requiring an independent data and safety monitoring committee or similar monitoring body; or
- f) Establishing a research monitoring process, so that the research can be closely scrutinized to ensure that potential conflicts do not undermine the integrity of the work and of the Institution.

Revision Dates

Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
12-08-2016	02-19-2016	03-03-2016	04-01-2016
None	N/A	06-23-2016	06-23-2016
07-27-2016	N/A	N/A	07-29-2016
01-29-2018	02-21-2018	02-22-2018	02-22-2018

6.3 Levels of Review

Levels of review for human subjects research include:

- Exempt
- Exempt- Limited IRB Review
- Expedited
- Full Board

The HRPP and the IRB (as applicable) will ensure that the research meets all required ethical and regulatory criteria for initial and continuing review and any modifications of approved research.

The primary reviewer must be a voting member of the IRB in all cases (including exempt- Limited IRB review) except the exempt categories. The voting members may also be on the HRPP staff, except in the case of full board review.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
12-12-2017	12-15-2017	12-21-2017	12-21-2017
01-29-2018	02-21-2018	02-22-2018	02-22-2018
12-22-2022	2-14-2023	3-16-2023	3-16-2023
5-14-2022	2-14-2023	3-16-2023	3-16-2023

6.4 Exempt Studies

Certain research involving human subjects will be deemed “exempt” under the Common Rule. The significance of an exemption is that the application of the Common Rule is limited to compliance with 45 CFR 46 and the described categories of exemption.

Exempt status does not lessen the ethical obligations to study participants as articulated in the Belmont Report, in discipline-specific codes of professional conduct, or other regulations. Thus, depending on the circumstances, researchers performing exempt studies may need to make provisions to obtain informed consent, protect confidentiality, minimize risks, and address problems or complaints.

To be deemed to be exempt, human subjects research activities must be reviewed and determined to fall within one or more of the explicit exemption categories listed in the federal regulations.

Studies determined to be exempt are acknowledged rather than approved.

6.4.1 Authority to Grant Exemptions

Exempt determinations can be made by any member of the IRB or by persons appointed as exempt designees by the Chair of the IRB, with the exception of Exempt- Limited IRB reviews, which must be performed by an IRB member. Identification of exempt designees will be made in writing once the designee has received appropriate training and has demonstrated the appropriate level of regulatory expertise to make exempt determinations.

6.4.2 Limitations on Exemptions

Pregnant women. All exempt categories can be applied to research on pregnant women.

Prisoners. None of the categories of exemption can be applied to research with prisoners unless prisoners are only incidentally included in a study of a broader population and the researcher will not have access to information regarding incarceration.

Children. Most of the categories of exemption can be applied to research with children. The exception is exempt category 2, which can only apply to observation of public behavior if the researcher is not participating in the activity being observed.

Risk: If the study presents a risk not articulated in the categories of exemption, such as the risk of causing distress to the subject, the IRB may review the study by an expedited or full board procedure.

6.4.3 Categories of Exempt Research

With the above exceptions, research activities not regulated by the FDA in which the only involvement of human subjects will be in one or more of the following categories are exempt from full board review:

6.4.3.1 Category 1

Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

6.4.3.2 Category 2

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

- (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §__.111(a)(7).

6.4.3.3 Category 3

(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; and

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §__.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

6.4.3.4 Category 4

Secondary research for which consent is not required. Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

6.4.3.5 Category 5

Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6.4.3.6 Category 6

Taste and food quality evaluation and consumer acceptance studies, (i) If wholesome foods without additives are consumed; or (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Note 1: Researchers must be able to demonstrate that the study meets the above criteria.

Note 2: Ingestion of alcohol or dietary supplements will not be considered exempt under this category. Studies including alcohol that are limited to sensory tests (such as smell or taste followed by expectoration prior to swallowing) may be considered for this exemption category depending on the specifics of the target population, the precautions taken to minimize risk, and the nature of the other study activities.

6.4.3.7 Category 7

Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §__.111(a)(8).

Note: OSU will only utilize this category if the collection of data or specimens was approved by an external IRB that uses broad consent and conducted a limited review.

6.4.3.8 Category 8

Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §__.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §__.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §__.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Note: OSU will only utilize this category if the collection of data or specimens was approved by an external IRB that uses broad consent and conducted a limited review.

6.4.4 FDA Exemptions

Refer to the section titled, “FDA Regulated Research” for categories of clinical investigations that are exempt from the requirements of IRB review.

6.4.5 EPA Exemptions

Studies funded or regulated by the Environmental Protection Agency (EPA) and studies involving EPA investigators must be reviewed by the Agency.

6.4.6 Procedures for Exemption Determination

To receive an exempt determination, investigators must submit the appropriate IRB application and study instruments used for data collection (e.g., surveys, questionnaires, data sets, interview questions, etc.)

All members of the research team must complete ethics training prior to initiating research activities.

To document the determination of exempt status, the exempt designee indicates whether the project is human subject research and if exempt, which exemption category applies. Any questions that need to be addressed in order to issue the determination will be communicated to the investigators by the exempt designee. The exempt designee may consult with the Chair, members of the IRB, consultants with particular subject matter expertise, or other parties as appropriate.

Annual renewal applications are not required for exempt research. An administrative check-in date of five years will be applied to the study and the PI should close the application at that time if all human subject research is complete.

The Chair or designee will review all new exempt applications and project modifications by the above procedure. Not all changes to exempt protocols require review. See guidance on HRPP website. Reportable events, such as deviations and unanticipated events, will be reviewed by the procedure described for review of those events regardless of review level.

Decisions related to exempt studies will be communicated in writing to the investigator. Documentation will include the applicable exemption category(ies).

All members of the IRB will be apprised of all exempt determinations. Any IRB member can request to review the full protocol by contacting the HRPP office.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
01-30-2015	05-14-2015	03-03-2016	04-01-2016
None	N/A	06-23-2016	06-23-2016
12-12-2017	12-15-2017	12-21-2017	12-21-2017
01-29-2018	02-21-2018	02-22-2018	02-22-2018
11-13-2018	11-20-2018	12-26-2018	01-20-2019
08-15-2019	05-18-2021	06-23-2021	06-23-2021
02-23-2022	03-08-2022	03-08-2022	03-08-2022
12-22-2022	2-14-2023	3-16-2023	3-16-2023

6.5 Expedited Review

An IRB may use the expedited review procedure to review the following:

1. Some or all of the research appearing on OHRP's list of categories of research eligible for expedited review unless found by the reviewer(s) to involve more than minimal risk,
2. Minor changes in previously approved research during the period for which approval is authorized

6.5.1 Authority to Grant Approval

Approval for studies reviewed by an expedited procedure can be granted by the Chair or their designee. The designee must be a voting member of the IRB. In many cases, the primary reviewer will also be a member of the HRPP staff. Expedited submissions will be reviewed by a primary reviewer, with a secondary reviewer or consultant on an as needed basis.

6.5.2 Categories of Research Eligible for Expedited Review

[Federal Register: November 9, 1998 (Volume 63, Number 216)]

The activities listed below should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects. However, reviewers must document their rationale if they determine that research appearing on the expedited review list is more than minimal risk.

The categories in this list apply regardless of the age of subjects, except as noted.

The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

The expedited review procedure may not be used for classified research involving human subjects.

The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

Research Categories one (1) through seven (7) pertain to both initial and continuing IRB review:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (**Note:** Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Note: Per the FDA Center for Devices and Radiological Health, category 1(b) includes non-significant risk devices. ⁷

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - b) From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times

⁷ Sheila Brown, FDA, Center for Devices and Radiological Health (telephone conversation, 2015).

per week. [Children are defined in the DHHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."][45 CFR 46.402(a)]

3. Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

Note 1: Current interpretation from OHRP is that this category can apply to research involving materials that were previously collected for any purpose, provided that any materials collected for research were not collected for the currently purposed research, or research involving materials that will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). [reference: Huron presentation, November 14, 2012, OHRP Regulatory Interpretations that you need to know but have never been told.]

Note 2: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. See Exempt Categories and 45 CFR 46 101(b)(4). This listing refers only to research that is not exempt.

6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Note: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. See Exempt Categories and 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.

8. Continuing review of research previously approved by the convened IRB as follows:
 - a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; *or*
 - b) Where no subjects have been enrolled and no additional risks have been identified [since last review]; *or*
 - c) Where the remaining research activities are limited to data analysis.

Note: Category (8) identifies three situations in which research that is greater than minimal risk and has been initially reviewed by a convened IRB may undergo subsequent continuing review by the expedited review procedure. The decision to conduct a renewal under categories 8(a-c) can be made by the Chair or Vice Chair without the protocol being returned to full board for re-classification. Annual review must take place each subsequent year to ensure that if and when the expedited category ceases to apply, the renewal is reviewed by a full board procedure.

For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever the conditions of category (8)(a), (b), or (c) are satisfied for that site. However, with respect to category 8(b), while the criterion that "no subjects have been enrolled" is interpreted to mean that no subjects have ever been enrolled at a particular site, the criterion that "no additional risks have been identified" is interpreted to mean that neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Note: The determination that "no additional risks have been identified" does not need to be made by the convened IRB.

6.5.3 Expedited Review Procedures

Under an expedited review procedure, the review may be carried out by the IRB Chair or by one or more reviewers designated by the Chair from among the voting members of the IRB. IRB members who serve

as designees to the IRB Chair for expedited review will be matched as closely as possible with their field of expertise to the study.

All trained, voting members of the IRB are eligible to conduct expedited reviews. The HRPP staff will select expedited reviewers from the roster who have the qualifications, experience and knowledge in the content of the protocol to be reviewed, as well as knowledge of the requirements to approve research under expedited review. IRB members with a conflict of interest in the research disclose the COI to the HRPP staff upon receipt of the assignment and the study will be re-assigned to a non-conflicted member.

When reviewing research under an expedited review procedure, the IRB Chair, or designated IRB member(s), should receive and review all documentation submitted by the PI. The reviewer will also receive and complete the appropriate reviewer worksheet(s) which will serve as documentation of the expedited category or categories as well as whether the research meets the regulatory criteria for approval. If the research does not meet the criteria for expedited review, then the reviewer will indicate that the research requires full review by the IRB and the protocol will be placed on the next agenda for an IRB meeting.

In reviewing the research, the reviewers will follow the review procedures described later in this section and may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth below.

Reviewers will indicate approval, required modifications, or requirement for convened board review on reviewer worksheet and return the worksheet to the HRPP office. If modifications are required, the HRPP staff will inform the investigator in writing.

In the event that expedited review is carried out by more than one IRB member and the expedited reviewers disagree, the HRPP Administrator and/or IRB Chair may make a final determination. Upon the discretion of the HRPP Administrator or IRB Chair, the protocol will be submitted to the full board for review.

6.5.4 Informing the IRB

All members of the IRB will be apprised of all expedited review approvals via written monthly reports. Any IRB member can request to review the full protocol by contacting the HRPP office.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
03-18-2016		06-23-2016	06-23-2016
06-24-2016	07-14-2016	07-29-2016	07-29-2016
11-08-2017	12-15-2017	12-21-2017	12-21-2017
01-29-2018	02-21-2018	02-22-2018	02-22-2018
11-13-2018	11-20-2018	12-26-2018	01-20-2019
08-15-2019	05-18-2021	06-23-2021	06-23-2021

6.6 Convened IRB Meetings

All human subjects research involving greater than minimal risk will be reviewed at a convened meeting of the full board, except when an expedited review procedure is permitted by regulation.

6.6.1 IRB Meeting Schedule

The schedule for IRB meetings may be found on the HRPP website. Special meetings may be called at any time by the Chair or the Administrator.

6.6.2 Preliminary Review

An HRPP staff member will perform a preliminary review of all protocol materials submitted to the HRPP office for determination of completeness and accuracy. Initial pre-review sent from staff to the PI (prior to review by an IRB member) will include clarifying questions; requests for missing documents, or letters of support or permission; discrepancies and inconsistencies; missing sections or elements in sections of the documents; missing training; and clear regulatory or policy issues. Only complete submissions will be placed on the IRB agenda for review. The investigator will be informed in writing of missing materials. HRPP staff will also conduct a preliminary review of each submission for compliance with federal regulations and HRPP policies. Any issues identified during this preliminary review will be noted for the reviewers on the worksheet.

6.6.3 Primary and Secondary Reviewers

After it has been determined that the protocol submission is complete, an HRPP staff member, in consultation with the Administrator (as necessary), will assign protocols for review paying close attention to the scientific content of the protocol, the potential reviewer's area of expertise and representation for vulnerable populations involved in the research.

At least one reviewer will be assigned to each protocol and a reviewer may be assigned several protocols or other research items for review. Reviewers are assigned to all protocols requiring initial review, continuing review, and review of modifications.

Initial protocols requiring full board review will be assigned to a primary and secondary reviewer, with a consultant on an as-needed basis.

When the IRB is presented with a protocol that may be outside of the knowledge base or representative capacity of the IRB members, a consultant will be sought. Protocols for which appropriate expertise cannot be obtained for a given meeting will be deferred to another meeting when appropriate expertise can be achieved. See section on consultants for additional information.

Primary reviewers are responsible for:

1. Having a thorough knowledge of all of the details of the proposed research.
2. Performing an in-depth review of the proposed research.
3. Leading the discussion of the proposed research at the convened meeting and leading the IRB through the regulatory criteria for approval.
4. Making suggestions for changes to the proposed research, where applicable.
5. Completing all applicable IRB reviewer forms.

Secondary reviewers are responsible for:

1. Having a thorough knowledge of all of the details of the proposed research.

2. Performing an in-depth review of the proposed research with a particular focus on the documents and methods related to consent and recruitment.
3. Making suggestions for changes to the proposed research that differ from, or were not identified by, the primary reviewer.
4. Completing all applicable IRB reviewer forms.

An absent reviewer can submit their written comments for presentation at the convened meeting, as long as there is another reviewer present at the convened meeting, who has read the materials and can serve as the reviewer.

All of the IRB members receive and are expected to review all studies, not just the ones they are responsible for reviewing.

6.6.4 Pre-Meeting Distribution of Documents

Required materials must be submitted at least one week prior to the convened meeting for inclusion on the following IRB agenda. However, submissions will rarely be added to the agenda before pre-meeting stipulations have been addressed. The meeting agenda will be prepared by an HRPP staff member under the supervision of the HRPP Administrator and distributed to the IRB members and the IO prior to the meeting. IRB members receive the agenda and materials for review one week prior to the scheduled meeting. At a minimum, agenda packets include the agenda, minutes from the previous meeting, and any study submissions for review.

6.6.5 Materials received by the IRB

Each IRB member receives and reviews the following documentation, as applicable, for all protocols on the agenda:

- Internal or external protocol
- Proposed Consent / Parental Permission / Assent Form(s) or Guides
- Recruitment materials
- Data collection instruments
- Approval documents from external IRB
- Investigator's brochure
- Scientific review from sponsor or review committee
- Letters of support or permission from external sites

If an IRB member requires additional information to complete their review they may contact the investigator directly or may ask the HRPP office to make the request of the investigator.

6.6.6 Quorum

A quorum consists of a simple majority (more than half) of the voting membership, including at least one member whose primary concern is in a non-scientific area. If research involving an FDA-regulated article is involved, a licensed physician must be included in the quorum. Whenever possible, at least one unaffiliated member and one member representing the perspective of participants will be present at convened meetings, but this is not required for quorum.

The IRB Chair, with the assistance of the HRPP staff, will confirm that an appropriate quorum is present before calling the meeting to order. The IRB Chair will be responsible for ensuring that the meetings remain appropriately convened.

At meetings of the IRB, a quorum must be established and maintained for the deliberation and vote on all matters requiring a vote. The IRB Chair, with the assistance of the HRPP staff, will confirm that an appropriate quorum is present before calling the meeting to order and that quorum is maintained until the meeting is adjourned. If a quorum is not maintained, the pending action item(s) must be deferred until quorum is established or until the next meeting. The HRPP staff will document, in the minutes, the time of arrival and departure for all IRB members and notify the IRB Chair if a quorum is lost.

IRB members are considered present and participating at a duly convened IRB meeting when either physically present or participating through electronic means (e.g., teleconferencing or video conferencing) that permits them to listen to and speak during IRB deliberations and voting. When not physically present, the IRB member must have received all pertinent materials prior to the meeting and must be able to participate actively and equally in all discussions.

Opinions of absent members that are transmitted by mail, telephone, facsimile or e-mail may be considered by the attending IRB members but may not be counted as votes or to satisfy the quorum for convened meetings.

In some cases, primary members may not count towards quorum for every meeting. For example, the Prisoner Representative only counts towards quorum when his/her presence is required for the review of a protocol involving incarcerated subjects. Other members may serve similar roles and their impact on quorum will be noted in the roster.

6.6.7 Meeting Procedures

The IRB Chair, or Vice-Chair in the event that the IRB Chair is absent, will call the meeting to order once it has been determined that a quorum is in place. In the event that neither the Chair or Vice Chair is able to chair the meeting, either of them can designate this role to a qualified, voting member. The Chair will refrain from making motions whenever possible and the Vice Chair will chair any portion of the meeting during which the Chair is acting in the role of primary or secondary reviewer.

The IRB meeting minutes will be distributed to the Board for review and edits. Any suggestions for changes will be incorporated into the minutes by HRPP staff. If there are no changes, the IRB Chair will accept the version as final. If it is determined that edits or corrections are necessary, the minutes will be amended. If the amendments are considered to be minor (e.g., typographical errors, revised language provided by members present), then the minutes will be considered accepted after the HRPP staff makes the changes and Chair has accepted. If the amendments are considered to be major, they will be presented again at the following IRB meeting for discussion.

The Chair or Vice-Chair will query the members and non-members present about any conflicts of interest with the items appearing on the agenda and will remind members to recuse themselves from the discussion and vote by leaving the room when that agenda items is being reviewed.

Other business, such as introduction of new members, policy discussion, and continuing education may be presented. The board will discuss all submissions included on the agenda. The Primary and Secondary Reviewer present an overview of the research and lead the IRB through the regulatory criteria for approval. All voting members present at a convened meeting have full rights, except in the case of a conflict of interest. In order for the research to be approved, it must receive the approval of a majority of those voting members present at the meeting and meet all of the criteria for approval.

It is the responsibility of the HRPP staff member(s) present to record the proceedings and take minutes of the meeting. The audio recording of each meeting is destroyed after the minutes for that meeting are approved.

6.6.8 Guests

At the discretion of the IRB, the Principal Investigator may be invited to the IRB meeting to answer questions about their proposed or ongoing research. The Principal Investigator will be asked to leave for the discussion and subsequent vote on their research proposal.

In accordance with Oregon’s Public Meetings Law, the public may attend IRB meetings and will be given notice of the time and place of these meetings. The meetings will be accessible to everyone, including persons with disabilities. The Public Meetings Law guarantees the public the right to view government meetings, but not to participate in them. While guests are permitted to attend IRB meetings, they may not participate unless requested by the IRB Chair or Administrator to do so.

Executive sessions, which exclude the public, may be called during any regular, special, or emergency meeting. Such sessions will be convened and conducted in accordance with Oregon’s Public Meetings Law.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
03-04-2016	N/A	06-23-2016	06-23-2016
07-27-2016	N/A	N/A	07-29-2016
12-12-2017	12-15-2017	12-21-2017	12-21-2017
1-29-2018	02-21-2018	02-22-2018	02-22-2018
11-13-2018	11-20-2018	12-26-2018	01-20-2019
1-2-2022	2-14-2023	3-16-2023	3-16-2023

6.7 Cooperative Research Projects

Investigators at OSU may participate in research projects that involve collaborators and/or human subjects at other institutions. In some instances, OSU is the coordinating center and all activities are organized by OSU. In other instances, the OSU investigator(s) is a collaborator on a study that is being conducted under the jurisdiction of another IRB.

In the conduct of cooperative research projects, OSU acknowledges that each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with applicable federal regulations. To avoid duplication of effort, OSU may enter into an agreement as either the relying or responsible IRB. This mechanism is made possible by 45 CFR 46.114, 21 CFR 56.114, and NOT-OD-16-094.

A formal relationship must be established between OSU and the other Institution through either an Authorization Agreement or a Memorandum of Understanding. If OSU will cede oversight to another institution, this relationship must be formalized before OSU investigators can initiate research activities. If OSU will be the IRB of record for another institution, this relationship must be formalized before OSU

investigators provide the external investigators with data or samples and before investigators from the external institution initiate research activities.

It is the policy of OSU to assure that all facilities participating in a human subjects study receive adequate documentation about the study in order to protect the interests of study participants. Before a study can begin, it must be approved by the IRB of record for each participating facility and, where appropriate, the IRB of record for the coordinating facility.

For cooperative research, the PI must identify all Institutions participating in the research, the responsible IRB(s), and the procedures for dissemination of protocol information (IRB initial and continuing approvals, relevant reports of unanticipated problems, protocol modifications, and interim reports) between all participating Institutions.

When an authorization agreement is the appropriate mechanism for eliminating the need for dual review, the OSU HRPP staff will make the initial determination as to which IRB will act as the IRB of record and then make a recommendation to the IO (if federally funded) or the Associate Vice President for Research (if not federally funded). The IO or AVPR make the final determination, subject to the acceptance of any Federal department or agency supporting the research, and are the signatory officials for the agreements.

OSU will only cede IRB oversight to external institutions with a current Federal wide Assurance with OHRP.

If OSU is the coordinating facility, the PI must document how human subject protection information will be communicated to the other participating facilities engaged in the research study. The PI is responsible for serving as the single liaison with outside regulatory agencies, with other participating facilities, and for all aspects of internal review and oversight procedures. The PI is responsible for ensuring that all participating facilities obtain review and approval from their local IRB and adopt all protocol modifications in a timely fashion. The PI is responsible for ensuring that the research study is reviewed and approved by any other appropriate committees at the coordinating facility and at the participating facilities prior to enrollment of participants.

Once a reliance agreement is in place, the PIs at the coordinating and participating sites are responsible for ensuring researchers have the currently approved documentation. If OSU is the IRB of record, the OSU approval notice and approved documents should be provided to the external IRB(s) by the external collaborator(s). If OSU is ceding oversight to an external IRB, the OSU PI is responsible for providing the current study documents and approval letter from the reviewing IRB to the OSU IRB.

Local policies will be enforced at the discretion of the HRPP. When feasible, site-specific modifications will be required so that the proposals align with local requirements. When OSU is the relying institution, the expiration date of the reliance will mirror the expiration date selected by the external institution. In the absence of an expiration date set forth by the reviewing institution, reliance agreements will expire after five years.

6.7.1 §46.114 Cooperative research.

Cooperative research projects under 46.114 are those projects covered by the Common Rule that involve more than one institution. In the conduct of cooperative research projects, each institution is

responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.

Effective January 2020, any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

The following research is not subject to this provision:

- Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or
- Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

6.7.2 §56.114 Cooperative research.

In complying with the FDA regulations, institutions involved in multi-institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.

6.7.3 Research Funded by the NIH

Effective May 25, 2017, a single IRB of record will be used in the ethics review of non-exempt human subjects research protocols funded by the NIH that are carried out at more than one site in the U.S. This policy applies only to sites where the same research protocol is being conducted at more than one site; it does not apply to studies that involve more than one site but the sites have different roles in carrying out the research. NIH will grant exceptions to the policy if the use of a single IRB is prohibited by federal, state, or tribal laws. This policy applies to research supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. This policy does not apply to career development, research training, or fellowship awards, nor does it apply to non-U.S. sites participating in NIH-funded, multi-site studies.

6.7.4 Exempt Research

OSU will not enter into reliance agreements for exempt studies, as this is an extra-regulatory process when the Common Rule and FDA regulations do not apply. The PI from each institution must submit an IRB application to their respective HRPP or IRB for review. OSU may execute an Independent Investigator Agreement if a non-OSU study team member is not affiliated with an organization that has an IRB.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
06-04-2015	12-18-2015	06-23-2016	06-23-2016
06-24-2016	07-14-2016	07-29-2016	07-29-2016
10-05-2017	N/A	10-05-2017	10-05-2017
12-12-2017	12-15-2017	12-21-2017	12-21-2017

03-06-2018	N/A	03-22-2018	03-22-2018
08-02-2018	11-20-2018	12-26-2018	01-20-2019
08-01-2019	05-18-2021	06-23-2021	06-23-2021
01-02-2022	02-14-2023	03-16-2023	03-16-2023

7 FDA-Regulated Research

7.1 Policy

FDA regulations apply to any research that involves a test article in a clinical investigation involving human subjects as defined by the FDA regulations. For FDA regulated research, the IRB must apply the FDA regulations at 21 CFR 50 and 21 CFR 56, as well as, where appropriate, 45 CFR 46. (See Guidance Document “Comparison between FDA and HHS Regulations”)

Use of investigational drugs must be conducted according to FDA IND regulations, 21 CFR Part 312, and other applicable FDA regulations. Use of an investigational device in a clinical trial to obtain safety and effectiveness data must be conducted according to FDA’s IDE regulations, 21 CFR Part 812, and other applicable FDA regulations.

If the research involves drugs or devices and there is no IND/IDE, the PI must provide a rationale why it is not required.

The IRB will review the application and determine:

1. Whether there is, or should be, an IND/IDE and if so, whether there is appropriate supporting documentation.
2. If the research involves drugs or devices with no IND/IDE, and whether the research meets the exemption criteria below.

If there is any ambiguity about whether an IND or IDE is needed, the IRB may request that the PI provide a determination from the FDA.

The PI may choose to request such a determination pre-emptively by taking the following steps related to an IND:

- a) Complete FDA forms 1571 and 1572. These forms are available on the [FDA Website](#).
- b) Submit completed forms to FDA, along with a copy of the protocol to be submitted to the IRB.
- c) Include cover letter specifically requesting a written determination regarding the need for an IND.
- d) FDA will respond within 30 days. The response may then be submitted to the IRB.

The PI may choose to request such a determination pre-emptively by taking the following steps related to an IDE:

- a) The pre-submission process for IDEs is outlined in the “Requests for Feedback on Medical Device Submission: The Pre-Submission Program and Meetings with Food and Drug Administrative Staff” guidance document. Pre-submission can include general questions or can be specific to study risk determinations.
- b) FDA will respond within 75-90 days for pre-submissions.

Note: Study risk determinations do not have a pre-defined timeline.

The following procedures describe the use of investigational drugs and devices in research under the auspices of the IRB.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
02-18-2015	12-18-2015	06-23-2016	06-23-2016

7.2 Definitions

Relevant definitions for regulatory terms appear in the HRPP's online Glossary of IRB-related Research Terms.

Revision Dates			
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11-12-2010	N/A	07-18-2014	07-18-2014
06-04-2015	12-18-2015	06-23-2016	06-23-2016

7.3 FDA Exemptions

The following categories of clinical investigations are exempt from the requirements of FDA regulations for IRB review:

1. Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the Institution is subject to IRB review. [21 CFR §56.104(c)]. **Procedures for this exemption are not elaborated on in this document, as this type of research has never occurred at OSU.**
2. Taste and food quality evaluations and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. [21 CFR §56.104(d)]

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
04-13-2015	12-18-2015	06-23-2016	06-23-2016

7.4 Investigational New Drugs (INDs)

An Investigational New Drug Application (IND) is a request for authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans. An IND is required when:

- The research involves a drug, as defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) [21 U.S.C. 321(g)(1)].
- The research is a clinical investigation as defined in the IND regulations (21 CFR 312.3), AND
- The clinical investigation is not otherwise exempt from the IND requirements in part 312 (see section IND Exemptions section below).

Whether the IND regulations apply to a planned clinical investigation does not depend on whether the intent of the clinical investigation is commercial or noncommercial. (See *Guidance for Clinical Investigators, Sponsors, and IRBs: Investigational New Drug Applications (INDs) – Determining Whether Human Research Studies Can Be Conducted Without an IND, September 2013*)

7.4.1 Drugs and Biologics

The definition of the term **drug** in section 201(g)(1) of the FD&C Act includes, among other things, “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease . . .” and “articles (other than food) intended to affect the structure or any function of the body of man or other animals.” It is important to note that the drug definition is not limited to compounds intended for a therapeutic purpose. The definition also includes compounds intended to affect the structure or function of the body, without regard to whether the compound is intended to influence a disease process. For example, the definition includes compounds administered to healthy individuals to prevent pregnancy or treat male pattern baldness. (See *Guidance for Clinical Investigators, Sponsors, and IRBs: Investigational New Drug Applications (INDs) – Determining Whether Human Research Studies Can Be Conducted Without an IND, September 2013*)

Biological products include, among other products, bacterial vaccines, allergenic extracts, gene therapy products, growth factors, cytokines, and monoclonal antibodies.

7.4.2 Dietary Supplements

A dietary supplement is not considered a drug and is not subject to the premarket approval requirements for drugs if the intended use for which it is marketed is only to affect the structure or any function of the body and not intended for therapeutic purpose. If there is a clinical investigation intended to evaluate if a dietary supplement has the ability to diagnose, cure, mitigate, treat, or prevent a disease, and IND is required under part 312. For example, a clinical investigation designed to study the relationship between a dietary supplement’s effect on normal structure or function in humans (e.g. guarana and maximal oxygen uptake) or to characterize the mechanism by which a dietary supplement acts to maintain such structure or function (e.g. fiber and bowel regularity) would not need to be conducted under an IND. However, a clinical investigation designed to evaluate a dietary supplement’s ability to prevent osteoporosis or to treat chronic diarrhea or constipation would need to be conducted under an IND.

Under the Dietary Supplement Health and Education Act (DSHEA) of 1994, a dietary supplement is not considered a drug and is not subject to the premarket approval requirements for drugs if the intended use for which it is marketed is only to affect the structure or any function of the body (i.e., not intended to be used for a therapeutic purpose).

Whether a study falls under FDA oversight is determined by the intent of the clinical investigation. If the clinical investigation is intended only to evaluate the dietary supplement’s effect on the structure or function of the body, FDA regulations do not apply. However, *disease claims* (claims to diagnose, cure,

mitigate, treat, or prevent a disease) require FDA approval. Studies involving the ingestion of dietary supplements that are not subject to FDA oversight are still covered by the regulations at 45 CFR 46 and will be reviewed at a convened meeting of the IRB.

Whether an IND is needed for a study evaluating a dietary supplement is determined by the intent of the study. If the study is intended only to evaluate the dietary supplement's effect on the structure or function of the body, an IND application may not be required. When the intention is to make disease claims, an IND application must be reviewed by the FDA unless the agency waives that requirement.

When dietary supplements are used as drugs in the context of a research study, they are generally not exempt from the requirements for an IND because they are not lawfully marketed as drugs; they are marketed as supplements.

The IRB requires that studies involving dietary supplements be submitted to the FDA for a pre-IND review prior to receiving IRB approval.⁸

7.4.3 Food

A food used as such (i.e., primarily for taste, aroma, or nutritive value) and not for therapeutic purpose or to affect the structure or function of the body, other than by providing nutrition, is not a drug. For studies intended to evaluate the effects of a food, the analysis for whether an IND is needed turns on the intent of the clinical investigation. A food is considered to be a drug if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," exempt that a food may bear an authorized health claim about reducing the risk of a disease without becoming a drug. The FDA regulates conventional foods (including baby formula) that are intended to affect the structure or function of the body as foods, not drugs, as long as the intended structure or function effect derives from the product's character as food – its taste, aroma, or nutritive value. For example, a clinical investigation intended only to evaluate the nutritional effects of food (including medical foods) would not require an IND, but an investigation intended to evaluate other effects of a food on the structure or function of the body would. A study of the effect of iron on hemoglobin levels in which subjects were fed beef or lamb as a source of iron would not require an IND, but a study of the effect of soy isoflavones on bone metabolism would.

7.4.4 Structure and Function vs. Disease Claim

The examples below are provided to illustrate the difference between a structure and function claim and a disease claim. For additional guidance see *Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide, January 9, 2002* (<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm103340>).

- a) A statement is a disease claim if it mentions a specific disease or class of diseases. For example, a claim that a product is "protective against the development of cancer" or "reduces the pain and stiffness associated with arthritis" would be a disease claim.

⁸ Informed by documentation from and conversation with Lesley Maloney, Senior Policy Advisor in the Office of the Commissioner, Office of Policy, FDA (11/28/2016).

- b) Some claims imply disease treatment or prevention because they are so intimately tied to a disease. For example, "inhibits platelet aggregation" or "reduces cholesterol" are such characteristic signs or symptoms associated with stroke and cardiovascular disease and interventions to treat those diseases that any claim about them would be an implied disease claim.

7.4.4.1 Studies Intended to Support a Health Claim

Section 201(g) of the FD&C Act provides that a health claim in the label or labeling of a food (conventional food or dietary supplement) characterizing the relationship between a substance (food or food component) and a disease or health-related condition does not cause the food to be a drug on the basis of that claim, provided the claim is authorized under and made in accordance with the requirements of section 403(r)(1)(B) and (r)(3) of the FD&C Act 22 (for conventional foods) or under section 403(r)(1)(B) and (r)(5)(D) (for dietary supplements).

Notwithstanding this provision, however, a clinical study designed to evaluate the relationship between a food substance and a disease and intended to provide support for such a claim is required to be conducted under an IND (21 CFR part 312), unless the substance-disease relationship being studied is already the subject of an authorized health claim. Section 201(g) provides, in effect, an exemption from the normal operation of the drug definition — it permits the use of health claims that would, without the exemption, cause a conventional food or dietary supplement to be a drug. However, the exemption does not apply until the health claim has been authorized by FDA. Therefore, a study conducted to support a new or expanded health claim would require an IND. For example, a study designed to evaluate whether vitamin D may reduce the risk of one or more site-specific cancers would require an IND, as there is currently no authorized health claim for this substance-disease relationship. Similarly, a study conducted to support a petition to amend the health claim for soluble fiber from certain foods and reduced risk of coronary heart disease (21 CFR 101.81) to include a new type of fiber would require an IND. (See *Guidance for Clinical Investigators, Sponsors, and IRBs: Investigational New Drug Applications (INDs) – Determining Whether Human Research Studies Can Be Conducted Without an IND, September 2013*)

7.4.5 Bioequivalence and Bioavailability Studies

FDA regulations describe criteria under which bioavailability or bioequivalence (BA/BE) studies using unapproved versions of approved drug products can be conducted without submission of an IND (21 CFR 320.31(b) and (d)). Although these regulations are intended to facilitate development of generic drugs, a planned BA/BE study need not be intended for that purpose to be exempt from the IND regulations. A BA/BE study in humans does not require an IND if all of the following conditions are met:

- The drug product does not contain a new chemical entity (21 CFR 314.108), is not radioactively labeled, and is not cytotoxic.
- The dose (single dose or total daily dose) does not exceed the dose specified in the labeling of the approved version of the drug product.
- The investigation is conducted in compliance with the requirements for review by an IRB [21 CFR part 56] and with the requirements for informed consent [21 CFR part 50].
- The sponsor meets the requirements for retention of test article samples [21 CFR 320.31(d)(1)] and safety reporting [21 CFR 320.31(d)(3)]. (See *Guidance for Clinical Investigators, Sponsors, and IRBs: Investigational New Drug Applications (INDs) – Determining Whether Human Research Studies Can Be Conducted Without an IND, September 2013*)

7.4.6 IND Exemptions

Under 21 CFR 312.2, an IND is not necessary if the research falls in one of the following categories:

Exemption 1.

In order for this exemption to apply, all of the following must be true:

- a. The drug product is lawfully marketed in the United States.
- b. The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug.
- c. If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product.
- d. The investigation does not involve a route of administration or dosage levels or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.
- e. The investigation is conducted in compliance with 21 CFR 50 and 56.
- f. The investigation is conducted in compliance with requirements of 21 CFR 312.7.

Exemption 2.

In order for this exemption to apply, all three (a, b, and c) must be true:

- a. A clinical investigation is for an in vitro diagnostic biological product that involves one or more of the following:
 - 1) Blood grouping serum
 - 2) Reagent red blood cells
 - 3) Anti-human globulin
- b. The diagnostic test is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure.
- c. The diagnostic test is shipped in compliance with 21 CFR 312.160.

Exemption 3.

- a. A drug intended solely for test in vitro or in laboratory research animals if shipped in accordance with 21 CFR 312.160.

Exemption 4.

- a. A clinical investigation involving use of a placebo if the investigation does not otherwise require submission of an IND.

7.4.7 IND Requirements

If an IND is required, the IRB and study team will adhere to the FDA regulations at 21 CFR 50, 56, and 312, and the following related guidance:

Basic Information about IND Requirements:

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm>)

Guidance for Clinical Investigators (INDs):

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm176259.htm>)

Information specific to Investigator-initiated IND applications:

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm343349.htm>

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02-19-2015	12-18-2015	06-23-2016	06-23-2016
12-01-2016	N/A	12-21-2017	12-21-2017

7.5 Investigational Device Exemptions (IDEs)

An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE **before** the study is initiated.

Clinical evaluation of devices that have not been cleared for marketing requires:

- an investigational plan approved by an institutional review board (IRB). If the study involves a significant risk device, the IDE must also be approved by FDA;
- informed consent from all patients;
- labeling stating that the device is for investigational use only;
- monitoring of the study and;
- required records and reports.

(More information, see:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm>)

7.5.1 Medical Devices

Medical devices, as defined by the FDA, may include software; [mobile medical applications](#); accessories, components, and modifications of existing devices. Investigators are responsible for obtaining a determination from the FDA regarding the applicability of the IDE requirements prior to the submission of an IRB application.

7.5.2 Devices Exempted from IDE Requirements

An IDE is not necessary if:

1. The research involves a device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time;
2. The research involves a device other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of 21 CFR 807 in determining substantial equivalence;

3. The research involves a diagnostic device, if the sponsor complies with applicable requirements in 21 CFR 809.10(c) and if the testing:
 - a. Is noninvasive,
 - b. Does not require an invasive sampling procedure that presents significant risk,
 - c. Does not by design or intention introduce energy into a subject, and
 - d. Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure;
4. The research involves a device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk;
5. The research involves a device intended solely for veterinary use;
6. The research involves a device shipped solely for research on/or with laboratory animals and labeled in accordance with 21 CFR 812.5(c);
7. The research involves a custom device as defined in 21 CFR 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.

7.5.3 Risk Determination

NSR device studies must follow the abbreviated requirements at 21 CFR 812.2(b). These abbreviated requirements address labeling, IRB approval, informed consent, monitoring, records, reports, and prohibition against promotion. However, there is no need to make progress reports or final reports to FDA. NSR device studies do not have to have an IDE application approved by FDA. Sponsors and IRBs do not have to report the IRB approval of an NSR device study to FDA. This means that an IRB may approve an NSR device study and an investigator may conduct the study without FDA knowing about it. An IRB's NSR determination is important because the IRB serves as the FDA's surrogate for review, approval, and continuing review of the NSR device studies. An NSR device study may start at the institution as soon as the IRB reviews and approves the study and without prior approval by FDA. (See *Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors: Significant Risk and Nonsignificant Risk Medical Device Studies, January 2006*).

The IRB will adhere to the requirements found at 21 CFR 50, 56, 812.

7.5.4 IDE and Related Requirements

For investigational devices, Non-Significant Risk (NSR) device studies follow abbreviated IDE requirements and do not have to have an IDE application approved by the FDA. If the FDA or a sponsor has identified a study as NSR, then the investigator must provide an explanation and documentation of that determination.

If an IDE is required, the IRB and study team will adhere to the FDA regulations at 21 CFR 50, 56, and 812, and the following related guidance:

Responsibilities for sponsors and/or investigators of both SR and NSR studies:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046702.htm>

Complete information about Investigator responsibilities for SR Device studies:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm049864.htm>

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02-19-2015	12-18-2015	06-23-2016	06-23-2016

7.6 Responsibilities

7.6.1 Investigator Responsibilities

The PI is responsible for ensuring that the research is conducted according to all regulatory guidelines and the HRPP policies and procedures.

The PI must obtain approval from the IRB before initiating any research activities.

The PI proposing the drug or device research will be required to provide a plan for the following (as applicable):

- Investigational drug or device accountability, including labeling, shipping, storage, security, dispensing, administration, return, disposition and/or disposal;
- Record keeping related to accountability in accordance with the FDA regulations [21 CFR 312(d) and 21 CFR 812(g)];

The PI shall report all unanticipated problems involving risk to subjects or others to the IRB, in accordance with the relevant section of this policy.

Information the Investigator Provides to the IRB:

Professional qualifications to do the research (including a description of necessary support services and facilities)

Study protocol which includes/addresses:

- title of the study
- purpose of the study (including the expected benefits obtained by doing the study)
- sponsor of the study
- results of previous related research
- subject inclusion/exclusion criteria
- justification for use of any special/vulnerable subject populations (for example, the decisionally impaired, children)
- study design (including as needed, a discussion of the appropriateness of research methods)
- description of procedures to be performed
- provisions for managing adverse reactions
- the circumstances surrounding consent procedure, including setting, subject autonomy concerns, language difficulties, vulnerable populations

- the procedures for documentation of informed consent, including any procedures for obtaining assent from minors, using witnesses, translators and document storage
- compensation to subjects for their participation
- any compensation for injured research subjects
- provisions for protection of subject's privacy
- extra costs to subjects for their participation in the study
- extra costs to third party payers because of subject's participation

Investigator's Brochure (when one exists)

The case report form (when one exists)

The proposed informed consent document

- containing all requirements of 21 CFR 50.25(a)
- containing requirements of 21 CFR 50.25(b) that are appropriate to the study
- meeting all requirements of 21 CFR 50.20
- translated consent documents, as necessary, considering likely subject population(s)

Requests for changes in study after initiation

Reports of unexpected adverse events

Progress reports

Final report

Institutional forms/reports

For research involving investigational new drugs:

- The PI must inform the IRB when a study involving investigational drugs has been terminated by the sponsor.
- The PI will report to the sponsor any adverse effect that may reasonably be regarded as caused by, or probably caused by, the drug [21 CFR 312 (b)] according to the procedures in the protocol.

The PI will maintain the following:

- Current curriculum vitae (CV)
- Protocol
- Records of receipt and disposition of drugs
- List of any co-investigators with their curriculum vitae
- Certification that all physicians, dentists, and/or nurses responsible in the study have appropriate valid licenses for the duration of the investigation, and
- Case histories with particular documentation on evidence of drug effects. Emphasis is on toxicity and possible untoward happenings. All unexpected adverse effects are reportable; even if the investigator considers that the event is not related to the drug. All unexpected adverse effects shall be reported immediately to the IRB in the manner defined by the protocol
- IRB letters of approval
- Other documents as outlined in this manual

For research involving investigational devices:

If a device is considered NSR by the PI or sponsor, but after review the IRB determines the device to have significant risk, upon receipt of written notice the PI is responsible for notifying the sponsor (if

applicable) of the IRB's determination. The PI must provide the IRB with confirmation of this action and documentation of IDE approval from the FDA.

If the PI is storing the devices, he/she must maintain a log indicating the identification/serial number of the device, name of subject, date dispensed, by whom it was dispensed, and amount remaining.

The PI will maintain the following:

- Current curriculum vitae (CV)
- Protocol of the study
- Records of animal study reports
- Records of receipt and disposition of devices
- List of any co-investigators with their curriculum vitae
- Certification that all physicians, dentists, and/or nurses responsible in the study have appropriate valid licenses for the duration of the investigation
- Case histories with particular documentation on evidence of effects. Emphasis is on safety and possible untoward happenings. All adverse device effects are reportable
- IRB letters of approval
- Device training
- Other documents as outlined in this manual

Following completion of the study the termination procedure for investigational devices must be applied. If the devices are kept by the investigator, he/she must maintain a log regarding the receipt, use and/or re-dispensing of the device and the disposition of remaining devices at the conclusion of the investigation.

The PI will submit to the sponsor and to the IRB a report of any unanticipated adverse device effect occurring during an investigation as soon as possible, but in no event later than 3 working days⁹ after the investigator first learns of the effect.

7.6.2 IRB Responsibilities

The IRB will review the research in accordance with the following requirements and the same criteria it would use in considering approval of any research involving an FDA-regulated product (21 CFR 56.111).

The IRB will review the control plan for all test articles and determine whether it is adequate. If the Chair determines that the IRB does not have the necessary expertise to evaluate the plan, outside consultation will be used.

For research involving investigational devices:

1. Unless the FDA has already made a risk determination for the study, the IRB will review NSR studies and determine if the device represents significant or non-significant risk and report the findings to the PI in writing. The IRB will consider the risks and benefits of the medical device compared to the risks and benefits of alternative devices or procedures. Non-significant risk device studies do not require submission of an IDE application but must be conducted in

⁹ FDA requires 10 days. This has been shortened to three days to be consistent with the unanticipated problem reporting requirements set forth in other areas of this document.

accordance with the abbreviated requirements of IDE regulations. If the study that has been submitted as NSR is considered SR, the IRB may approve the study, but the study cannot begin until an IDE is obtained.

2. Determination of NSR/SR must be made at a convened meeting of the board.
3. The IRB will document in the minutes and provide written documentation to the PI of the rationale for determining whether a device is classified as NSR/SR.
4. Studies involving a Significant Risk Device will only be reviewed by the full board. If the full board determines that the device is NSR and the study is minimal risk, the board may further determine that the study may be reviewed by an expedited procedure.
5. If the FDA has already made the SR or NSR determination for the study, the agency's determination is final and the IRB does not need to make a risk determination.

7.6.3 Import and Export of Investigational Devices

A person who imports or offers to import an investigational device shall be considered an agent for the foreign exporter and shall either act as the sponsor of the clinical investigation or ensure that another person acts as the agent and the sponsor of the investigation. That is, the sponsor of an IDE MUST be located in the United States. Any investigational device imported into the U.S. must be labeled and used in accordance with FDA regulations.

Export of an investigational device is subject to the provisions set forth in sections 801(e) and 802 of the FD&C Act. Prior FDA approval may be required before an investigational device can be exported outside of the United States. This includes investigational medical devices that are considered exempt from the IDE requirements or have a non-significant risk determination.

More information:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051383.htm>

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07-27-2016	N/A	N/A	07-29-2016
01-29-2018	Formatting only	Formatting only	02-22-2018

8 Submission Types

8.1 Determination of Human Subjects Research

The responsibility for initial determination as to whether an activity constitutes human subjects research (HSR) rests with the investigator. Since the Institution will hold them responsible if the determination is not correct, investigators are urged to request a confirmation that an activity does not constitute human subjects research from the HRPP office. Requests for determinations must include sufficient information about the activity to support the determination.

Investigators who think that their project may not meet the definition of HSR should complete and submit a Determination Form to the IRB for review.

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03-18-2016	12-18-2015	06-23-2016	06-23-2016

8.2 Determination of Engagement

OSU is considered *engaged* in a research project when the involvement of OSU employees or agents in that project includes any of the following:

- a) An institution is automatically considered to be engaged in human subjects research whenever it receives a direct federal award to support such research or is otherwise funding human subjects research elsewhere. In the case of a direct federal award, the primary awardees Institution bears ultimate responsibility for protecting human subjects under that award.
- b) Intervention for research purposes with any human subjects of the research by performing invasive or noninvasive procedures.
- c) Intervention for research purposes with any human subject of the research by manipulating the environment.
- d) Interaction for research purposes with any human subject of the research.
- e) Obtaining the informed consent of human subjects for the research.
- f) Obtaining for research purposes identifiable private information or identifiable biological specimens from any source for the research. In general, obtaining identifiable private information or identifiable specimens includes, but is not limited to:
 - Observing or recording private behavior;
 - Using, studying, or analyzing for research purposes identifiable private information or identifiable specimens provided by another Institution; and
 - Using, studying, or analyzing for research purposes identifiable private information or identifiable specimens already in the possession of the investigators.

Although the OHRP guidance on engagement is intended for non-exempt studies, the criteria for this determination will be applied to both exempt and non-exempt studies at the discretion of the HRPP.

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10-17-2018	12-14-2018	01-10-2019	01-20-2019

8.3 §46.118 Determinations

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as Institutional type grants when selection of specific projects is the Institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds.

Under the federal regulations (§46.118) and in accordance with the OSU IRB's policies and procedures, these applications need not be reviewed by an IRB before an award may be made. However, no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB.

Such determinations are granted to satisfy sponsoring agency requirements or to allow investigators to have access to funding to begin aspects of the project that do not involve human subjects. Funds may not be used to conduct research with human subjects until a study-specific protocol has been reviewed and approved by the IRB or determined to be exempt by the HRPP.

Investigators seeking a §46.118 Determination must contact the HRPP.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
06-28-2016	07-14-2016	07-29-2016	07-29-2016
01-02-2022	02-14-2023	03-16-2023	03-16-2023

8.4 Initial Application & Protocol

All OSU researchers proposing to initiate research involving human subjects must submit an initial application and protocol and any other relevant materials for review.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
05-09-2016	12-18-2015	06-23-2016	06-23-2016
01-29-2018	02-21-2018	02-22-2018	02-22-2018

8.5 Continuing Review

8.5.1 Continuing review of research reviewed by the full board

The IRB will conduct a continuing review of ongoing research at intervals that are appropriate to the level of risk for each research protocol, but not less frequently than once per year.

8.5.1.1 Approval Period

For each initial or continuing approval the IRB will indicate an approval period with an expiration date specified. IRB approval is considered to have lapsed at midnight on the expiration date of the approval.

The approval date and approval expiration date are clearly indicated on all notices sent to the PI and must be strictly adhered to.

Modifications and other actions to an approved protocol do not alter the date by which continuing review must occur.

The regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. Therefore, continuing review and re-approval of research must occur by

midnight of the date when IRB approval expires. If the IRB performs continuing review within 30 days before the IRB approval period expires, the IRB may retain the anniversary date as the date by which the continuing review must occur. This process is rare and used at the discretion of the IRB.

8.5.1.2 Continuing Review Process

Continuing review provides the IRB with an opportunity to reassess the totality of the project and assure that risks to subjects are being minimized and are still reasonable in relation to anticipated benefits to the subjects and the knowledge that is expected to result.

Studies originally approved at a convened meeting can only be reviewed by another procedure upon a vote of the full board.

It is the PI's responsibility to ensure that the continuing review of ongoing research is approved prior to the expiration date.

Investigators must submit the following for continuing review:

- a) Continuing review application;
- b) A copy of the last signed consent form, if a consent form is used in the study (names should be redacted to ensure confidentiality);
- c) A copy of the last signed parental permission form and/or assent form, if such forms are used in the study (names should be redacted to ensure confidentiality).

Researchers are strongly encouraged to use consent forms that were stamped or watermarked with an expiration date, as applicable. However, use of unstamped but otherwise unaltered consent documents will not be considered to be a protocol deviation or non-compliance. It is the PI's responsibility to track document versions and use the currently approved documents.

If the PI is reporting complaints, problems, or other reportable events at the time of renewal, an HRPP staff member may contact the researcher to obtain more information. The relevant procedure for this identified issue will then be followed.

The entire study file will be made available to IRB members prior to the convened meeting. Continuing review applications and amendments may be submitted simultaneously. However, one may not be submitted if the other is already under review but not yet approved.

8.5.2 Research for which continuing review is not required

Unless the IRB determines otherwise, continuing review of research is not required in the following circumstances:

- Research involving no more than minimal risk. That includes studies determined to be exempt and expedited
- Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
 - Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
 - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

8.5.3 Continuing Review of Expedited Research

When continuing review of expedited studies is deemed necessary, the entire study file is available to the reviewer(s) so that they may determine whether the research continues to meet the criteria for review by an expedited procedure and, if so, whether the research continues to meet the regulatory criteria for approval.

Generally, if research did not qualify for expedited review at the time of initial review, it does not qualify for expedited review at the time of continuing review, except in limited circumstances described by expedited review categories (8) and (9) at 63 FR 60364-60367 (see Expedited Review Categories).

8.5.4 Lapse in IRB Approval

All research activity must stop when IRB approval expires. This includes recruitment, enrollment, consent, interventions, interactions, and data collection. Research that continues after the approval period has expired is research conducted without IRB approval. This policy applies even if the investigator has provided the renewal information before the expiration date. Therefore, investigators must allow sufficient time for IRB review before the expiration date.

The HRPP office will notify the investigator of the lapse in approval within 10 business days of expiration.

For studies assigned an expiration date, if approval expires outside of review (i.e., no continuing review information was submitted prior to the expiration date), the file is administratively closed. Decisions of this kind must be made in a manner that ensures that closure will not harm enrolled participants.

A new application must be submitted to the IRB for review and approval prior to re-initiation of the research. Data previously collected under an approved protocol may be referenced in the new application and used in data analysis.

The investigator can petition the IRB to continue an individual participant's research intervention and/or interaction during a period of lapsed IRB approval if a safety concern or ethical issue exists.

8.5.5 Period of Approval

Full Board – up to one year. At the time of initial review and at continuing review, the IRB will make a determination regarding the frequency of review of the research protocols. All protocols reviewed by a full board procedure will be reviewed by the IRB at intervals appropriate to the degree of risk but no less than once per year. In some circumstances, a shorter review interval may be required. The meeting minutes will reflect the IRB's determination regarding review frequency for studies reviewed by the full board.

In the event that the full board votes to reclassify a study as expedited under category 8 or 9, the review process and approval period will follow the expedited procedure. Up to and including the potential for a five-year approval period from the date of that renewal.

FDA-regulated Expedited – up to one year. All FDA-regulated protocols reviewed by an expedited procedure will be reviewed by the IRB at intervals appropriate to the degree of risk but no less than once per year. In some circumstances, a shorter review interval may be required. The frequency of review will be documented in the reviewer worksheet.

Expedited – up to five years. Unless FDA-regulated, expedited studies will receive a five-year administrative check-in date. If the research is completed by the administrative check-in date, the researcher should close the application.

Exempt – up to five years. Exemptions will receive a five-year administrative check-in date. If the research is completed by the administrative check-in date, the researcher should close the application.

Since non-exempt studies do not automatically require continuing review, when deemed necessary by the reviewer, the reviewer(s) will determine, justify, and document a shorter period of approval.

For studies assigned an expiration date, investigators should submit a final report on or before the expiration date.

8.5.5.1 Review More Often Than Annually

Research that meets any of the following criteria may require review more often than annually:

- a) Significant risk to research subjects (e.g., death, permanent or long lasting disability or morbidity, severe toxicity) without the possibility of direct benefit to the subjects
- b) The involvement of especially vulnerable populations likely to be subject to coercion (e.g., terminally ill)
- c) A history of serious or continuing non-compliance on the part of the PI

The following factors may also be considered when determining which studies require review more frequently than on an annual basis:

- a) The probability and magnitude of anticipated risks to subjects
- b) The likely medical condition of the proposed subjects
- c) The overall qualifications of the PI and other members of the research team
- d) The specific experience of the Principal Investigator and other members of the research team in conducting similar research
- e) The nature and frequency of adverse events observed in similar research at this and other Institutions
- f) The novelty of the research making unanticipated adverse events more likely
- g) Any other factors that the IRB deems relevant

In specifying an approval period of less than one year, the IRB may define the period with either a time interval or a maximum number of subjects either studied or enrolled. If a maximum number of subjects studied or enrolled is used to define the approval period, it is understood that the approval period in no case can exceed one year and that the number of subjects studied or enrolled determines the approval period only when that number of subjects is studied or enrolled in less than one year. If an approval period of less than one year is specified by the IRB the reason for more frequent review must be documented in the minutes, if reviewed by the full board, or in the reviewer worksheet, if reviewed by an expedited procedure.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014

05-24-2016	12-18-2015	06-23-2016	06-23-2016
06-24-2016	07-14-2016	N/A	07-29-2016
12-01-2016 11-13-2017 12-13-2017	12-15-2017	12-21-2017	12-21-2017
01-29-2018	02-21-2018	02-22-2018	02-22-2018
02-20-2018	02-20-2018	03-22-2018	03-22-2018
11-13-2018	12-14-2018	01-10-2019	01-20-2019
01-02-2022	02-14-2023	03-16-2023	03-16-2023

8.5.5.2 Determination of Approval, Expiration, and Administrative Check-In Dates

For each initial or continuing approval of non-exempt studies, the IRB will indicate an approval period with either an expiration date or administrative check-in date specified. IRB approval is considered to have lapsed at midnight on the expiration date of the approval.

Full Board. Per OHRP guidance (2010), when an IRB conducts the initial review of a research project at a convened meeting and approves the research for one year without requiring either (a) changes to the protocol or informed consent document(s), or (b) submission of clarifications or additional documents for simple concurrence, the effective date of the initial approval is the date of that IRB meeting. In such circumstances, the expiration date may be as late as one year after the date of that IRB meeting (45 CFR 46.109(e)).

If the IRB determines at a convened meeting that the study can be approved pending minor revisions, and revisions can be reviewed by either the Chair or another individual designated by the IRB, the approval period starts on the date the adequacy of the revisions are verified by the Chair (or any other individual(s) designated by the IRB). The role of the designated individual(s) will be documented in the minutes.

Expedited. The approval period begins on the date the IRB Chair or IRB member(s) gives final approval to the protocol or the date that the adequacy of the minor revisions were verified by the Chair or IRB member.

Exempt. An exemption begins on the date that the Chair, or an individual(s) designated by the Chair, indicates final acknowledgement that the study meets the required criteria.

8.6 Project Modifications

8.6.1 Regulatory requirement

The IRB must follow written procedures for ensuring prompt reporting to the IRB of proposed changes in a research activity, and ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects.

8.6.2 Policy

Investigators may wish to modify or amend their approved applications. Investigators must seek IRB approval before making any changes in approved research.

Modifications may be appropriate if they are within the scope of what the IRB originally authorized. For example, if a researcher wishes to add a population to an existing study, but not alter the study procedures or purpose, a modification request may be appropriate. Likewise, modifying a procedure without changing the study's purpose or study population may also be appropriate. If, however, the researcher wishes to add a population and revise study procedures, he or she may need to submit a new application for approval.

Investigators must submit documentation to inform the HRPP about the proposed changes to the study. Documentation should include the appropriate HRPP forms and revised versions of all relevant study documents (e.g., protocol, consent form, etc.).

HRPP staff will determine whether the proposed changes (a) require a reclassification of the review level, (b) may be approved through an expedited review process (if the changes to a full board study are minor), or (c) whether the modification warrants full board review.

8.6.3 Modifications to Full Board Studies

8.6.3.1 Minor Change

An IRB may use expedited review procedures to review **minor changes** to studies that were previously approved by the full board. A voting member of the IRB must conduct the review. A minor change is one that, in the judgment of the IRB reviewer, makes no substantial alteration in:

- a) The level of risks to subjects
- b) The research design or methodology (adding procedures that are not eligible for expedited review would not be considered a minor change)
- c) The number of subjects enrolled in the research (no greater than 10% of the total requested)
- d) The qualifications of the research team (change in PI is not considered to be minor)
- e) The facilities available to support safe conduct of the research, or
- f) Any other factor which would warrant review of the proposed changes by the convened IRB or was used to initially to evaluate the risks, benefits, or any other criteria for approval

Modifications meeting all of these criteria may be reviewed by an expedited procedure. When evaluating a minor change, reviewers will also determine whether the research continues to meet the regulatory criteria for approval. The reviewer will also consider whether information about those modifications might relate to participants' willingness to continue to take part in the research and if so, whether to provide that information to participants.

8.6.3.2 Full Board Review of Project Modifications

When a proposed change in a research study is not minor, then the IRB must review and approve the proposed change at a convened meeting before the change can be implemented. The only exception is a change necessary to eliminate apparent immediate hazards to the research subjects. In such a case, the IRB should be promptly informed of the change following its implementation and should review the change to determine that it is consistent with ensuring the subjects' continued welfare.

The entire study file is provided to the primary reviewer and is available to all IRB members. All revised documents are provided to the board members for review. At the meeting, the Primary Reviewer presents an overview of the modifications and leads the IRB through the completion of the regulatory criteria for approval. The IRB will determine whether the research with the proposed modifications continues to meet the regulatory criteria for approval.

When the IRB reviews modifications to previously approved research, they consider whether information about those modifications might relate to participants' willingness to continue to take part in the research and if so, whether to provide that information to participants.

8.6.4 Modifications to Expedited Studies

Modifications to expedited studies require review and approval prior to implementation of the change. The sole exception is a change to the total target enrollment number. Modifications to expedited studies can be reviewed by any qualified, voting member of the board.

8.6.5 Modifications to Exempt Studies

Review of modifications to exempt protocols are limited to those that could impact the review level or category, the risks or benefits, or any other criteria that lead to the initial determination of exemption. A list of which modifications require review is available to researchers on the HRPP website. Modifications to exempt studies can be reviewed by IRB members or the Chair's exempt designees.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
12-05-2017	12-15-2017	12-21-2017	12-21-2017
01-29-2018	02-21-2018	02-22-2018	02-22-2018
05-18-2018	12-8-2018	01-10-2019	01-20-2019
01-02-2022	02-14-2023	03-16-2023	03-16-2023

8.6.6 Exceptions

8.6.6.1 Policy

Exceptions to approved protocols cannot be made without the prior approval of the IRB. Exceptions made without prior IRB approval are deviations and constitute non-compliance.

8.6.6.2 Definition

Exception. A protocol exception is a single occurrence of an intentional action or process that departs from the approved protocol, such as seeking permission to enroll a single subject who does not meet eligibility criteria.

8.6.6.3 Procedure

It is the responsibility of the Investigator to request permission from the IRB for planned exceptions to the approved protocol. Exceptions must be approved by the IRB Chair before being implemented. The Chair may elect to send exceptions to the full board for review or seek consultation from members or

non-members prior to making a determination. An acknowledgement will be sent to the PI if the exception is acceptable; a disapproval notice will be sent if it is not.

8.6.6.4 Review

If the requested exception increases risks to subjects, decreases benefits, or negatively affects participants' rights, safety, welfare, or the integrity of the resultant data, the Chair will disapprove the exception and a Disapproval Notice will be sent to the PI. In either case, the matter will appear on the next full board agenda as a non-actionable item.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
03-08-2018	N/A	03-22-2018	03-22-2018
05-18-2018	12-14-2018	01-10-2019	01-20-2019

8.7 Reportable Events

Investigators are required to submit reports of deviations, adverse events, and unanticipated problems in accordance with the requirements outlined in other sections of this policy.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016

8.8 Significant New Findings

A significant new finding is anything that develops during the course of the research that may relate to a subject's willingness to continue participation; may impact their rights or welfare; increases the risks to subjects or others; or decreases the benefits to the subjects or of the study in general.

During the course of research, significant new knowledge or findings about the medication or test article and/or the condition under study may develop. The PI must report any significant new findings to the IRB and the IRB will review them with regard to the impact on the subjects' rights and welfare. These reports may be submitted to the IRB as a project modification or as part of the continuing review process or as an unanticipated problem; whichever is most appropriate to the findings.

Since the new knowledge or findings may affect the risks or benefits to subjects or subjects' willingness to continue in the research, the IRB may require, during the ongoing review process, that the PI contact the currently enrolled subjects to inform them of the new information. The IRB will communicate this to the PI. The consent document may need to be revised and the IRB may require that the PI obtain written consent again from currently enrolled subjects, acknowledging receipt of this new information and affirming their continued participation.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014

None	N/A	06-23-2016	06-23-2016
05-30-2018	12-14-2018	01-10-2019	01-20-2019

8.9 Final Reports

The completion of the study is a change in activity and should be reported to the IRB. A final report allows the HRPP to close its files and assess information that may be used by the IRB in the evaluation and approval of related studies. Any qualified staff member may review final reports.

If the final report contains complaints, problems, or other reportable events, an HRPP staff member will contact the researcher to obtain more information. The relevant procedure for this identified issue will then be followed.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
12-05-2017	12-15-2017	12-21-2017	12-21-2017

9 Review of Research

9.1 Criteria for IRB Approval of Research

In order for the IRB to approve non-exempt human subjects research, it must determine that the following requirements are satisfied:

- a) Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- b) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- c) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence.
- d) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by the Federal Regulations.
- e) Informed consent will be appropriately documented, or appropriately waived, in accordance with the Federal Regulations and local policy.
- f) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

- g) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- h) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

The above criteria must be satisfied for each review (initial, continuing, and project modification). However, not all criteria are relevant for every study.

9.1.1 Risk/Benefit Assessment

The goal of the risk/benefit assessment is to ensure that the risks to research subjects posed by participation in the research are justified by the anticipated benefits to the subjects and/or society. To that end, the IRB must:

- Judge whether the anticipated benefit, either of new knowledge or of improved health for the research subjects, justifies asking any person to undertake the risks, and
- Disapprove research in which the risks are judged unreasonable in relation to the anticipated benefits.

The assessment of the risks and benefits of proposed research involves a series of steps:

1. Identify and evaluate the risks associated with the research, as distinguished from the risks of non-research activities or therapies;
2. Determine whether the risks will be minimized to the extent possible;
3. Identify the probable benefits to be derived from the research;
4. Determine whether the risks are reasonable in relation to the benefits to subjects, if any, and assess the importance of the knowledge to be gained;
5. Ensure that potential subjects will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits;

Risks to subjects are reasonable in relation to anticipated benefits, if any, and to the importance of the knowledge that may reasonably be expected to result.

The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

9.1.1.1 Determination of Risk

At the time of initial and continuing review, the IRB will make a determination regarding the risks associated with the research protocols. Risks associated with the research will be classified as either “minimal” or “greater than minimal”. If the study is reviewed by the full board, the meeting minutes will reflect the IRB’s determination regarding risk level. The risk level of all non-exempt studies will also be documented in the reviewer worksheets for each study.

9.1.2 Scientific Merit

IRB review of scientific merit and the methodology of a proposed research protocol is a basic expectation of the IRB and refers to the overall evaluation of ethics, risks, and benefits. In order to approve research involving human subjects, the IRB shall determine that risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.

To put subjects in harm's way, add risk, or simply inconvenience subjects is not considered ethical if the research has no merit. The extent of scientific review by the IRB takes into consideration other scientific peer reviews undergone by the study before it comes to the IRB. In making this determination, the IRB may draw on its own knowledge and disciplinary expertise, and/or the IRB may draw on the knowledge and disciplinary expertise of others, such as reviews by a funding or regulatory agency. Documented interdepartmental and intradepartmental review also adds validity to the research proposed. All such reviews provide assurance that experts have evaluated the study and found it to be meritorious.

9.1.3 Equitable Selection of Subjects

In order to approve research involving human subjects, the IRB must determine that selection of subjects is equitable. In making this assessment the IRB will take into account the purpose of the research and the setting in which the research will be conducted. The IRB will not approve a study that fails to provide adequate scientific and ethical justification for excluding persons who might benefit from the research, nor will the IRB approve a study that fails to provide scientific and ethical justification for targeting a category of subjects who are vulnerable to coercion or undue influence.

9.1.4 Recruitment of Subjects

The investigator will provide the IRB with information about recruitment methods, including how participants will be identified and all materials to be used to recruit them (e.g., fliers, advertisements, listserv postings, planned correspondence).

9.1.4.1 Advertisements

The IRB must approve the final content of any and all advertisements and recruitment materials prior to posting and/or distribution for studies that are conducted under the purview of the IRB.

This information should be submitted to the IRB with the initial application or as an amendment to the protocol.

The IRB reviews the material to assure that it is accurate, not coercive or unduly optimistic, and not creating undue influence on the subject to participate, which includes but is not limited to:

- a) Statements implying a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and protocol
- b) Claims, either explicit or implicit, that the activity, intervention, drug, biologic or device is safe or effective for the purposes under investigation
- c) Claims, either explicit or implicit, that the activity, intervention, or test article is known to be equivalent or superior to any other drug, biologic or device
- d) Use of terms like "new test," "new treatment," "new method," or "new drug" without explaining that it is investigational
- e) Promise of "free tests," or "free treatment" when, in actuality, the participants will just not be charged for taking part in the investigation
- f) Emphasis on compensation (e.g., bold type, larger font, etc.) [only relevant to non-exempt studies]
- g) Inclusion of exculpatory language

Recruitment materials should be limited to the information the prospective subjects need to determine their eligibility and interest. Recruitment materials must include:

- a) Title of the study
- b) Name of the PI
- c) Clear statement that this is research
- d) Contact information for interested individuals

When appropriately worded, the following items may be included:

- a) Condition being studied and/or the purpose of the research
- b) Primary criteria that will be used to determine eligibility for the study
- c) Time or other commitment required of the subjects
- d) Location of the research
- e) Potential direct or societal benefits
- f) Recruitment material and compensation plan cannot include coupons or discounts on the purchase price of the study product, if marketed

Once approved by the IRB, recruitment material associated with non-exempt studies cannot be altered or manipulated in any way without prior IRB approval. Recruitment materials associated with exempt studies can be revised without IRB approval so long as they conform to this section of the policy.

9.1.5 Compensation for Research Subjects

Payment to research subjects may be an incentive for participation or a way to reimburse a subject for travel and other experiences incurred due to participation. However, payment for participation is not considered a research benefit. Regardless of the form of remuneration, investigators must take care to avoid unduly influencing subjects. Compensation should reflect the degree of risk, effort, inconvenience, or discomfort associated with participation.

Research subjects should not be disadvantaged by their participation in research. Payments should reflect the degree of risk, inconvenience, or discomfort associated with participation. Appropriate compensation to all subjects for time and expenses is acceptable.

Participants in a single study may receive unequal compensation under three circumstances:

- The investigator demonstrates that not all subjects are experiencing the same degree of risk, inconvenience or discomfort. For example, subjects participating in only one component of a study may be compensated less than subjects who consent to participating in multiple components of a study. Similarly, subjects traveling longer distances may be compensated at a higher rate to reflect greater travel expenses. However, subjects who are higher wage earners should not receive greater compensation than lower wage earners in the same study for participating in the same study activities.
- OSU students who enroll in the study will be compensated with extra credit and another (non-OSU student) cohort will be uncompensated or minimally compensated.
- Some OSU students who enroll in the study will be compensated with extra credit and another OSU student cohort will be uncompensated or minimally compensated due to lack of access to extra credit. For example, students can receive extra credit through the subject pool in the School of Psychological Science, but eligible subjects will be recruited campus-wide.
Note: When two or more OSU cohorts will be differently compensated, the details of those differences must be articulated in the consent document(s).

Exceptions may be made at the discretion of the Board if the difference in incentives is nominal.

Investigators who wish to pay research subjects must provide the details of the compensation plan in the protocol and consent documents. The IRB will review both the amount of compensation and the proposed method of disbursement (e.g., cash, gift cards, etc.). Compensation involving extra credit must include an alternative non-research activities requiring equal or lesser effort for which students may be given extra credit.

When the study involves multiple activities or multiple visits, the entire payment should not be contingent upon completion of the entire study. Completion bonuses, if offered, should not be so great that it unduly influences participants to remain in the study if they wish to withdraw. The consent form must describe the terms and type of compensation, as well as the conditions under which subjects would receive partial payment or no payment.

Compensation offered in the form of checks and compensation greater than or equal to \$600 paid within one calendar year, requires the collection of identifying information for the purposes of tax reporting. In these cases, the consent document must inform subjects that they will be asked to provide their Social Security Number or Individual Tax Identification Number to receive payment. In the event that the target population is known not to possess such identification, a flat tax may be withheld from payments large enough to require reporting to the Internal Revenue Service (IRS). If this is the approach to be taken by the PI, the consent document should include a brief statement indicating that taxes will be withheld from the study payment and an estimate of the net amount subjects should anticipate.

9.1.5.1 Raffles and Lotteries

The use of lotteries and raffles in research studies involving more than minimal risk may be permitted if all of the following conditions are met:

- All subjects are at least 18 years of age
- Study participation is not required for entry into the drawing
- Limit 1 drawing per study
- Limit 1 entry per drawing
- Baseline compensation will be provided to all enrolled participants
- Compensation plan does not create the potential for undue inducement

Raffles and lotteries may be used to compensate subjects enrolled in studies involving no more than minimal risk without meeting the above listed conditions.

Policy originally approved March 16, 2010. Revisions approved May 21, 2013. Revisions approved by the IO on April 9, 2014. Revisions approved by the full board on October 16, 2018.

9.1.6 Data and Safety Monitoring

For low risk studies, continuous, close monitoring by the study investigator or an independent individual may be an adequate and appropriate format for monitoring, with prompt reporting of problems to the IRB, sponsor and regulatory bodies as appropriate.

For all research that is more than minimal risk, the investigator must submit a Data and Safety Monitoring Plan (DSMP). The plan may stand alone or be incorporated into other sections of the protocol and should describe the procedures for safety monitoring, reporting of unanticipated problems

involving risks to subjects or others, descriptions of interim safety reviews and the procedures planned for transmitting the results to the IRB. This description should include information regarding an independent Data and Safety Monitoring Board (DSMB), if one exists, or an explanation why an independent data safety monitor is not necessary.

The IRB determines that the monitoring plan makes adequate provision for monitoring the reactions of subjects and the collection of data to ensure the safety of subjects and address problems that may arise over the course of the study. The overall elements of the monitoring plan may vary depending on the potential risks, complexity, and nature of the research study. The method and degree of monitoring needed is related to the degree of risk involved.

The IRB has the authority to require a DSMB as a condition for approval of research where it determines that such monitoring is needed. When DSMBs are utilized, IRBs conducting continuing review of research may rely on a current statement from the DSMB indicating that it has and will continue to review study-wide adverse events, interim findings, and any recent literature that may be relevant to the research, in lieu of requiring that this information be submitted directly to the IRB.

9.1.7 Privacy and Confidentiality

The IRB will determine whether adequate procedures are in place to protect the privacy **of subjects and to** maintain the confidentiality of the data.

Privacy is a subject's control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) and private information with others.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical or academic record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

The IRB must determine whether the activities in the research constitute an invasion of privacy. In order to make that determination, the IRB must obtain information regarding how the investigators are getting access to subjects or subjects' private, identifiable information and the subjects' expectations of privacy in the situation. Investigators must have appropriate authorization to access the subjects or the subjects' information.

In developing strategies for the protection of subjects' privacy, consideration should be given to:

- a) Methods used to identify and contact potential participants
- b) Settings in which an individual will be interacting with an investigator
- c) Appropriateness of all personnel present for research activities
- d) Methods used to obtain information about participants and the nature of the requested information
- e) Information that is obtained about individuals other than the "target participants," and whether such individuals meet the regulatory definition of "human subject" (e.g., a subject provides information about a family member for a survey). See Botkin, JR JAMA 2001; 285:207-211 for

Recommendation for Investigators and Institutional Review Boards Regarding Privacy of Family Members in Research.

- f) How to access the minimum amount of information necessary to complete the study

Confidentiality involves the methods that an investigator uses to ensure that information obtained by researchers about their subjects is not inappropriately divulged.

If anyone, including the investigator, can readily ascertain the identity of the subjects from the data, then the IRB must determine if appropriate protections are in place to minimize the likelihood that the information could be inappropriately divulged. Safeguards designed to protect confidentiality should be commensurate with the potential degree of harm from inappropriate disclosure. The PI will provide the information regarding the privacy and confidentiality of research subjects at the time of initial review through the completion of the application, protocol, and/or other applicable materials. The IRB will review all information received from the PI and determine whether or not the privacy and confidentiality of research subjects is sufficiently protected.

At the time of initial review, the IRB assesses whether there are adequate provisions to protect subject privacy and maintain confidentiality. The IRB does this through the evaluation of the methods used to obtain information about:

- a) Subjects
- b) Individuals who may be recruited to participate in studies
- c) The use of personally identifiable records
- d) The methods used to protect the confidentiality of research data

The IRB shall evaluate the effectiveness of proposed de-identification techniques, coding systems, encryption methods, storage facilities, access limitations, external protections (e.g., Certificate of Confidentiality), and other proposed safeguards in determining the adequacy of confidentiality protections. In reviewing confidentiality protections, the IRB shall consider the nature, probability, and magnitude of harms that would be likely to result from a disclosure of collected information outside the research.

9.1.8 Compliance with all Applicable State and Local Laws

The IRB follows and must adhere to all applicable state and local laws in the jurisdictions where the research is taking place. All consent forms must be consistent with applicable state and local laws.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
11-08-2017	12-15-2017	12-21-2017	12-21-2017
01-29-2018	02-21-2018	02-22-2018	02-22-2018
10-16-2018	12-14-2018	01-10-2019	01-20-2019
01-02-2022	02-14-2023	03-16-2023	03-16-2023

9.2 Possible IRB Actions and Determinations

Possible IRB actions and determinations include:

- a) Human Subjects Research Determination
- b) Engagement Determination
- c) Approval in Principle
- d) Acknowledge
- e) Approve
- f) Defer for minor revisions
- g) Defer for major revisions
- h) Disapprove
- i) Close
- j) Suspend
- k) Terminate
- l) Administrative withdrawal or closure

9.2.1 Human Subjects Research Determination

Studies are considered “Not Human Subjects Research” (NHSR) if they do not meet the regulatory definitions of human subjects and/or research defined in the Common Rule (§46.102).

In addition, research using de-identified or coded information or specimens that were not collected by the current investigator, nor collected for the currently proposed project do not need IRB review. To be considered NHSR, the study team members must not be able to link the coded data or specimens back to the individual subjects. If the provider of the data or specimens has access to the identities of the subjects, the provider and recipient investigators must enter into a written agreement that states that under no circumstances will the identities of the subjects be released to the investigator (see OHRP Guidance on Research Involving Coded Private Information or Biological Specimens).

Oversight determinations will be made by HRPP staff and formal responses will be issued to the investigator.

9.2.2 Engagement Determination

Under some circumstances, the OSU IRB may determine that the conduct of research activities involving human subjects research do not engage the Institution in research and those activities will not require IRB review. Engagement determinations are made in accordance with OHRP’s 2008 Guidance on Engagement of Institutions in Human Subjects Research and their 2011 Correspondence on “Non-engaged” Scenarios.

Engagement determinations should be made by the IRB, not investigators. Investigators who think that their project may not engage the Institution in research should complete and submit a request for a determination. Requests are reviewed by appropriately qualified or trained HRPP staff, in consultation with the Administrator or Chair as needed, for final approval. A determination will then be issued to the investigator.

9.2.3 §.118 Determination

A request for a §46.118 Determination (“Approval in Principle”) must be sponsor-driven, rather than in anticipation of a request from the funding source. Applications for an Approval in Principle will be reviewed by appropriately qualified or trained HRPP staff in consultation with the Administrator or Chair as needed, for final approval. A formal notice, either approving or denying the application, will then be issued to the investigator.

9.2.4 Acknowledge

Submissions that may be acknowledged rather than approved include applications and other materials related to exempt research, reportable events, and documentation of relevant new information (e.g., progress reports to funding agencies). Voting members of the board, the Chair, and the Chair's designees have the authority to make determinations related to these submissions.

9.2.5 Approve

Submissions that are approved include non-exempt submissions that have met all relevant criteria and conditions. Only voting members of the board have the authority to approve these submissions.

Depending upon the nature of the required conditions, the IRB could designate any of the following individuals or groups of individuals to determine that the conditions of approval have been satisfied:

- The IRB chairperson;
- Another IRB member or group of IRB members with particular subject matter expertise or experience;
- A consultant with particular subject matter expertise who is not an IRB member; and/or
- An HRPP Administrator or other qualified IRB administrative staff person, who need not be an IRB member.¹⁰

9.2.6 Approved with Conditions

Approve with Conditions: The Board determines that the submission can be approved once specific, minor revisions are made. These revisions are presented to the PI for incorporation by simple concurrence. Revisions must be made by the PI exactly as designated by the IRB or reviewer(s). **If meeting one or more of the criteria for approval hinges on the revisions, the IRB must defer for major revisions instead of minor.** Examples of minor revisions include:

- Confirmation of specific assumptions or understandings on the part of the IRB regarding how the research will be conducted (e.g., confirmation that the research excludes children);
- Submission of additional documentation (e.g., certificate of ethics training) so long as the content of said documentation would not impact the determination that the study meets the criteria for approval;
- Precise language changes to protocol or informed consent documents; or
- Substantive changes to protocol or informed consent documents along with clearly stated parameters that the changes must satisfy.

For protocols reviewed by the full board, the needed revisions are agreed upon at the IRB meeting, however precise language for the pending items need not be agreed upon during the meeting. A vote for minor revisions may occur even when the precise language for the stipulations has not been written, but the Chair and/or Primary and Secondary reviewers must review the content of the notice and confirm that it reflects the intent of the vote prior to sending stipulations to the PI.

For protocols reviewed under expedited review, the minor revisions are drafted by the reviewer(s).

In order to receive approval for a protocol approved with conditions:

¹⁰ See OHRP Guidance on IRB Approval of Research with Conditions, section D, November 2010

- **Full Board:** The investigator's response, the revised documents, and the previously submitted documents are given to the IRB Chair, Vice Chair, a subcommittee of the IRB for review, the primary reviewer, or a qualified member of the HRPP office (voting or non-voting) [see *OHRP Guidance on IRB Approval of Research with Conditions, 11/10/2010*]. The reviewer(s) will be determined at the time of the convened meeting when a vote for minor revisions has occurred. The reviewer(s) may verify the adequacy of the revisions and issue approval documents or return the submission as inadequately revised, without further action by the IRB.
- **Expedited:** The investigator's response, the revised documents and the previously submitted documents are given to the primary reviewer, or a qualified member of the HRPP office as indicated by the reviewer. The reviewer(s) may verify the adequacy of the revisions and issue approval documents or return the submission as inadequately revised.

Approval of the study documents will not be granted and an approval notice will not be issued until all of the requests are addressed to the satisfaction of the IRB or the reviewer(s).

The outcome of the IRB's deliberations is communicated to the investigator in writing and the outcome of the review will be communicated to the IRB members either in the monthly list of reviewed studies (if approved) or in the minutes (if additional review and discussion is required). If the study is reviewed by an expedited procedure, the outcome will be documented in the reviewer worksheet of the investigator's response.

9.2.7 Defer for major revisions

Defer for major revisions: This action is taken when substantial modification or clarification is required, or insufficient information is provided to adequately assess the risks, benefits, or other aspects of the study. IRB approval of the proposed research cannot occur until subsequent review of the material the PI submitted has been reviewed by the convened IRB or the expedited reviewer(s).

For protocols reviewed by the full board, the needed revisions are agreed upon at the IRB meeting. If the precise language for the pending items is not agreed upon during the meeting, a vote for major revisions may still occur but the phrasing of the pending items will be determined by the Chair and/or Primary and Secondary reviewers prior to sending the notice to the PI.

In order to receive approval for a protocol deferred for major revisions:

Full Board: The investigator's response must be submitted for review at a subsequent, convened meeting of the same IRB. When the PI submits a response and revised documents, the submission and materials are distributed to the IRB and placed on the agenda for re-review at a subsequent meeting.

Expedited: The investigator's response, the revised documents and the previously submitted documents are given to the same reviewer(s) for re-review.

Final approval or exempt determination will not be granted until all of the requests are addressed to the satisfaction of the IRB, the reviewer(s) or the HRPP.

The outcome of reviews and IRB decisions are communicated to the investigator in writing.

IRB decisions concerning amended submissions are documented in the minutes of the IRB meeting or in the file for expedited review.

Note: Failure to submit a response to IRB-stipulated changes or inquiries related to deferred protocols within 60 days of the IRB date of determination may result in administrative closure of the IRB file. The PI will receive notification of the closure of the IRB file, including an explanation for this action. An extension beyond 60 days may be granted by the IRB if sufficient cause is provided by the PI.

9.2.8 Disapprove

The IRB has determined that the research cannot be conducted at OSU or by employees or agents of OSU or otherwise under the auspices of OSU. A re-submission of a previously disapproved study will be reviewed by the full board, regardless of risk level. Whether a study is sufficiently similar to be considered the same study will be at the discretion of the IRB Chair.

9.2.9 Close

A study may be closed by an investigator when data collection and analysis of any identifiable data are complete. A study may also be administratively closed by the HRPP staff if it expires outside of review (prior to the submission of a continuing review application). The HRPP staff may also administratively close a study if a renewal is pending a response from the PI and no substantive response is received after 60 days. In any case, the IRB shall notify the PI of the closure in writing.

9.2.10 Suspend or Terminate

IRB approval may be suspended or terminated if research is not being conducted in accordance with IRB or regulatory requirements or has been associated with unexpected problems or serious harm to subjects.

Suspension of IRB approval is a directive of the convened IRB or IRB Chair or the Administrator to temporarily stop some or all previously approved research activities. Suspension directives made by the IRB Chair or Administrator must be reported to a meeting of the convened IRB. Suspended protocols remain open and require continuing review.

Termination of IRB approval is a directive of the convened IRB to stop permanently all activities in a previously approved research protocol. Terminated protocols are considered closed and no longer require continuing review. Terminations of protocols approved under expedited review must be made by the convened IRB.

The IRB shall notify the PI in writing of such suspensions or terminations and shall include a statement of the reasons for the IRB's actions. The terms and conditions of the suspension must be explicit. The investigator shall be provided with an opportunity to respond in person or in writing.

When study approval is suspended or terminated by the convened IRB or an authorized individual, in addition to stopping all research activities, the convened IRB or individual ordering the suspension or termination will notify any subjects currently participating that the study has been suspended or terminated. The convened IRB or individual ordering the suspension will consider whether procedures for withdrawal of enrolled subjects are necessary to protect their rights and welfare of subjects (see "Protection of Currently Enrolled Participants").

If follow-up of subjects for safety reasons is permitted/required by the convened IRB or individual ordering the suspension or termination, the convened IRB or individual ordering the suspension or termination will require that the subjects should be so informed and that any adverse events/outcomes be reported to the IRB and the sponsor.

Investigator MUST continue to provide reports on adverse events and unanticipated problems to both the IRB and sponsor just as if there had never been a suspension (i.e., all events that need to be reported during a study need to continue to be reported during the suspension period.)

When study is suspended or terminated, the IRB will follow procedures for Reporting to Regulatory Agencies and Institutional Officials.

Note: Suspension or termination of protocols approved by the IRB can also be issued by Institutional officials acting outside of and unrelated to the IRB (i.e., not necessarily related to protecting the rights and welfare of study participants). Such Institutional actions can be made by the President, Vice Presidents, Provost, Senior Vice Provost, Vice Provosts, and Deans. Such Institutional actions may be made for any reason in furtherance of the Institution's interest provided, however, that the aggrieved PI is entitled to all rights and procedures afforded to him/her under the OSU Grievance Policy.

9.2.11 Investigator Hold

An investigator may request an administrative hold on a protocol when the investigator wishes to temporarily or permanently stop some or all approved research activities. An administrative hold is initiated by an investigator. Administrative holds are not suspensions or terminations and may therefore be lifted at the discretion of the investigator.

Investigators must notify the IRB in writing that:

- a) They are voluntarily placing a study on administrative hold
- b) A description of the research activities that will be stopped
- c) Proposed actions to be taken to protect current participants
- d) Actions that will be taken prior to IRB approval of proposed changes in order to eliminate apparent immediate harm

Upon receipt of written notification of the investigator hold, the HRPP staff places the research on the agenda for review.

The IRB Chair and/or Administrator, in consultation with the investigators, determine whether any additional procedures need to be followed to protect the rights and welfare of current participants as described in "Protection of currently enrolled participants" below.

The IRB Chair and/or Administrator, in consultation with the investigators, determine how and when currently enrolled participants will be notified of the administrative hold.

Investigators may request a modification of the administrative hold by submitting a project revision. The revision may include ending the administrative hold. The revision will be added to the next full board agenda for review. The primary reviewer will be the Chair unless there is a conflict of interest or the Chair is unavailable, in which case the primary reviewer will be the Vice Chair.

9.2.12 Protection of Currently Enrolled Participants

Before an administrative hold, termination, or suspension, is put into effect the convened IRB or IRB designee considers whether any additional procedures need to be followed to protect the rights and welfare of current participants. Such procedures might include:

- Transferring participants to another investigator
- Making arrangements for clinical care outside the research
- Allowing continuation of some research activities under the supervision of an independent monitor
- Requiring or permitting follow-up of participants for safety reasons
- Requiring adverse events or outcomes to be reported to the IRB and the sponsor
- Notification of current participants
- Notification of former participants

9.2.13 Administrative withdrawal or closure

Failure to submit a response to stipulated changes or inquires within 60 days of notice from the HRPP will result in administrative closure if the submission is a renewal or administrative withdrawal for all other submission types including initial applications or submissions related to an approved or acknowledged study. The PI will receive notification of the closure or withdrawal, including an explanation for this action.

An extension beyond 60 days may be granted by the HRPP in the event of emergency or exigent circumstances.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
01-12-2015	05-14-2015	03-03-2016	04-01-2016
None	N/A	06-23-2016	06-23-2016
06-24-2016	07-14-2016	07-29-2016	07-29-2016
01-29-2018	02-21-2018	02-22-2018	02-22-2018
08-22-2018	12-14-2018	01-10-2019	01-20-2019
3-10-2021	5-18-2021	06-23-2021	06-23-2021
01-02-2022	02-14-2023	03-16-2023	03-16-2023

9.3 Reporting IRB Actions

All IRB actions are communicated to the Principal Investigator (PI), or designated primary contact person for the protocol, in writing. Once approved, the HRPP will send the PI a notice and the approved version of the study documents. For a deferral, the notification will include the modifications required for approval along with the basis for requiring those modifications.

The IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing [§46.109(d) IRB review of research].

All IRB actions and letters to investigators are filed in the record management system.

The IRB reports its findings and actions to the Institution in the form of its minutes, which are distributed by HRPP staff, made available to the Institutional official, and are stored permanently and securely in the HRPP office or electronically on a secure local or cloud-based server.

In the case of sponsored research, IRB actions will be reported to the sponsor by the investigator. Exceptions to this policy include determinations of non-compliance and direct requests from the sponsor.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
4-28-2015	12-18-2015	06-23-2016	06-23-2016
02-20-2018	02-20-2018	03-22-2018	03-22-2018
01-02-2022	02-14-2023	03-16-2023	03-16-2023

9.4 Appeal of IRB Decisions

In cases where there is disagreement between the IRB and the PI regarding the nature and extent of the requested changes and these disagreements cannot be resolved, the PI and/or the IRB may make an appeal to the IO. The IO may organize a meeting to help facilitate discussion between the IRB and the PI. While the IO may provide input and make recommendations to the IRB for expeditious resolution of the matter, final determinations for approval remain under the purview of the IRB.

Since the IO is responsible for policies and procedures followed by the IRB, the IO may review IRB decisions to ensure that the decision-making process is appropriate. If the IO has concerns regarding the process that the IRB has followed in making a decision, he/she may require the IRB to reconsider the decision. However, the IO cannot overrule an IRB decision.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016

10 Obtaining Informed Consent from Research Subjects

10.1 Policy

The following procedures describe the requirements for obtaining consent from participants in non-exempt research conducted under the auspices of OSU. These procedures are not intended to preempt any applicable Federal, state, or local laws that require additional information to be disclosed in order for informed consent to be legally effective. This section of policy does not cover research determined by HRPP to be exempt under applicable federal regulations, but all researchers including those conducting exempt research are expected to follow the ethical principles outlined in the Belmont Report, discussed in section 1.4 of this policy. These ethical responsibilities include obtaining informed

consent from subjects when this is an appropriate mechanism for upholding the ethical principles outlined in this policy.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
12-15-2017	12-15-2017	12-21-2017	12-21-2017
01-29-2018	02-21-2018	02-22-2018	02-22-2018
08-15-2019	05-18-2021	06-23-2021	06-23-2021
02-23-2022	03-08-2022	03-08-2022	03-08-2022

10.2 Definitions

Legally Authorized Representative (LAR). A legally authorized representative is an individual or body authorized under applicable law to provide permission on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. Where the law is silent, the IRB will use its discretion in determining who may provide consent for a subject's participation.

Legal guardian. "Guardian" is one type of LAR and means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. In Oregon, a "Guardian" of a minor means a person or agency having the powers and responsibilities of a parent to make binding decisions for a child."

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
12-11-2017	N/A	12-21-2017	12-21-2017
01-29-2018	02-21-2018	02-22-2018	02-22-2018
11-13-2018	12-14-2018	01-10-2019	01-20-2019

10.3 Basic Requirements

The requirement to obtain the legally effective informed consent of individuals before involving them in research is one of the central protections provided for by the Federal regulations and the OSU IRB. Investigators are required to obtain informed consent from a subject or the subject's legally authorized representative. When informed consent is required, it must be sought prospectively, and properly documented.

The informed consent process involves three key features: (1) disclosing to the prospective human subject information needed to make an informed decision; (2) facilitating the understanding of what has been disclosed; and (3) promoting the voluntariness of the decision about whether or not to participate in the research.

Informed consent is a process of information exchange that may include reading and signing the consent document. The informed consent process is the critical communication link between the prospective Human Subject and an Investigator, beginning with the initial approach of an Investigator and continuing through the completion of the study. Investigators must have received the appropriate training and be

knowledgeable about the study protocol in order that they may answer questions to help provide understanding to the study participant or potential study participant. The following are some of the ways that the exchange of information between the Investigator and study participant may occur:

- Face to face contact
- Mail (paper or electronic)
- Telephone
- Fax
- Initial screen of an online form or first page of a paper form

Investigators must obtain consent prior to entering a subject into a study and/or conducting any study activities, unless consent is waived by the IRB.

If someone other than the investigator obtains consent from a subject, the investigator needs to formally delegate this responsibility, and the person so delegated must have received appropriate training to perform this activity. The person so delegated must be knowledgeable enough about both the research to be conducted and the consent process, to be able to answer questions about the study and to assess whether or not the subject is able to comprehend the information provided.

Sample or draft consent documents may be developed by a Sponsor or cooperative study group. However, the IRB-of-record is the final authority on the content of the consent documents that are presented to the prospective study subjects.

These informed consent requirements are not intended to preempt any applicable federal, state, or local laws that require additional information to be disclosed for informed consent to be legally effective.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
12-15-2017	12-15-2017	12-21-2017	12-21-2017

10.4 Informed Consent Process

Except as provided elsewhere in this policy:

1. Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.
2. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
3. The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.

4. The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
5. When the consent document is expected to exceed three pages, it must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
6. Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
7. No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
8. For subjects who are not fluent in English, informed consent must be obtained in a language that is understandable to the subject (or the subject's legally authorized representative). In accordance with this policy, the IRB requires that the informed consent process include an appropriate and qualified translator when the prospective subject does not understand the language of the person who is obtaining consent. A qualified translator is one who is either a professional translator, an individual with a master's degree in languages, or a native speaker of the relevant language(s). The informed consent documents must be in a language understandable to the proposed participants. Therefore, the IRB will review the document and a back translation of the exact content contained in the foreign language informed consent document which must be provided by the Investigator, with the credentials of the translator detailed in the IRB application or amendment form. The IRB cannot verify the accuracy of translated documents. Therefore, verification of the back translation must be made available before the IRB may approve the translated documents. The requirement for back translation will be waived if the translation is certified by a qualified translator. Translated documents will be processed in a manner consistent with documents presented in English.
9. The PI is responsible for insuring that each prospective subject is adequately informed about all aspects of the research and understands the information provided.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
12-14-2017	12-15-2017	12-21-2017	12-21-2017
02-13-2018	02-21-2018	02-22-2018	02-22-2018

10.5 Basic Elements of Informed Consent

To be valid, the consent process must provide the following basic elements of information to potential subjects:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject.
3. A description of any benefits to the subject or to others that may reasonably be expected from the research.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject must be maintained.
6. For research involving more than minimal risk, an explanation as to the availability of medical treatment in the case of research-related injury, including who will pay for the treatment and whether other financial compensation is available.
7. An explanation of whom to contact on the research team for answers to pertinent questions about the research or to voice concerns or complaints about the research, and whom to contact in the event of a research-related injury to the subject.
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 - a. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
 - b. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
10. As appropriate, contact information for the IRB to obtain answers to questions about the research; to voice concerns or complaints about the research; to obtain answers to questions about their rights as a research participant; in the event the research staff could not be reached; and in the event the subject wishes to talk to someone other than the research staff.

Additional elements of informed consent to be applied, as appropriate:

1. A statement that the particular [research activity] may involve risks to the subject, that are currently unforeseeable. Include when the research involves investigational test articles or other procedures in which the risks to subjects is not well known.
2. A statement that if the subject is or becomes pregnant, the particular [research activity] may involve risks to the embryo or fetus, that are currently unforeseeable. Include when the research involves pregnant women or women of childbearing potential and the risk to fetuses of the drugs, devices, or other procedures involved in the research is not well known.
3. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's (or legally authorized representative's) consent.

4. Any additional costs to the subject that may result from participation in the research. Costs of IND product are not chargeable to the subject without FDA permission. Costs of IDE product are chargeable to the subject, and are controlled by regulation.
5. The consequences of a subject's decision to withdraw from the research. Include when withdrawal from the research is associated with adverse consequences.
6. Procedures for orderly termination of participation by the subject. Include when the protocol describes such procedures.
7. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject. Include when the research is long term and interim information is likely to be developed during the conduct of the research.
8. The approximate number of subjects involved in the study. Include when the research involves more than minimal risk.
9. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
10. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
11. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
12. For FDA-regulated studies, the possibility that the Food and Drug Administration may inspect the records needs to be included in the statement regarding subject confidentiality.
13. For applicable FDA-regulated or NIH-funded clinical trials, informed consent documents must include a specific statement that refers to the trial's description on www.ClinicalTrials.gov.
14. For NIH-funded studies collecting individually identifiable, informed consent documents must include information about the protections afforded by a Certificate of Confidentiality.

Revision Dates			
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11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
12-05-2017	12-15-2017	12-21-2017	12-21-2017
01-29-2018	02-21-2018	02-22-2018	02-22-2018
11-13-2018	12-14-2018	01-10-2019	01-20-2019

10.6 Documentation of Informed Consent

Except as provided elsewhere in this manual, informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. When FDA-regulated, signatures must also be dated (§21CFR50.27(a)).

A written copy shall be given to the person signing the informed consent form.

Except as provided elsewhere in this manual, the informed consent form may be either of the following:

- (1) A written informed consent form that meets the requirements outlined in this manual. The investigator shall give either the subject or the subject’s legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject’s legally authorized representative.
- (2) A short form written informed consent form stating that the elements of informed consent required by § __.116 have been presented orally to the subject or the subject’s legally authorized representative, and that the key information required by § __.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject’s legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject’s legally authorized representative, in addition to a copy of the short form.

The IRB must receive all foreign language versions of the short form document as a condition of approval, but not necessarily at the time of initial submission. If the study is to be reviewed by the full board, expedited review of these versions is acceptable after initial approval if the protocol, the full English language informed consent document, and the English version of the short form document have already been approved by the convened IRB.

Revision Dates			
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11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
12-05-2017	12-15-2017	12-21-2017	12-21-2017
01-29-2018	02-21-2018	02-22-2018	02-22-2018
12-24-2018	N/A	01-10-2019	01-20-2019

10.7 Posting of Clinical Trial Consent Form

For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal website that will be established as a repository for such informed consent forms.

If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal website (e.g. confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.

The informed consent form must be posted on the Federal website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

OHRP Announcement on 08/28/2018: *“At this time, two publicly available federal websites that will satisfy the consent form posting requirement, as required by the revised Common Rule, have been*

identified: ClinicalTrials.gov and a docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021). HHS and other Common Rule departments and agencies are developing instructions and other materials providing more information to the regulated community about this posting requirement.”

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-13-2018	12-14-2018	01-10-2019	01-20-2019

10.8 Waiver of Informed Consent

10.8.1 Full Board and Expedited Studies

An IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above; or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

- a) The research involves no more than minimal risk to the subjects;
- b) The research could not practicably be carried out without the requested waiver or alteration;
- c) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- d) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- e) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

10.8.1.1 Screening, Recruiting, or Determining Eligibility

The federal regulations permit an IRB to approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject’s legally authorized representative, if either of the following conditions are met:

- (1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
- (2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

Examples of circumstances when a waiver of consent would not be appropriate under criteria 2 include:

- a) When consent was previously requested for future use and not provided by the individual
- b) When the identity of the potential subjects is known to the researcher(s) but the information contained in the records is not (e.g., employment or medical records of colleagues).

10.8.1.2 Broad Consent

If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

10.8.2 FDA-Regulated Research

An IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above; or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

1. The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The clinical investigation could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

FDA does not object to a sponsor initiating, or an investigator conducting, a minimal risk clinical investigation for which an IRB waives or alters the informed consent requirements as described above.

IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More than Minimal Risk to Human Subjects (July 24, 2017)

Revision Dates			
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11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
12-05-2017	12-15-2017	12-21-2017	12-21-2017
01-29-2018	02-21-2018	02-22-2018	02-22-2018
11-13-2018	12-14-2018	01-10-2019	01-20-2019
08-15-2019	05-18-2021	06-23-2021	06-23-2021
02-23-2022	03-08-2022	03-08-2022	03-08-2022

10.9 Waiver of Documentation of Informed Consent

10.9.1 Expedited and Full Board Research

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds that the:

- a) Only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality;

Note 1: Subjects must be asked whether they want documentation linking them with the research, and their wishes must govern. (Example: domestic violence research where the primary risk is discovery by the abuser that the subject is talking to researchers.)

Note 2: In order to waive written documentation of consent where the only record linking the participant and the research would be the consent document, the IRB has to determine that the research is not FDA-regulated.

- b) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Procedures such as non-sensitive surveys, questionnaires and interviews generally do not require written consent when conducted by non-researchers; or
- c) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the documentation requirement is waived, the IRB requires the investigator to provide in the application materials a written summary of the information to be communicated to the subject, and the IRB will consider whether to require the investigator to provide subjects with a written statement regarding the research.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
12-05-2017	12-15-2017	12-21-2017	12-21-2017
01-29-2018	02-21-2018	02-22-2018	02-22-2018
11-13-2018	12-14-2018	01-10-2019	01-20-2019
08-15-2019	05-18-2021	06-23-2021	06-23-2021
02-23-2022	03-08-2022	03-08-2022	03-08-2022
01-02-2022	02-14-2023	03-16-2023	03-16-2023

10.10 Deception in Research¹¹

Definition: Deception occurs as the result of investigators providing false or incomplete information to participants for the purpose of misleading research subjects.

The IRB accepts the need for certain types of studies to employ strategies that include deception. However, employment of such strategies must be justified. In general, deception is not acceptable if, in the judgment of the IRB, the participant may have declined to participate had they been informed of the true purpose of the research.

In the event that a study includes the use of deception, the investigator must provide:

- Confirmation that the study design meets all of the criteria for a waiver of consent [§46.116(d)]¹²
- Justification for the deception

¹¹ Policy approved by IRB in 09/2011

¹² 46.116(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

- 1) The research involves no more than minimal risk to the subjects;
- 2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- 3) The research could not practicably be carried out without the waiver or alteration; and
- 4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

- A description of the manner of deception and how the deception will take place
- An explanation as to why deception is necessary to this protocol
- A description of whether the deception results in any increased risk to participants
- A indication of whether the deception may affect a subject’s willingness to participate in research
- A description of the post-study debriefing that includes offering the participant the option to withdraw their data from the study
 - If an exception to the requirement for a debriefing is requested, the study must be reviewed by the full board
- A description of any previous use of deception in similar research and a summary of any actual harms or reactions from participants to the use of deception
- A description of alternatives to deception that were considered and an explanation as to why these alternatives were rejected

10.10.1 Applicability to Exemptions

Exempt Category 1. Studies involving deception will not be considered to fall in to the exempt category of research conducted in established or commonly accepted educational settings, as deception is not a “normal educational practice.”

Revision Dates			
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11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
12-15-2017	12-15-2017	12-21-2017	12-21-2017
01-29-2018	02-21-2018	02-22-2018	02-22-2018

11 Vulnerable Subjects in Research

11.1 Policy

When some or all of the participants in non-exempt research conducted under the auspices of OSU are likely to be vulnerable to coercion or undue influence, the research must include additional safeguards to protect the rights and welfare of these participants.

At the time of initial review of non-exempt human subjects research the IRB will consider the scientific and ethical reasons for including vulnerable subjects in research. The IRB may determine and require that, when appropriate, additional safeguards be put into place for categories of subjects who are vulnerable to coercion or undue influence. See also *Equitable Subject Selection*.

The IRB must ensure that all of the regulatory requirements for the protection of vulnerable subjects are met and that appropriate additional protections for vulnerable subjects are in place. The following policy only applies to non-exempt research. If HRPP staff determine that research is exempt, which involves determining if certain vulnerable populations can be included under specific research exempt categories, this section of the policy should not be applied.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014

None	N/A	06-23-2016	06-23-2016
11-08-2017	12-15-2017	12-21-2017	12-21-2017
01-29-2018	02-21-2018	02-22-2018	02-22-2018
02-23-2022	03-08-2022	03-08-2022	03-08-2022

11.2 Definitions

Children are persons who have not attained the legal age for consent, under the applicable law of the jurisdiction in which the research will be conducted. According to Oregon law, minors are persons under the age of eighteen. The general rule in Oregon, however, is that a person may consent for his or her own medical care at the age of fifteen (15). Other statutes provide minors with the right to consent to certain types of medical care.

For example: emancipated minors, certain minors seeking care for drug addiction, sexually transmitted diseases, birth control, emotional disorders, or mental health treatment. Because Oregon law does not specifically address consent of children with majority status to research, the OSU IRB will review issues of consent related to enrollment of these children in research on a case-by-case basis.

Note: For research conducted in jurisdictions other than Oregon, the research must comply with the laws regarding the legal age of consent in all relevant jurisdictions. OSU’s Office of General Counsel will be consulted with regard to the laws in other jurisdictions.

Guardian means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. In Oregon, a “Guardian” of a minor means a person or agency having the powers and responsibilities of a parent to make binding decisions for a child.”

Note: For research conducted in jurisdictions other than Oregon, the research must comply with the laws regarding guardianship in all relevant jurisdictions. OSU’s Office of General Counsel will be consulted with regard to the laws in other jurisdictions.

Fetus means the product of conception from implantation until delivery.

Dead fetus means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means.

Neonate means a newborn.

Viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

Nonviable neonate means a neonate after delivery that, although living, is not viable.

Prisoner is any individual involuntarily confined or detained in a penal Institution. The term is intended to encompass individuals sentenced to such an Institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to

criminal prosecution or incarceration in a penal Institution, and individuals detained pending arraignment, trial, or sentencing.

Surrogate Consent is consent obtained from a legally authorized representative on behalf of a participant determined to lack decision-making capacity.

Revision Dates			
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11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
12-15-2017	12-15-2017	12-21-2017	12-21-2017

11.3 Involvement of Vulnerable Populations

If the IRB reviews research that involves categories of participants vulnerable to coercion or undue influence, the review process will include one or more individuals who are knowledgeable about or experienced in working with these participants.

DHHS-funded research that involves pregnant women, human fetuses, neonates, children, or prisoners, must comply with the requirements of the relevant subparts of the Common Rule. Research funded by other federal agencies may or may not be covered by the subparts.

OSU limits the application of the FWA to federally funded research. Consequently, under OSU's FWA the subparts only apply to DHHS-funded research and research funded by other federal agencies that require compliance with the subparts (FDA regulations include Subpart D, which applies to all FDA-regulated research).

The following policies and procedures, which are based on the subparts, apply to all research regardless of funding. The individual sections describe how the subparts apply to DHHS-funded research.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
11-08-2017	12-15-2015	12-21-2017	12-21-2017

11.4 Responsibilities

The PI is responsible for identifying the potential for enrolling vulnerable subjects in the research proposal. The PI is responsible for identifying subjects who are at risk for impaired decisional capacity.

The IRB shall include representation, either as members or ad hoc consultants, individual(s) who have experience with the vulnerable populations involved in a given research proposal.

The IRB reviews the PI's justifications for including vulnerable populations in the research to assess appropriateness of the research proposal.

The IRB must ensure that additional safeguards have been included in each study to protect the rights and welfare of vulnerable subjects as needed at the time of initial review of the research proposal.

Information reviewed as part of the continuing review process should include the number of participants considered as members of specific vulnerable populations and how many, if any, required independent monitoring (see below regarding monitoring).

For studies that do not have or are not required to have a Data and Safety Monitoring Board (DSMB) or a Data Monitoring Committee and have entered vulnerable subjects, the IRB needs to carefully review the safety monitoring plan, if one was required as part of the initial submission.

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11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016

11.5 Procedures

Initial Review of Research Proposal:

- a) The PI identifies the potential to enroll vulnerable subjects in the proposed research and provides the justification for their inclusion in the study.
- b) The IRB evaluates the proposed plan for consent of the specific vulnerable populations involved. If the research involves adults unable to consent, the IRB evaluates the proposed plan for obtaining permission from legally authorized representatives.
- c) The IRB evaluates and approves the proposed plan for the assent of participants.
- d) The IRB evaluates the research to determine the need for additional protections and consideration of the use of a data and safety monitoring board, committee, or plan as appropriate.
- e) The PI provides appropriate safeguards to protect the subject's rights and welfare, which may include the addition of an independent monitor. The independent monitor is a qualified individual not involved in the research study who will determine the subject's capacity to provide voluntary informed consent.
- f) The IRB assesses the adequacy of additional protections for vulnerable populations provided by the PI.

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11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016

11.6 Research Involving Pregnant Women, Human Fetuses and Neonates

11.6.1 Research Involving Pregnant Women or Fetuses

Research not funded by DHHS: Subpart B will be applied to studies involving **more than minimal risk**. All of the conditions below must be met.

DHHS-funded research: Subpart B will be applied, regardless of risk level. All of the conditions below must be met.

(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

(b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, **if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means**¹³;

(c) Any risk is the least possible for achieving the objectives of the research;

(d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of [subpart A](#) of this part;

(e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of [subpart A](#) of [this part](#), except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

(f) Each individual providing consent under paragraph [\(d\)](#) or [\(e\)](#) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

(g) For children as defined in [§46.402\(a\)](#) who are pregnant, assent and permission are obtained in accord with the provisions of [subpart D](#) of [this part](#);

(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

(i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

(j) Individuals engaged in the research will have no part in determining the viability of a neonate.

11.6.2 Research involving neonates

Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
2. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
3. Individuals engaged in the research will have no part in determining the viability of a neonate.

¹³ This is typically the case for OSU research and is the reason why pregnant women must be excluded from research involving more than minimal risk.

4. The requirements of Neonates of Uncertain Viability or Nonviable Neonates (see below in this section) have been met as applicable.

Neonates of Uncertain Viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions have been met:

The IRB determines that:

1. The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or
2. The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and
3. The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with the provisions of permission and assent, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

Nonviable Neonates. After delivery, nonviable neonates may not be involved in research covered by this subpart unless all of the following additional conditions are met:

1. Vital functions of the neonate will not be artificially maintained;
2. The research will not terminate the heartbeat or respiration of the neonate;
3. There will be no added risk to the neonate resulting from the research;
4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
5. The legally effective informed consent of both parents of the neonate is obtained in accord with the provisions of permission and assent, except that the waiver and alteration of the provisions of permission and assent do not apply.
6. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph.

Viable Neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of IRB Review Process and Research Involving Children.

11.6.3 Research Involving, After Delivery, the Placenta, the Dead Fetus or Fetal Material

Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, must be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.

If information associated with material described above in this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent sections of this manual are applicable.

11.6.4 Research Not Otherwise Approvable

11.6.4.1 Research Not Funded by DHHS

If the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and the research is not approvable under the above provisions, then the IRB will consult with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law). Based on the recommendation of the panel, the IRB may approve the research based on either:

1. That the research in fact satisfies the conditions of detailed above, as applicable; or
2. The following:
 - a. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;
 - b. The research will be conducted in accord with sound ethical principles; and
 - c. Informed consent will be obtained in accord with the provisions for informed consent and other applicable sections of this manual.

11.6.4.2 Research Funded by DHHS

DHHS-funded research that falls in this category must be approved by the Secretary of Health and Human Services. If the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and the research is not approvable under the above provisions, then the research will be sent to OHRP for DHHS review.

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11-12-2010	N/A	07-18-2014	07-18-2014
03-10-2015	05-14-2015	03-03-2016	04-01-2016
None	N/A	06-23-2016	06-23-2016
11-13-2017	12-15-2017	12-21-2017	12-21-2017
01-29-2018	02-21-2018	02-22-2018	02-22-2018
06-08-2018	12-14-2018	01-10-2019	01-20-2019
01-02-2022	02-14-2023	03-16-2023	03-16-2023

11.7 Research Involving Prisoners

The following applies to all research involving prisoners, regardless of funding source. The requirements in this section are consistent with Subpart C of 45 CFR 46.

11.7.1 Applicability

This policy applies to all biomedical and behavioral research conducted under the auspices of OSU involving prisoners as subjects. Even though the IRB may approve a research protocol involving prisoners

as subjects according to this policy, investigators are still subject to the Administrative Regulations of the Oregon Department of Corrections and any other applicable State or local law. [45 CFR 46.301]

11.7.2 Purpose

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this section to provide additional safeguards for the protection of prisoners involved in activities to which this section is applicable.

11.7.3 Composition of the IRB

In addition to satisfying the general requirements detailed in the IRB section of this manual, when reviewing research involving prisoners, the IRB must also meet the following requirements:

- A majority of the IRB (exclusive of prisoner members) must have no association with the prison(s) involved, apart from their membership on the IRB.
- At least one member of the IRB must be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement. *This must be a full voting member – not a consultant. A note is included on the FWA that this member does not count towards quorum because the member in this role will only be present in the event that a protocol involving prisoners is under review.*

11.7.4 Review of Research Involving Prisoners

1. At the recommendation of the Office for Human Research Protections (OHRP), OSU's IRB has elected to have all research involving prisoners reviewed by the convened Board (full Board review). However, expedited categories 8 and 9 may apply to continuing review of research involving prisoners.
2. The prisoner representative must review research involving prisoners, focusing on the requirements in Subpart C.
3. The prisoner representative must receive all review materials pertaining to the research (same as primary reviewer)
4. The prisoner representative must be present at a convened meeting when the research involving prisoners is reviewed. If the prisoner representative is not present, research involving prisoners cannot be reviewed or approved. The prisoner representative may attend the meeting by phone, video-conference, or webinar, as long as the representative is able to participate in the meeting as if they were present in person at the meeting.
5. The prisoner representative must present his/her review either orally or in writing at the convened meeting of the IRB when the research involving prisoners is reviewed.
6. Modifications.
 - a. Minor modifications to research may be reviewed using the expedited procedure described below, using either of the two procedures described based on the type of modification.
 - b. Modifications involving more than a minor change reviewed by the convened IRB must use the same procedures for initial review including the responsibility of the prisoner representative to review the modification and participate in the meeting (as described above).

7. Continuing review. Continuing review must use the same procedures as the initial review including the responsibility of the prisoner representative to review the continuing review materials. Expedited categories 8 and 9 may apply.
8. Expedited Review
 - a. Research involving individuals who are incarcerated may be reviewed by an expedited procedure under any of the following three circumstances:
 - i. Minor changes in previously approved research during the period for which approval is authorized
 - ii. Continuing review of research previously approved by the convened IRB as follows:
 1. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
 2. Where no subjects have been enrolled and no additional risks have been identified; or
 3. Where the remaining research activities are limited to data analysis.
 - iii. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
 - b. In each of the circumstances in paragraph (a) of this section, the expedited review must be completed by the prisoner representative.

11.7.5 Incarceration of an Enrolled Subject

If a participant becomes a prisoner while enrolled in a research study that was not reviewed according to Subpart C and Subpart C applies, the IRB must:

1. Confirm that the participant meets the definition of a prisoner.
2. Terminate enrollment or review the research study under Subpart C if it is feasible for the participant to remain in the study.
3. Before terminating the enrollment of the incarcerated participant the IRB should consider the risks associated with terminating participation in the study. If the participant cannot be terminated for health or safety reasons, one of two options are available:
 - a. Keep the participant enrolled in the study and review the research under Subpart C. If some the requirements of Subpart C cannot be met, but it is in the best interests of the participant to remain in the study, keep the participant enrolled and inform OHRP of the decision along with the justification.
 - b. Remove the participant from the study and keep the participant on the study intervention under an alternate mechanism such as compassionate use, off label use, etc.
4. If a participant is incarcerated temporarily while enrolled in a study.
 - a. Keep the participant enrolled if the temporary incarceration has no effect on the study
 - b. Handle according to the above guidance, if the temporary incarceration has an effect on the study

11.7.6 Additional Duties of the IRB

In addition to all other responsibilities prescribed for IRB in other sections of this manual, the IRB will review research involving prisoners and approve such research only if it finds that:

- The research falls into one of the following permitted categories [45 CFR 46.306]:
 - Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
 - Study of prisons as Institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
 - Research on conditions particularly affecting prisoners as a class (for example, research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults);
 - Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.
- Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
- The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
- Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
- The information is presented in language which is understandable to the subject population;
- Adequate assurance exists that the Parole Board will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
- Where the IRB finds there may be a need for follow-up examination or care of subjects after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing subjects of this fact.

11.7.7 Certification to HHS

This section only applies to research that is conducted or funded by DHHS.

Under 45 CFR 46.305(c), the Institution responsible for conducting research involving prisoners that is supported by HHS shall certify to the Secretary (through OHRP) that the IRB has made the seven findings required under 45 CFR 46.305(a). For all HHS conducted or supported research OSU's IRB will send to OHRP a certification letter to this effect, which will also include the name and address of the Institution and specifically identify the research protocol in question and any relevant HHS grant application or

protocol. HHS conducted or supported research involving prisoners as subjects may not proceed until OHRP issues its approval in writing to OSU on behalf of the Secretary under 45 CFR 46.306(a)(2).

Under its authority at 45 CFR 46.115(b), OHRP requires that the Institution responsible for the conduct of the proposed research also submit to OHRP a copy of the research proposal so that OHRP can determine whether the proposed research involves one of the categories of research permissible under 45 CFR 46.306(a)(2), and if so, which one. The term "research proposal" includes the IRB-approved protocol, any relevant HHS grant application or proposal, any IRB application forms required by the IRB, and any other information requested or required by the IRB to be considered during initial IRB review.

11.7.8 Waiver for Epidemiology Research with Prisoners

The Secretary of DHHS has waived the applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain research conducted or supported by DHHS that involves epidemiologic studies that meet the following criteria:

1. In which the sole purposes are
 - a. To describe the prevalence or incidence of a disease by identifying all cases, or
 - b. To study potential risk factor associations for a disease, and
2. Where the IRB has approved the research and fulfilled its duties under 45 CFR 46.305(a)(2)–(7) and determined and documented that
 - a. The research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and
 - b. Prisoners are not a particular focus of the research.
3. The specific type of epidemiological research subject to the waiver involves no more than minimal risk and no more than inconvenience to the human subject participants. The waiver would allow the conduct of minimal risk research that does not now fall within the categories set out in 45 CFR 46.306(a)(2).
4. The range of studies to which the waiver would apply includes epidemiological research related to chronic diseases, injuries, and environmental health. This type of research uses epidemiologic methods (such as interviews and collection of biologic specimens) that generally entail no more than minimal risk to the subjects.
5. In order for a study to be approved under this waiver, the IRB would need to ensure that, among other things, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.

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None	N/A	06-23-2016	06-23-2016

11.8 Research Involving Children

The requirements in this section are consistent with Subpart D of 45 CFR 46 and Subpart D of 21 CFR 50 and apply to all studies, regardless of funding source. Allowable Categories
 Non-exempt research on children must be reviewed and categorized by the IRB into one of the following groups:

1. Research not involving physical or emotional risk greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (i.e., minimal risk).
 - Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians as set forth in other sections.
2. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subject.
 - The risk is justified by the anticipated benefit to the subjects;
 - Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.
3. Research involving greater than minimal risk and no reasonable prospect of direct benefit to the individual subject, but likely to yield generalizable knowledge about the subject's disorder or condition.
 - The risk represents a minor increase over minimal risk;
 - The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
 - Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.
4. Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate serious problems affecting the health or welfare of children.
 - Federally-funded research in this category must be approved by the Secretary of Health and Human Services,
 - FDA-regulated research in this category must be approved by the Commissioner of Food and Drugs.
 - For non-federally-funded, non-FDA research, the IRB will consult with one or more experts in pertinent disciplines. The IRB will strongly consider the recommendation of the expert(s) and may approve the research based on either:
 - That the research in fact satisfies the conditions of the previous categories, as applicable; or
 - The following:
 - The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
 - The research will be conducted in accord with sound ethical principles; and
 - Informed consent will be obtained in accord with the provisions for informed consent and other applicable sections of this manual.
 - Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians as set forth in 46.408.

11.8.1 Parental Permission and Assent

11.8.1.1 Parental Permission

The IRB must determine that adequate provisions have been made for soliciting the permission of each child's parent(s) or guardian(s). Parents or guardians must be provided with the basic elements of consent and any additional elements the IRB deems necessary.

The IRB may find that the permission of one parent is sufficient for research to be conducted under Categories 1 & 2 above (46.404 and 46.405). The IRB's determination of whether consent must be obtained from one or both parents will be documented in the reviewer worksheet when a protocol receives expedited review, and in meeting minutes when reviewed by the convened committee.

Consent from both parents is required for research to be conducted under Categories 3 & 4 (46.406 and 46.407) above unless:

- One parent is deceased, unknown, incompetent, or not reasonably available; or
- When only one parent has legal responsibility for the care and custody of the child.

For research not covered by the FDA regulation, the IRB may waive the requirement for obtaining consent from a parent or legal guardian if:

- The research meets the provisions for waiver of informed consent, *or*
- If the IRB determines that the research protocol is designed for conditions or a subject population for which parental or guardian permission is not a reasonable requirements to protect the subjects (for example, neglected or abused children), provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and that the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

Parental permission may not be waived for research covered by the FDA regulations.

Permission from parents or legal guardians must be documented in accordance with and to the extent required by earlier sections regarding documentation of consent.

11.8.1.2 Assent from Children

Because "assent" means a child's affirmative agreement to participate in research, the child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way. When judging whether children are capable of assent, the IRB is charged with taking into account the ages, maturity, and psychological state of the children involved. The IRB has the discretion to judge children's capacity to assent for all of the children to be involved in a proposed research activity, or on an individual basis

The IRB should take into account the nature of the proposed research activity and the ages, maturity, and psychological state of the children involved when reviewing the proposed assent procedure and the content of the information conveyed to the prospective subjects. The assent procedure should reflect a

reasonable effort to enable the child to understand, to the degree they are capable, what their participation in the research activities would involve.

In most cases, a verbal assent process is appropriate for children up to 7 years of age. When appropriate, the assent process may be supplemented with a written form for children 8 to 17.

Regardless of which approach is chosen for soliciting assent, a summary of the proposed conversation and documents must be submitted to the IRB for review.

Parents and children will not always agree on whether the child should participate in research. Dissent from the child overrides consent from a parent except in the case when the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research. Similarly, a child typically cannot decide to be in research over the objections of a parent. There are individual exceptions to these guidelines but in general, children should not be forced to be research subjects, even when consent has been given by their parents.

If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research.

Even when the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances detailed in the Waiver of Informed Consent section of this manual.

11.8.1.3 Assent Form

When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

Researchers should propose a process and form that is age appropriate and study specific, taking into account the typical child's experience and level of understanding, and composing a document that treats the child respectfully and conveys the essential information about the study. The assent form should:

1. Explain why the research is being conducted;
2. Describe what will happen and for how long or how often;
3. State that it is up to the child to participate and that it is okay to say no;
4. Explain whether it will hurt and if so for how long and how often;
5. Indicate what the child's other choices are;
6. Describe any good things that might happen;
7. State whether there is any compensation for participating; and
8. Encourage questions.

Whenever possible, an assent document should be limited to one page. Illustrations, larger type, and other age appropriate improvements are encouraged when they have the potential to enhance comprehension.

11.8.1.4 Children Who are Wards

Children who are wards of the State or any other agency, Institution, or entity can be included in research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition, **only if such research is:**

1. Related to their status as wards; or
2. Conducted in schools, camps, hospitals, Institutions, or similar settings in which the majority of children involved as subjects are not wards.

If the research meets the condition(s) above, an advocate must be appointed for each child who is a ward (one individual may serve as advocate for more than one child), in addition to any other individual acting on behalf of the child as legal guardian or *in loco parentis*.

The advocate must be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

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11-12-2010	N/A	07-18-2014	07-18-2014
03-10-2015	05-14-2015	03-03-2016	04-01-2015
None	N/A	06-23-2016	06-23-2016
11-13-2017	12-15-2017	12-21-2017	12-21-2017
08-15-2019	05-18-2021	06-23-2021	06-23-2021
02-23-2022	03-08-2022	03-08-2022	03-08-2022
01-02-2022	02-14-2023	03-16-2023	03-16-2023

11.9 Persons with Impaired Decision-Making Capacity

The requirements in this section apply to all research involving persons with mental disabilities or persons with impaired decision-making capacity.

Decisional capacity in the research context has been interpreted by the American Psychiatric Association as requiring:

1. Ability to evidence a choice,
2. Ability to understand relevant information,
3. Ability to appreciate the situation and its likely consequences, and
4. Ability to manipulate information rationally.

Research involving persons with impaired decision-making capability may only be approved when each of the following conditions is met:

1. The investigator must demonstrate to the IRB that there is a compelling reason to include incompetent individuals or persons with impaired decision-making capacity as subjects.
2. Any risk to subjects is outweighed by the probability of direct benefit to the individual subject.

3. Procedures have been devised to ensure that each participant's legally authorized representative (LAR) is well informed regarding their role and obligation to protect the subject.
4. The proposal includes a plan to provide the LAR with a description of the proposed study and to explain to them that their obligation is to try to determine what the subject would do if competent, or if the subject's wishes cannot be determined, what they think is in the incompetent person's best interest.

11.9.1 IRB composition

The IRB membership must include at least one member who is an expert in the area of the research. Consideration may be given to adding another member who is a member of the vulnerable population, a family member of such a person or a representative of an advocacy group for that population. The IRB may utilize ad hoc members as necessary to ensure appropriate expertise.

11.9.2 Additional Safeguards

For research protocols that involve subjects with diminished or fluctuating decision-making capacity, the IRB may require investigators to include one or more of the following safeguards:

- Use of formal or informal capacity assessments;
- Use of independent and qualified professionals to assess whether potential subjects have the capacity to give voluntary, informed consent;
- Initial and/or ongoing communication with involved caregivers;
- Periodic repetition of the consent process with the subject and/or caregiver(s);
- Third party consent monitors used during the recruitment and consent process;
- Waiting periods to allow more time for the subject and/or caregivers to consider the information that has been presented;
- Use of multiple measures to inform the subject and assess comprehension (e.g., follow-up questions, multiple visits, audio or video recording and play back of consent-related conversations, use of an interpreter for hearing-impaired subjects, involvement of a trusted family member or friend).

11.9.2.1 Procedures for Determining Capacity to Consent

The decision-making capacity of a potential research subject should be evaluated when there are reasons to believe that the subject may not be capable of making voluntary and informed decisions about research participation.

The investigator and research staff must have adequate procedures in place for assessing and ensuring subjects' capacity, understanding, and informed consent or assent. The IRB will evaluate whether the proposed plan to assess capacity to consent is adequate.

The IRB will consider the qualifications of the assessor(s) and, when necessary, whether he or she is sufficiently independent of the research team and/or Institution. A range of professionals and methods may be utilized to assess capacity. In general, the assessor should be a researcher or consultant familiar with the conditions(s) resulting in the potential subject's lack of capacity to consent. The assessor should be qualified and available to conduct an initial assessment and, when appropriate, to monitor the subject for capacity over the course of the study.

In the event that a research participant becomes incompetent or impaired in decision-making capacity *after* enrollment, the PI is responsible for notifying the IRB.

11.9.3 Informed Consent and Assent

Whenever the participants have the capacity to give consent (as determined by qualified professionals), informed consent should be obtained and documented. When participants lack the capacity to give consent, investigators may obtain consent from a subject’s legally authorized representative (LAR).

A person who lacks the capacity to consent to participate in research should be informed about the study to the extent compatible with their ability to comprehend information and, if possible, the subject should give their assent to participate, sign and date the written consent or assent form. If the subject expresses resistance or dissent to participation, or to the use of surrogate consent by word or gesture, the subject shall be excluded from the research study. Under no circumstances may a researcher or caregiver override a subject’s dissent. If no resistance or dissent is expressed by the potential subject, the investigator shall document this fact and that the description of the research project was communicated to the subject.

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11-12-2010	N/A	07-18-2014	07-18-2014
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12 Unanticipated Problems, Serious or Continuing Noncompliance, and Any Suspension or Termination of IRB Approval

12.1 Regulatory Requirement

The IRB must follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and, as applicable, any department or agency head, OHRP, and/or FDA of any unanticipated problems involving risks to human subjects or others, any instance of serious or continuing noncompliance with the applicable HHS and/or FDA regulations, or the requirements or determinations of the IRB, and any suspension or termination of IRB approval [45 CFR 46.103(a) and (b)(5), 21 CFR 56.108(b)].

12.2 Unanticipated Problems & Adverse Events

12.2.1 Policy

The IRB complies with DHHS and FDA regulations which state that Institutions must have written policies on reporting unanticipated problems involving risks to subjects or others to the IRB, Institutional officials and relevant federal agencies and departments.

The following procedures describe how unanticipated problems involving risk to subjects or others are handled in research under the auspices of the IRB.

Note: Refer also to the section of this policy manual titled “FDA-Regulated Research” if the study is regulated under 21 CFR.

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02-16-2015	12-18-2015	06-23-2016	06-23-2016
05-30-2018	12-14-2018	01-10-2019	01-20-2019

12.2.2 Definitions

Unanticipated problems (UPs) include any incident, experience, or outcome that meets **all** of the following criteria:

- **Unexpected** (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- **Related or possibly related** to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); **and**
- Suggests that the research places subjects or others at a **greater risk of harm** (including physical, psychological, economic, or social harm) than was previously known or recognized. For example, breach of confidentiality is considered to place subjects at risk, but is only unanticipated if it was not described as a risk in the consent form.

An *adverse event* is any untoward or unfavorable occurrence in a human subject, temporally associated with the subject's participation in the research. Adverse events encompass both physical and psychological harms.

Anticipated adverse events are adverse events that were expected and therefore articulated in the approved protocol, consent document, data and safety monitoring plan, and/or Investigator Brochure.

Attribution: Adverse event attribution will fall into one of the following categories:

- **Related or possibly related** to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); or
- **Unrelated** events are those that could in no way be attributed to study participation. These events are not reportable.

Severity: Adverse event severity will fall into one of the following categories:

- **Mild:** Event results in transient discomfort; does not influence performance or functioning; does not require intervention or treatment; does not limit or interfere with daily activities; expected to resolve quickly with no physical, psychological, social, or economic consequences.
- **Moderate:** Of sufficient severity to make the patient uncomfortable; may include worsening of conditions present at the onset of the study; treatment of symptom(s) may be needed; expected to resolve but short term physical, psychological, social, or economic consequences are possible.

- **Severe:** Event results in significant symptoms that prevents normal daily activities; may require hospitalization or invasive intervention. Long term physical, psychological, social, or economic consequences are possible.

12.2.3 Additional definitions relevant to FDA-regulated research (Drugs)

Adverse event means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related.

Life-threatening adverse event or life-threatening suspected adverse reaction. An adverse event or suspected adverse reaction is considered "life-threatening" if, in the view of either the investigator or sponsor, its occurrence places the patient or subject at immediate risk of death. It does not include an adverse event or suspected adverse reaction that, had it occurred in a more severe form, might have caused death.

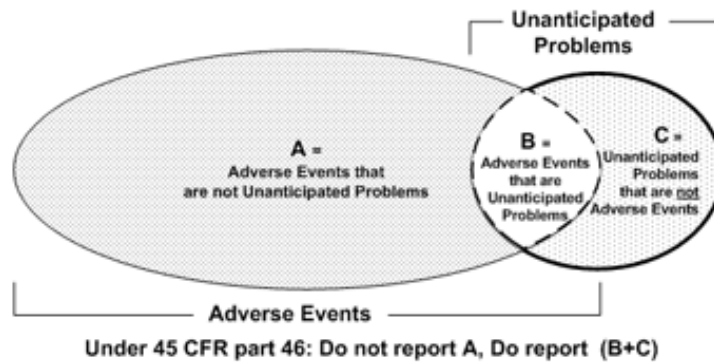
Serious adverse event or serious suspected adverse reaction. An adverse event or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: Death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

Suspected adverse reaction means any adverse event for which there is a reasonable possibility that the drug caused the adverse event. For the purposes of IND safety reporting, "reasonable possibility" means there is evidence to suggest a causal relationship between the drug and the adverse event. Suspected adverse reaction implies a lesser degree of certainty about causality than adverse reaction, which means any adverse event caused by a drug.

Unexpected adverse event or unexpected suspected adverse reaction. An adverse event or suspected adverse reaction is considered "unexpected" if it is not listed in the investigator brochure or is not listed at the specificity or severity that has been observed; or, if an investigator brochure is not required or available, is not consistent with the risk information described in the general investigational plan or elsewhere in the current application, as amended. "Unexpected," as used in this definition, also refers to adverse events or suspected adverse reactions that are mentioned in the investigator brochure as occurring with a class of drugs or as anticipated from the pharmacological properties of the drug, but are not specifically mentioned as occurring with the particular drug under investigation.

12.2.4 Additional definitions relevant to FDA-regulated research (Devices)

Unanticipated adverse device effect means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.



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	N/A	01-10-2019	01-20-2019
08-15-2019	5-18-2021	06-23-2021	06-23-2021

12.2.5 Reporting

Anticipated adverse events must be reported to the IRB within 30 business days if they are related or possibly related to the research and moderate to severe in nature.

Unanticipated problems must be reported to the IRB within three (3) business days.

NOTED EXCEPTION: An unanticipated death must be reported to the IRB within 24 hours of the discovery of the occurrence.

Examples of unanticipated problems that investigators must report to the IRB:

Unanticipated events which are related or possibly related to the research and which places subjects or others (e.g., investigators, students, the public, subjects' family members) at a greater risk of harm than was previously recognized.

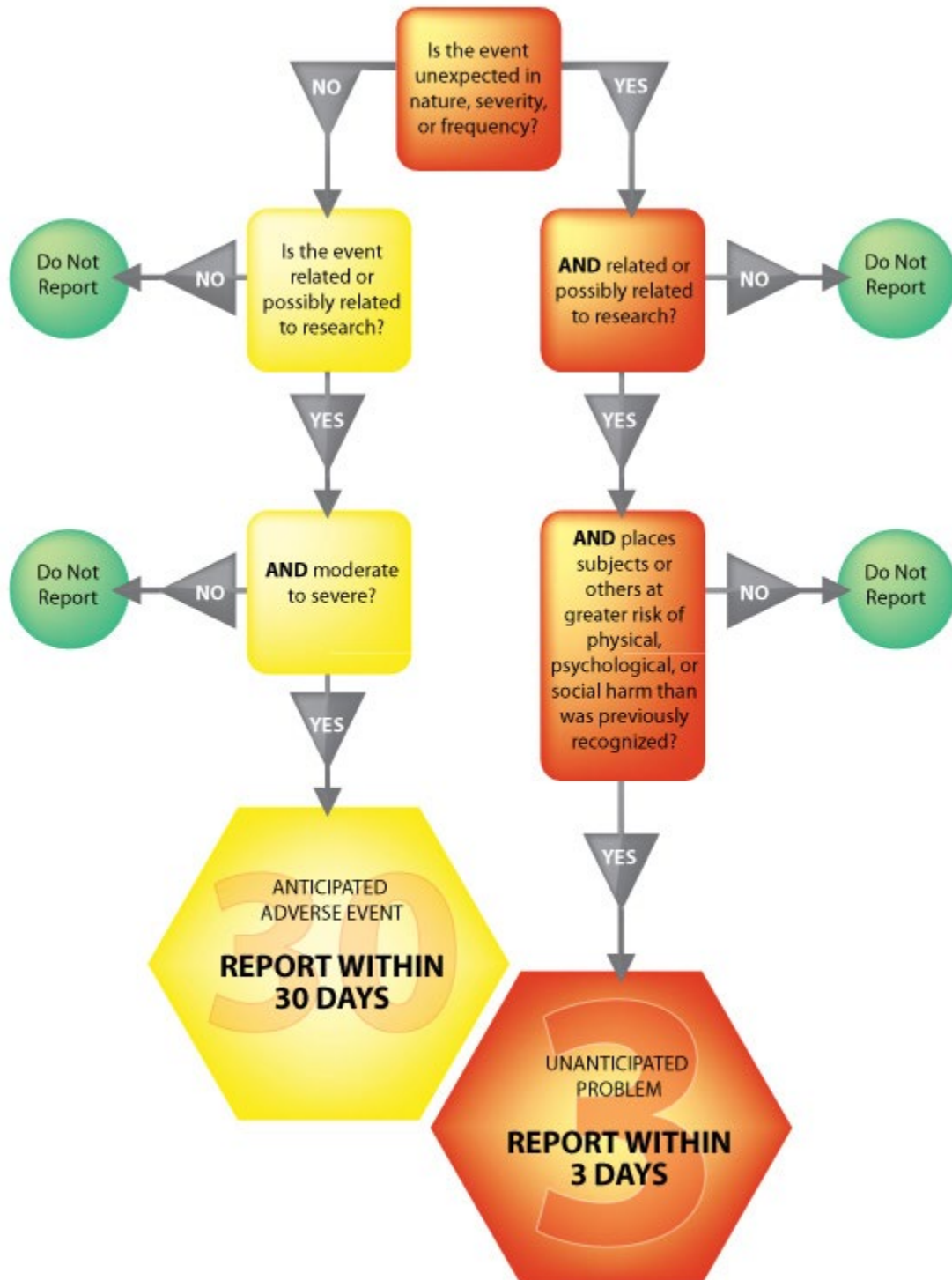
1. Information that indicates a change to the risks or potential benefits of the research. For example:
 - a. An interim analysis or safety monitoring report indicates that frequency or magnitude of harms or benefits may be different than initially presented to the IRB.
 - b. A paper is published from another study that shows that the risks or potential benefits of your research may be different than initially presented to the IRB.
2. A breach of confidentiality. This includes reporting to the Office of Equal Opportunity and Access triggered by Title IX; reporting to state or federal authorities triggered by a mandatory reporting law; disclosures required by subpoena; and other similar disclosures. Other breaches include loss of a field notebook; theft of a research computer; or a security violation in a locked space or restricted drive.
3. Incarceration of a participant in a protocol not approved to enroll prisoners.

4. Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant.
5. Complaint of a participant when the complaint indicates unanticipated risks or cannot be resolved by the research team.

Sponsor imposed suspension.

6. Any other event that indicates participant(s) or others might be at risk of serious, unanticipated harms that are reasonably related to the research.

12.2.6 Submission of Reports



The Principal Investigator must report adverse events and unanticipated problems to the HRPP office using the appropriate form (available on the HRPP website).

Upon receipt of a report of a possible unanticipated problem from someone other than the PI, the HRPP Administrator will notify the PI when appropriate.

12.2.7 Procedures for Handling Anticipated Adverse Events

An HRPP staff member will conduct an initial review of the report, brief the Administrator, and then forward the report to the IRB Chair along with any information regarding other similar events on that protocol and all currently approved documents. The Chair will confirm that the event was anticipated. The event will then be acknowledged and placed on the next agenda as non-actionable. If the event was not anticipated, or the frequency of the event exceeds what was expected, the procedure for reviewing unanticipated problems will be followed.

12.2.8 Procedures for Handling Reports of Possible Unanticipated Problems

12.2.8.1 Reporting a Death, Serious Injury, or Significant Breach of Sensitive Information

Upon discovery of a death, serious injury, or significant breach of sensitive information, the HRPP Administrator or Chair will notify the following individuals or offices:

1. Institutional Official
2. Associate Vice President for Research
3. Dean of the PI's College
4. PI's Department Head or equivalent
5. General Counsel
6. University Relations and Marketing
7. Risk Management Office
8. Office of Information Security

The Institutional Official will notify the Office of the President.

12.2.8.2 Report Review by HRPP staff and Chair

An HRPP staff member will conduct an initial review of the report. If the staff determines that immediate intervention may be required to protect participants or others from serious harm, they will immediately forward the report to the HRPP Administrator and Chair. If the Administrator or Chair agree with the staff member's assessment, they will notify the IO and contact the PI regarding the appropriate action or intervention (e.g., study suspension, investigator hold, etc.). The IO will determine whether additional parties, such as Risk Management or General Counsel, should also be informed.

If immediate intervention is not necessary, HRPP staff will ensure that the report is complete, review it with the Administrator, and then forward the report to the Chair (or other designated member) for further review.

The IRB Chair, or the Chair's designee, will make the final determination as to whether the event meets the definition of an unanticipated problem.

Based on the information received from the investigator, the IRB Chair may suspend research to ensure protection of the rights and welfare of participants. Suspension directives made by the IRB Chair or designee must be reported to a meeting of the convened IRB.

The IRB, IRB Chair, or designee has authority to require submission of more information by the PI, the sponsor, or others about any event occurring in a research protocol as a condition of the continuation of the IRB's approval of the research.

If the Chair or designee determines that the report does NOT constitute an unanticipated problem, serious or continuing non-compliance, or warrant suspension or termination, the report will be forwarded to the full board as a non-actionable item.

If the Chair or designee determines that the report **does** constitute an unanticipated problem, serious or continuing non-compliance, or warrant suspension or termination, but the study is exempt and the **risks to subjects or others is not greater than minimal**, the report will be forwarded to the full board as a non-actionable item.

If the Chair or designee determines that the report **does** constitute an unanticipated problem, serious or continuing non-compliance, or warrant suspension or termination, the study is exempt but the **risks to subjects or others is greater than minimal**, the report will be forwarded to the full board as an actionable item. At the discretion of the Chair, suspension or termination may occur prior to review by the full board.

If the Chair or designee determines that the report **does** constitute an unanticipated problem, serious or continuing non-compliance, or warrant suspension or termination, and the study is non-exempt (expedited, or full board), the report will be forwarded to the full board as an actionable item and to OHRP if HHS funded and/or FDA, if so regulated. At the discretion of the Chair, suspension or termination may occur prior to review by the full board.

The Chair or designee will serve as the primary reviewer for all unanticipated problems and adverse events. The Chair or designee and all members will be provided with all documents related to the report and will have access to the entire protocol file.

After review of the protocol and event report, the Board will make the following determinations:

- a. Whether the reported event is an unanticipated problem involving risks to participants or others according to the definition in this policy.
- b. Whether suspension or termination of IRB approval is warranted.
- c. What action is appropriate in response to the report.
- d. Whether further reporting to Institutional and/or federal officials is required.

12.2.8.3 Board Actions

If the IRB finds that the event **does not** constitute an unanticipated problem involving risks to participants or others, according to the definition in the policy, the IRB may recommend any of the following actions:

- a. No action
- b. Modifications to the protocol

- c. Revisions to the continuing review timetable
- d. Modifications to the consent process
- e. Modifications to the consent document
- f. Modifications requiring that additional information be given to current participants (e.g. whenever the information may relate to the participant's willingness to continue participation)
- g. Modifications requiring that additional information be given to past participants
- h. Additional training or oversight of the investigator and/or study staff
- i. Other actions appropriate for the local context or the nature of the event

The PI will be notified in writing, regardless of the action(s) chosen.

If the IRB finds that the event **does** constitute an unanticipated problem involving risks to participants or others, according to the definition in the policy, the IRB may recommend any of the following actions:

- a. Modifications to the protocol
- b. Revisions to the continuing review timetable
- c. Modifications to the consent process
- d. Modifications to the consent document
- e. Modifications requiring that additional information be given to current participants (e.g. whenever the information may relate to the participant's willingness to continue participation)
- f. Modifications requiring that additional information be given to past participants
- g. Additional training or oversight of the investigator and/or study staff
- h. Reconsideration of IRB approval
- i. Requirement that current participants re-consent to participation
- j. Monitoring of the research
- k. Monitoring of the consent process
- l. Referral to other Institutional area (e.g., legal counsel, risk management, Institutional official)
- m. Study suspension or termination: If a report suggests that participant safety is at risk, the IRB may immediately suspend or terminate the research. Any suspension or termination of research by the IRB must be promptly reported, in writing, to the IO, and OHRP (if HHS funded), and FDA (if FDA-regulated research).
- n. Other actions appropriate for the local context or the nature of the event

Not greater than minimal risk. If, after reviewing a report, the IRB finds that the event is an unanticipated problem involving risks to participants or others but that such risk is not greater than minimal, the IRB will notify the investigator in writing of its findings.

Greater than minimal risk. If, after reviewing a report, the IRB finds that the event is an unanticipated problem involving risks to participants or others and that such risk is greater than minimal, or that suspension or termination of approval is warranted, the IRB will notify the investigator in writing of its findings, with copy to:

- a. all study team members
- b. the Institutional Official
- c. other compliance areas within the Research Office

- d. General Counsel
- e. the Institutional Compliance Office
- f. the Principal Investigator’s Unit Head, Associate Dean for Research and Dean (or equivalent)
- g. the Information Security Officer, if the event involved violations of information security requirements
- h. others as deemed appropriate by the IRB Chair or the Institutional Official

Note 1: Refer also to the section of this policy manual titled “Reporting to Regulatory Agencies and Institutional Officials” if the study is funded or otherwise supported by DHHS.

Note 2: Refer also to the section of this policy manual titled “FDA-Regulated Research” if the study is regulated under 21 CFR.

12.2.9 IND Safety Reports

The sponsor or sponsor-investigator, **not the IRB**, must notify FDA and all participating investigators in an IND safety report of potential serious risks, from clinical trials or any other source, as soon as possible, but in no case later than 15 calendar days after the sponsor determines that the information qualifies for reporting. *See 21 CFR 312.32 for additional information.*

12.2.10 IDE Reports

An investigator shall submit to the sponsor **and to the reviewing IRB** a report of any unanticipated adverse device effect occurring during an investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect.

A sponsor who conducts an evaluation of an unanticipated adverse device effect under 812.46(b) shall report the results of such evaluation to FDA **and to all reviewing IRB's** and participating investigators within 10 working days after the sponsor first receives notice of the effect. Thereafter the sponsor shall submit such additional reports concerning the effect as FDA requests. *See 21 CFR 812.150 for additional information.*

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
03-18-2016	N/A	06-23-2016	06-23-2016
05-11-2018	N/A	N/A	05-11-2018
11-13-2018	12-14-2018	01-10-2019	01-20-2019

12.3 Protocol Deviations

12.3.1 Policy

It is the responsibility of the Investigator to adhere to the IRB-approved protocol, unless a deviation is required to avoid an immediate hazard to the participant. The Investigator must submit project revision to the IRB and receive written approval prior to implementation of any change to the protocol. All deviations must be reported to the IRB. However, departures from the study design and/or procedures that are due solely to a study participant’s non-adherence are not considered to be deviations and do not need to be reported to the IRB unless they impact the participant’s safety or well-being, or if a

pattern of protocol deviations indicate a need for changes in the protocol and/or informed consent document(s). Examples of such departures include:

- participant did not return for a scheduled study visit
- participant chose to skip survey questions
- participant in longitudinal study was lost to follow up

A deviation that increases risk, has the potential to recur, or is undertaken to eliminate an immediate hazard, is also an *Unanticipated Problem*.

Repetitive or repeated deviations may constitute *continuing* non-compliance.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
05-18-2018	12-14-2018	01-10-2019	01-20-2019

12.3.2 Definitions

A deviation is any alteration or modification of an IRB-approved protocol made without prior IRB approval. Deviations inherently constitute non-compliance, but whether that non-compliance is deemed minor, serious, and/or continuing is dependent on the facts of the situation. See the section regarding non-compliance for additional definitions and examples.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
02-11-2015	12-18-2015	06-23-2016	06-23-2016
03-08-2018	N/A	03-22-2018	03-22-2018
04-04-2018	N/A	N/A	01-20-2019
05-18-2018	N/A	01-10-2019	01-20-2019

12.3.3 Deviations related to FDA-regulated device research

Deviations from the investigational plan. An investigator shall notify the sponsor and the reviewing IRB (see 56.108(a) (3) and (4)) of any deviation from the investigational plan to protect the life or physical wellbeing of a subject in an emergency. Such notice shall be given as soon as possible, but in no event later than 5 working days after the emergency occurred. Except in such an emergency, prior approval by the sponsor is required for changes in or deviations from a plan, and if these changes or deviations may affect the scientific soundness of the plan or the rights, safety, or welfare of human subjects, FDA and IRB in accordance with 812.35(a) also is required.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014

02-16-2015	12-18-2015	06-23-2016	06-23-2016
06-24-2016	N/A	N/A	07-29-2016
05-18-2018	12-14-2018	01-10-2019	01-20-2019

12.3.4 Reporting and Review

Deviations must be reported to the IRB within 10 business days after the PI becomes aware that the deviation has occurred. The HRPP staff will review the deviation for completeness, brief the Administrator, then forward the report to the IRB Chair (or designee) for review.

The IRB Chair will make an initial determination as to the nature and seriousness of the deviation. Deviations will be reviewed in accordance with the policies and procedures related to non-compliance.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
02-10-2015	12-18-2015	06-23-2016	06-23-2016
05-18-2018	12-14-2018	01-10-2019	01-20-2019

12.4 Concerns or Complaints about the Conduct of Research

The Administrator will promptly assess, handle, and, if necessary, investigate all complaints and concerns about the conduct of research that are received by the HRPP from investigators, research participants, community members, and others.

The HRPP staff will ensure that all complaints will be documented in submission forms and reviewer worksheets or in a note to file, reviewed with the HRPP Administrator, then referred to the Chair for review. The Chair will determine whether the complaint warrants suspension of the research project to avoid an immediate hazard; is an allegation of non-compliance; or meets the definition of an unanticipated problem. The appropriate, related procedure will be followed.

If the complaint is non-actionable, a description of the complaint and resolution (if any) will appear on the agenda for the next convened meeting.

If the Chair considers the complaint to be actionable, it will appear on the next agenda to be reviewed at a convened meeting.

As appropriate, the HRPP will notify the PI of any complaints made directly to the HRPP and any actions required or taken.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
05-09-2016	N/A	06-23-2016	06-23-2016
12-15-2017	12-15-2017	12-21-2017	12-21-2017
12-26-2018	N/A	01-10-2019	01-20-2019

12.5 Concerns or Complaints about the HRPP

Under development by Lean Team and Research Office.

12.6 Non-compliance

12.6.1 Policy

Study personnel involved in human subjects research are required to comply with the laws and regulations governing those activities, as well as with requirements and determinations of the IRB. Investigators and their study staff are required to report instances of possible non-compliance to the IRB. However, any individual or employee may report observed or apparent instances of non-compliance to the IRB. In such cases, the reporting party is responsible for making these reports in good faith, maintaining confidentiality and cooperating with any IRB and/or Institutional review of these reports.

If an individual, whether investigator, study staff or other, is uncertain whether there is cause to report non-compliance, he or she may contact the IRB Chair or Administrator directly to discuss the situation informally.

Individuals reporting possible non-compliance may choose to remain anonymous. However, the individual will be reminded that others may know who they are based on the details of the allegation.

Suspected non-compliance may also be identified by the IRB, rather than reported to the IRB. This may occur during the review of another type of report (e.g., deviation, complaint, or continuing review application) or during the course of an audit.

The procedures below describe how non-compliance is handled by the HRPP. This section does not pertain to allegations of misconduct.

Note: Refer also to the section of this policy manual titled “FDA-Regulated Research” if the study is regulated under 21 CFR

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
02-16-2015	12-18-2015	06-23-2016	06-23-2016

12.6.2 Definitions

Non-compliance. Non-compliance is defined as failure to adhere to the research plan as approved by the IRB of record; failure to comply with any of the regulations and policies described in this document; or failure to follow the determinations of the IRB. Non-compliance may be minor or sporadic, or it may be serious or continuing. Non-compliance may be unintentional or willful.

Minor non-compliance. Any behavior, action or omission in the conduct or oversight of research involving human participants that deviates from the approved research plan, federal regulations or institutional policies but, because of its nature, the research project, or subject population, does not (or did not):

1. adversely affect the rights and welfare of participants;
 2. increase risk to participants;
 3. decrease potential benefits; or
 4. compromise the integrity or validity of the research.
- Because a determination of minor non-compliance cannot involve an increase in risk, by definition it cannot constitute an unanticipated problem. Examples of minor non-compliance include, but are not limited to: adding study personnel without IRB approval
 - making minor word changes to an otherwise approved survey without first obtaining IRB approval

Serious non-compliance. Failure to follow the determinations of the IRB or any behavior, action or omission in the conduct or oversight of research involving human participants that deviates from the approved research plan, federal regulations or institutional policies and which, in the judgment of the convened IRB, has been determined to:

1. adversely affect the rights and welfare of participants;
2. increase risk to participants;
3. decrease potential benefits; or
4. compromise the integrity or validity of the research;
5. result from willful non-compliance on the part of the investigator(s) or study staff.

Examples of serious non-compliance include, but are not limited to:

- research being conducted without prior IRB approval
- involvement of subjects in research activities without their prior consent (in studies where consent was not specifically waived by the IRB)
- failure to disclose a conflict of interest
- conducting research activities (including recruitment or data analysis) during a lapse in IRB approval, (e) enrolling ineligible subjects
- failure to notify the IRB of reportable events within the required timeframe
- failure to follow the safety monitoring or data security plan

Continuing non-compliance. A pattern of non-compliance that, in the judgment of the convened IRB:

1. indicates a lack of understanding or disregard for the regulations or institutional requirements;
2. suggests a likelihood that instances of non-compliance will continue without intervention; involves multiple instances of non-compliance; or
3. involves a failure to respond to a request to resolve an episode of non-compliance.

Examples of continuing non-compliance include, but are not limited to:

- investigator exceeds approved enrollment on more than one occasion or in more than one study
- failure to disclose a known or suspected study-related risk on more than one occasion or in more than one study

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
02-10-2015	12-18-2015	06-23-2016	06-23-2016
08-16-2019	5-18-2021	06-23-2021	06-23-2021

12.6.3 Review of Potential Non-compliance

All potential non-compliance will be reviewed by the IRB Chair and Administrator, who will review all relevant materials and information. Examples include, but need not be limited to:

1. IRB approval and approved documents
2. Grant or contract
3. DSMB reports
4. Publications
5. Information from collaborating, previous, or planned sites of research

The Chair or Administrator may choose to interview the investigator(s), other study team members, the individual(s) making the allegation or complaint, and any other individual(s) who may have relevant information.

In the event that the IRB Chair and Administrator find that there is reason to suspect that the potential non-compliance also involves research misconduct, they will report that information in accordance with the OSU Policy on Scientific and Scholarly Misconduct. In the event of a misconduct investigation, the IRB Chair and Administrator will determine whether it is appropriate to suspend the IRB investigation and/or the research protocol until the conclusion of the misconduct investigation.

If, in the judgment of the Chair, non-compliance did not occur, the determination is reported in writing to the PI and, if applicable, the reporting party.

If, in the judgment of the Chair, non-compliance did occur, the matter will be processed according to the section on Review of Findings of Non-compliance.

If, in the judgment of the Chair, the matter warrants suspension of the research before completion of any review or investigation to ensure protection of the rights and welfare of participants, the Chair may suspend the research with subsequent review by the IRB.

The Chair may determine that additional expertise or assistance is required to make these determinations and may form an ad hoc committee to assist with the review and fact gathering process. When an ad hoc committee assists in the review process, the Chair is responsible for appointing the members and assuring that minutes of the meeting are generated and kept to help support any determinations or findings made by the ad hoc committee.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
08-27-2015	12-18-2015	06-23-2016	06-23-2016

12.6.4 Review of Findings of Non-compliance

Minor Non-compliance

When the Chair determines that the non-compliance occurred, but the non-compliance does not meet definition of serious or continuing non-compliance, the determination is reported in writing to the PI and if applicable the reporting party. The Chair will work with the PI to develop a corrective action plan to prevent future non-compliance. The report of non-compliance and corrective action is reported to the IRB through the “expedited review report”. If however, the PI refuses to cooperate with the corrective action plan, the matter is referred to a convened meeting of the IRB with notification to the IO.

Serious or Continuing Non-compliance

When the Chair determines that non-compliance has occurred and that the non-compliance meets the definition of serious or continuing non-compliance, the report of non-compliance is referred for review by the IRB at the next convened meeting. However, the Chair may use discretion and call an emergency IRB meeting should the circumstances warrant such an urgent meeting.

All findings of serious or continuing non-compliance referred to the IRB will be reviewed at a convened meeting. All IRB members will receive all documents relevant to the allegation.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
02-11-2015	12-18-2015	06-23-2016	06-23-2016

12.6.5 Actions

At this stage, the IRB may:

1. vote to request additional information
2. vote on a specific finding
3. require the PI to take one or more actions, and/or
4. take one or more actions described below

12.6.6 Request for Information

Request for information may or may not require a convened inquiry. If a formal inquiry is warranted, the procedures below shall be followed:

Inquiry Procedures

The IRB may, at its discretion, convene an inquiry. Examples of matters that may warrant an inquiry into suspected serious or continuing noncompliance include:

1. Subjects' complaint(s) that rights were violated;
2. Report(s) that investigator is not following the protocol as approved by the IRB;
3. Unusual and/or unexplained adverse events in a study;
4. Repeated failure of investigator to report required information to the IRB.

The inquiry will be led by either the full board or a subcommittee appointed by the Chair. The inquiry can include any or all of the following:

1. Review of protocol(s) in question;
2. Review of sponsor audit report of the investigator;
3. Review of any relevant documentation, including consent documents, case report forms, subject's investigational and/or medical files etc., as they relate to the investigator's execution of her/his study involving human subjects;
4. Interview of appropriate personnel;
5. Preparation of a written report of the findings, which is presented to the full IRB at its next meeting;
6. Review of other sources of information, as appropriate.

Note: The results of the inquiry will be reviewed at a convened IRB meeting.

12.6.7 Vote on Specific Findings

1. Finding that there is no issue of non-compliance;
2. Finding that there is non-compliance that is neither serious nor continuing;
3. Finding that there is serious or continuing non-compliance.

Regardless of the determination, the PI will be notified in writing. The notification will include any actions required by the PI or taken by the IRB (see examples below).

If the determination is that there is, or may be, serious or continuing non-compliance, the notification will be copied to the IO, Dean, Associate Dean for Research, Unit Head, and the Institutional Compliance Office.

12.6.8 Required Actions

1. Request for a corrective action plan from the investigator (see later section regarding Corrective Action Plans)
2. Request for an increase in data and safety monitoring of the research activity
3. Request for a status report after each participant receives intervention
4. Request for additional investigator and staff training
5. Notification to current subjects, if the information about the non-compliance might affect their willingness to continue participation
6. Require modification of the protocol
7. Require modification of the information disclosed during the consent process
8. Other actions as appropriate

12.6.9 Board Actions

A finding of noncompliance may result in the IRB taking one or more of the following actions:

1. Verification that participant selection is appropriate and observation of the actual informed consent
2. Directed audit of targeted areas of concern
3. Modification of the continuing review cycle
4. Study suspension or termination: If a report suggests that participant safety is at risk, the IRB may immediately suspend or terminate the research. Any suspension or termination of research by the IRB must be promptly reported, in writing, to the IO, and OHRP (if HHS funded), and FDA (if FDA-regulated research).
5. Copy Notifications to:

- all study team members
- the Institutional Official
- other compliance areas within the Research Office
- General Counsel
- the Institutional Compliance Office
- the Graduate School
- Scholars or University Archives
- the Principal Investigator's Unit Head, Associate Dean for Research and Dean (or equivalent)
- the Information Security Officer, if the event involved violations of information security requirements
- the journal Editor
- others as deemed appropriate by the IRB Chair or the Institutional Official

In cases where the IRB determines that the event of non-compliance also meets the definition of unanticipated problems involving risks to subjects or others, the policy and procedure for review of such events will also be followed.

The investigator is informed of the IRB determination and the basis for the determination in writing and is given a chance to respond. However, there is no formal appeals process.

Note: If the IRB determines that the non-compliance was serious or continuing and the study is federally funded, refer also to the section of this policy manual titled "Reporting to Regulatory Agencies and Institutional Officials" if the study is funded or otherwise supported by DHHS.

12.6.10 Corrective Action Plans

A corrective action plan may be required when noncompliance is serious or continuing. Corrective action plans should explain the steps that will be taken to prevent or minimize future occurrences associated with the deficiencies or deviations and include the following¹⁴:

1. Root cause assessment. A thorough review should be undertaken to determine each deficiency and its impact on the research, data integrity, and why the deficiency is occurring and possible resolutions to the deficiency. The assessment should focus on identifying underlying problems that contribute to error rather than focusing on mistakes made by individuals.
2. Corrective actions. These are actions taken to resolve a problem and may include ensuring that the immediate corrections previously taken removed any risk of harm or further harm to the subject and future subjects and that the deviation was appropriately reported to the sponsor and IRB. Additional reporting may be necessary once the impact on the rights, welfare, and safety of the subjects has been assessed and the root cause of the noncompliance is known.
3. Preventative actions. These are actions to address the root cause of the problem and to prevent a deficiency or deviation from recurring.

¹⁴ Adapted from guidance from Emory University Clinical Trials Audit and Compliance and from "A Practical Approach to Addressing Regulatory Deficiencies in Human Subjects Research: The Development of a Comprehensive Corrective Action Plan", December 6, 2010, Marion Olson, Wanda Quezada, Evanna Thompson, Macri Montemayor, Martha J. Matza, 2010 AER Conference poster

4. Plan to monitor. The PI should document training the study team members to successfully implement the plan. The effectiveness of the plan should be evaluated at proscribed time points and amended as needed to ensure that the corrective action plan has addressed the root cause. Adherence to the plan should be monitored. If the objectives of the plan are not being met, it should be revised to address the issues. Monitoring reports should be submitted to the IRB.

While appropriate measures should be taken to eliminate immediate risks to subjects, corrective action plans should not be implemented until IRB approval has been obtained.

Revision Dates			
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11-12-2010	N/A	07-18-2014	07-18-2014
06-08-2015	12-18-2015	06-23-2016	06-23-2016
11-28-2018	12-21-2018	01-10-2019	01-20-2019

12.7 Reporting to Regulatory Agencies and Institutional Officials

12.7.1 Scope

The procedures outlined below are applicable only when the study is funded by DHHS. Notifications related studies that are not funded, or otherwise supported, by DHHS will occur by copy on notifications to the PI.

Federal regulations require prompt reporting to appropriate Institutional officials, and the [DHHS] department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing non-compliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval. The OSU IRB will comply with this requirement and the following procedures describe how these reports are handled.

Note: Refer also to the section of this policy manual titled “FDA-Regulated Research” if the study is regulated under 21 CFR.

Revision Dates			
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11-12-2010	N/A	07-18-2014	07-18-2014
01-22-2015	12-18-2015	06-23-2016	06-23-2016

12.7.2 Procedures

1. HRPP staff will initiate these procedures as soon as the IRB takes any of the following actions:
 - a. Determines that an event may be considered an unanticipated problem involving risks to participants or others
 - b. Determines that non-compliance was serious or continuing
 - c. Suspends or terminates approval of research

2. The Administrator or designee is responsible for preparing reports or letters that include the following information:

- a. The nature of the event (Unanticipated problem involving risks to participants or others, serious or continuing non-compliance, suspension or termination of approval of research)
 - b. Name of the Institution conducting the research
 - c. Title of the research project and/or grant proposal in which the problem occurred
 - d. Name of the principal investigator on the protocol
 - e. Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement)
 - f. A detailed description of the problem including the findings of the organization and the reasons for the IRB's decision
 - g. Actions the Institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.)
 - h. Plans, if any, to send a follow-up or final report by the earlier of
 1. A specific date
 2. When an investigation has been completed or a corrective action plan has been implemented
3. The IRB Chair and the IO review the letter and modify the letter/report as needed.
4. The IO is the signatory for all correspondence from the Institution to Federal Agencies.
5. The Administrator or designee sends a copy of the report to:
- a. The IRB by including the letter in the next agenda packet as an information item
 - b. The Institutional Official
 - c. The following federal agencies:
 - OHRP, if the study is subject to DHHS regulations or subject to a DHHS Federalwide assurance (non-exempt studies funded, conducted, or otherwise supported by any agency that has signed on to the Common Rule)
 - FDA, if the study is subject to FDA regulations.
 - Reporting to a regulatory agency is not required if the event occurred at a site that was not subject to the direct oversight of OSU, and the agency has been notified of the event by the investigator, sponsor, another organization, or other mechanisms.
 - d. Principal Investigator
 - e. Sponsor, if the study is sponsored
 - f. Contract research organization, if the study is overseen by a CRO
 - g. Principal Investigator's Unit Head, Associate Dean for Research and Dean (or equivalent)
 - h. The Information Security Officer, if the event involved violations of information security requirements
 - i. General Counsel, if appropriate
 - j. Institutional Compliance Office
 - k. Others as deemed appropriate by the IRB Chair or the Institutional Official

The Office for Research and Award Administration (OSRAA) and any other relevant ancillary reviewers (e.g., Conflict of Interest or Environmental Health and Safety [EH&S]) will be copied on the notice of suspension or termination that is sent to the PI.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
05-09-2016	N/A	06-23-2016	06-23-2016

13 Special Topics

13.1 National Institutes of Health Definitions and Requirements

Clinical Research is research with human subjects that is:

- Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: (a) mechanisms of human disease, (b), therapeutic interventions, (c) clinical trials, or (d) development of new technologies.
- Epidemiological and behavioral studies.
- Outcomes research and health services research.

Studies falling under 45 CFR 46.101(b) (4) (Exemption 4) are not considered clinical research by this definition.

Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Health-related biomedical or behavioral outcome, as related to the definition of a clinical trial, means the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life.

Examples: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

Intervention, as related to the definition of a clinical trial, means a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints.

Examples: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

Prospectively assigned, as related to the definition of a clinical trial, means a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects

(individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

13.1.1.1 ClinicalTrials.gov

Studies must be registered with ClinicalTrials.gov if:

- (1) they involve drugs, devices, or biologics that are regulated by the FDA, or
- (2) they are funded by the NIH and meet the NIH definition of a clinical trial, or
- (3) there is a plan to publish the results in a medical journal and the study meets the International Committee of Medical Journal Editors (ICMJE) definition of a clinical trial.

Revision Dates			
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11-12-2010	N/A	07-18-2014	07-18-2014
02-19-2015	N/A	N/A federal requirement	02-19-2015
06-23-2016	06-23-2016	06-23-2016	06-23-2016
11-08-2017	12-15-2017	12-21-2017	12-21-2017

13.2 Certificates of Confidentiality

Certificates of Confidentiality (“Certificate” for the purposes of this section) protect research information by prohibiting certain disclosures and conditioning others upon consent from the subject. The protections and requirements of Certificates are outlined in 42 U.S.C. 241(d) and NIH policy (when applicable), and summarized below. Certificates are obtained as follows:

- Certificates are issued automatically when research is conducted or supported by NIH and falls within the scope of the NIH policy.
- Research that is not funded by NIH (non-NIH research) may still have the protections afforded by Certificates through successful application to the NIH, FDA, or other authorized Federal agencies or departments. Additional information about Certificates and the application process for non-NIH research is available on the [NIH CoC Website](#).

13.2.1 Definitions

Identifiable, sensitive information means information that is about an individual and that is gathered or used during the course of biomedical, behavioral, clinical, or other research and

- Through which an individual is identified; or
- For which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

13.2.2 Protections and Requirements

When a Certificate is issued, whether automatically or under an approved application, the person(s) engaged in the research must not disclose or provide the name of a subject or any information, document, or biospecimen that contains identifiable, sensitive information about the subject and that was compiled for the purposes of the research:

- In any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, unless the disclosure is made with the consent of the individual to whom the information, document, or biospecimen pertains; or The information in this resource is based upon information available at the time of publication: Sept 20, 2017 2
- To any other person not connected with the research, unless:
 - Required by Federal, State, or local laws (e.g., adverse event reporting to the FDA, transmissible disease reporting required under State law), but excluding proceedings as described in “1” above;
 - Necessary for the medical treatment of the subject to whom the information, document, or biospecimen pertains and made with the consent of the subject;
 - Made with the consent of the individual to whom the information, document, or biospecimens pertains; or
 - Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

Additional Protections: Identifiable, sensitive information protected under a Certificate, and all copies thereof, are immune from the legal process, and shall not, without the consent of the of the individual to whom the information pertains, be admissible as evidence or used in any action, suit, or other judicial, legislative, or administrative proceeding. Identifiable, sensitive information that has been collected under a Certificate, and all copies thereof, are protected for perpetuity. Nothing in the rule (42 U.S.C. 241(d)) may be construed to limit the access of a subject to information about himself or herself collected during the research. When consent is obtained, the consent should inform subjects that a Certificate is in place and describe the protections and limitations.

13.2.3 NIH Policy

The NIH Policy on Certificates applies to *“all biomedical, behavioral, clinical, or other research funded wholly or in part by the NIH, whether supported through grants, cooperative agreements, contracts, other transaction awards, or conducted by the NIH Intramural Research Program, that collects or uses identifiable, sensitive information”* that was commenced or ongoing after December 13, 2016.

Certificates are automatically granted, and the requirements of such must be complied with, whenever a NIH-funded activity falls within the scope of the policy. Investigators and institutions are responsible for determining when a NIH-funded activity falls within the scope of the policy. NIH policy expands upon 42 U.S.C. 241(d) by explaining that NIH considers research in which identifiable, sensitive information is collected or used, to include:

- Human subjects research as defined in 45 CFR 46, including research determined to be exempt (except for exempt research when the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects);

- Research involving the collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual; The information in this resource is based upon information available at the time of publication: Sept 20, 2017 3
- Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, **regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained; or**
- Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual, as defined in subsection 301(d) of the Public Health Service Act.

13.2.4 NIH Certificate Policy Determination

The HRPP staff will determine if the NIH policy applies to an NIH-funded research activity that involves human subjects. The questions outlined in the NIH policy will be used to guide the analysis. When it has been determined that the NIH policy does not apply, investigators are responsible for consulting with HRPP whenever they are proposing changes to the NIH-funded activity that may impact or change the analysis.

The NIH policy includes additional responsibilities and requirements for internal controls and for ensuring that recipients of identifiable, sensitive information protected by a Certificate understand that they are also subject to the requirements of subsection 301(d) of the Public Health Service Act.

13.2.5 Application Procedures for non-NIH Research

Any person engaged in human subjects research that collects or uses identifiable, sensitive information may apply for a Certificate. For most research, Certificates are obtained from NIH, an investigator may apply for a Certificate through the NIH Institute or Center funding research in a scientific area similar to the project.

If the research is conducting a sensitive research project that is covered by the Agency for Healthcare Research and Quality (AHRQ) confidentiality statute (42 U.S.C. section 299c-3(c)) or the Department of Justice (DoJ) confidentiality statute (42 U.S.C. section 3789g), then a Certificate may not be needed.

If there is an Investigational New Drug Application (IND) or an Investigational Device Exemption (IDE), the sponsor can request a Certificate from the FDA. Certificates may also be issued by other Federal agencies and departments, such as CDC, SAMSHA, or HRSA.

13.2.6 Review by Human Research Protection Program

Investigators are responsible for clearly representing in the IRB submission that a Certificate is in place, or that an application for Certificate has been submitted. When the Certificate application is in process or pending, the IRB may condition final approval upon its receipt.

For studies that are already underway, investigators must submit a Project Revision form to the HRPP, along with updated consent language (as applicable), when a Certificate is applied for, or when automatically issued under the NIH policy.

When reviewing research under a Certificate, the HRPP will evaluate whether the research plan is consistent with the obligations to protect information and specimens under a Certificate and whether the consent language, if applicable, discloses the Certificate and appropriately describes the associated protections and limitations. Sample consent language is available on the NIH Certificate Website and in the template consent forms available on the HRPP website.

When research is not funded by NIH and is not covered by an automatically issued Certificate, the IRB may require an investigator to apply for a Certificate if the research includes identifiable, sensitive information and the IRB determines that a Certificate is necessary to minimize risks and adequately protect subjects' privacy and the confidentiality of subjects' information or specimens.

Revision Dates			
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11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
10-01-2017	N/A	N/A	10-1-2017
12-15-2017	12-15-2017	12-21-2017	12-21-2017

13.3 Mandatory Reporting

While any person may make a report if they have reasonable cause to believe that a child or elder person was abused or neglected, Oregon State law mandates that certain persons who suspect child or elder abuse or neglect report this to the appropriate authorities. Under the current state law, all OSU employees are considered to be mandatory reporters.

The IRB's policy requires the solicitation of informed consent from all adult research subjects and assent from children involved as research subjects, in addition to the consent of their parents.

If the study will involve children or the site of research is participants' homes or other locations in which researchers could witness child abuse or neglect, the training that investigators have taken pertaining to mandatory reporting will be outlined in the protocol. In situations where conditions of abuse or neglect might be revealed, mandated reporters should make themselves known as such to parents of children under age 18, to subjects who are children, and to subjects who are potential victims of abuse or neglect.

13.3.1 Mandatory Reporting in International Settings

If it is possible that researchers might witness child abuse or neglect in an international setting, the following information about mandatory reporting should be included in the protocol:

- Local laws that govern reporting of child abuse in the country of study, if applicable.
- Indication of what is culturally 'normal' and what would fall outside of 'normal' punishment for children.
- The plan should a researcher encounter a situation that is outside 'normal' practices.
- Indication in the consent form of the plan for reporting to local authorities for situations outside 'normal' practices, if applicable.

Under Oregon Law, employees of the University are required to report instances of child abuse to Oregon Authorities regardless of where the child abuse occurred. However, the IRB has had multiple conversations with Oregon authorities and it is unclear what would happen with that information. Therefore, while it is still required, disclosure to Oregon Authorities does not need to be added to the consent form, as it is unlikely to pose a risk to participants within the country of study.

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11-12-2010	N/A	07-18-2014	07-18-2014
03-02-2015	N/A	N/A OR state law	03-02-2015
None	N/A	06-23-2016	06-23-2016

13.4 Title IX Sexual Harassment and Sexual Violence

All OSU employees are required to consult with the University Title IX Coordinator, or designee, in the Office of Equity and Inclusion if they receive information about sexual harassment or sexual violence that meets one or more of the following criteria:

- Is alleged to have been perpetrated by an OSU student, staff, or faculty member, OR
- Has occurred on OSU property or during an OSU activity, OR
- Has created continuing effects in the educational setting

The requirement to consult with the Office of Equity and Inclusion is specific to OSU employees. Student researchers who learn of reportable events should discuss this information with the Principal Investigator (PI) on the study. It is then the responsibility of the PI to contact the Title IX Coordinator.

If the research topic is sexual harassment or sexual violence:

If there is a reasonable expectation that the target population will disclose information triggering the need for consultation with the Office of Equity and Inclusion, a plan for this circumstance must be included in the research protocol and the consent form.

In the event that individually identifying information about the research participant is disclosed to the Office of Equity and Inclusion or other non-study team members, this would constitute an anticipated adverse event and the corresponding form must be submitted to the IRB within 30 days of this disclosure.

If the research topic is not sexual harassment or sexual violence:

If a research participant discloses information triggering the need for consultation with the Office of Equity and Inclusion, this will constitute a reportable event to the IRB since it could not have been anticipated. The Principal Investigator must complete and submit the “Unanticipated Problem” form within three days of learning of the issue.

Relevant References

University Policy Prohibiting Sexual Harassment: <http://oregonstate.edu/oei/sexual-harassment-and-violence-policy>

Additional resources: <http://studenthealth.oregonstate.edu/sexual-violence-resources>

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11-12-2010	N/A	07-18-2014	07-18-2014
06-23-2016	06-23-2016	06-23-2016	06-23-2016

13.5 Research Involving OSU Students and Employees as Subjects

Students and employees recruited as research subjects are more vulnerable to coercion because of the possibility that they may perceive grades, employment or other benefits as dependent upon their participation in research. Challenges related to maintaining confidentiality are also greater when the subjects are affiliated with OSU or known to the researchers.

Therefore, additional safeguards may be required to protect the rights and welfare of these individuals. One such safeguard is that, absent sound justification, researchers should not enroll (a) themselves, (b) employees who report to them directly, or (c) students currently enrolled in a class taught by the researcher, in studies determined to involve greater than minimal risk to subjects. Additional safeguards may be required at the Board's discretion.

Recruitment of Students

1. Justification for Targeting Students: Researchers who plan to exclude individuals who are not students must be able to provide a rationale, *other than convenience*, for restricting the study population to students and must show that the recruitment method does not lead potential subjects to think they will be compromised by not participating. Examples of such rationale include: a) participation as a valuable educational experience demonstrated by a substantive plan for debriefing, b) the need for an alternative mechanism for study compensation (e.g. extra credit) due to lack of monetary resources, c) the existence of a formal student subject pool and related departmental policy. Note that investigators and instructors may not impose penalties on students who fail to show up for scheduled research-related appointments.
2. Direct Recruitment: Investigators may make study-related announcements (such as study title and investigator contact information) or provide recruitment materials (such as fliers) to students in OSU classrooms, so long as the investigator is not also the class instructor. Exceptions may be granted if the purpose of the research is directly connected to students in a particular class. For example, if the research is intended to examine teaching methods in a particular course taught by the investigator. Recruitment methods should permit students to self-identify outside of the classroom so as to maintain confidentiality and minimize the potential for peer pressure. For example, students should be provided with contact information for a study team member who they may contact for more information after class, rather than be asked to express interest at the time of the announcement.
3. Indirect Recruitment: IRB-approved recruitment materials may be posted anywhere on the OSU campus with the appropriate departmental permission (e.g. unit office sign-off if necessary).
4. Mass email from Registrar: Investigators seeking approval from the Registrar's Office to email recruitment materials or study announcements to students must explain this recruitment method in the protocol and provide the Registrar with a copy of the IRB approval letter before

such an email may be sent. The Registrar may or may not grant such a request, regardless of IRB approval.

5. Consent: A student may not be compelled to participate in research as part of a course requirement. Investigators will ensure that students know that they may choose not to participate in the research and that their decision will not affect their grade, class standing, or relationship with any instructor.
6. Extra Credit: If extra credit is offered in exchange for participation, an alternate means of earning equivalent extra credit for an equivalent commitment of time and effort should be made available for those who cannot, or choose not to participate in a study. This alternative assignment must be articulated in the research protocol and referenced in the consent document. In the event that a formal subject pool is being utilized, the consent document may refer the student to the departmental policy or class syllabus for other options for earning extra credit.
7. Use of Class Time: Submissions proposing the use of class time for research should include an explanation of the benefit of the research to the students. Specifically, the investigator should explain how participation in the research would be a learning experience for the students and how the research is relevant to the course of study being taught in that class. An alternative activity should be provided for students who choose not to participate.
8. Use of Class Assignments and other Education Records for Research Purposes: Instructors should not use students' education records in research without the prior permission from the Registrar and the informed consent of the students. Researchers should complete the [feasibility determination form](#) required by the Office of the Registrar before submitting a study application to the HRPP. If a study indicates educational records will be used in the research, the HRPP will notify the Office of the Registrar on the approval or determination letter..
9. Consent to Future Research: The Office of the Registrar will not approve a consent process that asks OSU students to consent to future unspecified research.

Recruitment of Employees

1. Justification for Targeting Employees: Researchers who plan to exclude individuals who are not employees must be able to provide a rationale, *other than convenience*, for restricting the study population to employees and must show that the recruitment method does not lead potential subjects to think they will be compromised by not participating.
2. Consent: An employee may not be required to participate in research as a condition of employment. Investigators will ensure that employees know that they may choose not to participate in the research and that their decision will not affect their employment or benefits at OSU.
3. Direct Recruitment: Investigators may make study-related announcements or provide recruitment materials to employees at regular meetings. However, recruitment methods should permit employees to self-identify as interested in participation in a way that maintains confidentiality. For example, employees should be provided with contact information for a study team member who they may contact for more information.
4. Indirect Recruitment: IRB-approved recruitment materials may be posted anywhere on the OSU campus with the appropriate departmental permission (e.g. unit office sign-off if necessary).
5. Use of Employee Data in Research: Researchers should not use employee data for research purposes without the prior written consent of the employees and documented permission from the OSU Department of Human Resources.

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11-12-2010	N/A	07-18-2014	07-18-2014
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09-18-2017	09-22-2017	10-05-2017	10-05-2017
02-07-2018	N/A	02-22-2018	02-22-2018
08-15-2019	05-18-2021	06-23-2021	06-23-2021

13.6 Student Research

13.6.1 Human Subjects Research and Course Projects

Research activities involving human subjects that are designed as part of a course requirement for purposes of learning experience only and are not designed to develop or contribute to generalizable knowledge do not require IRB review and approval if:

- Results of the research are viewed only by the course instructor for teaching purposes and discussed within the classroom for teaching and learning purposes; and
- Results of the research are not made public through presentation (outside of the classroom) and are not published in paper or electronic format (e.g., cannot be made available on the internet, cannot be published in a journal, etc.).

13.6.1.1 Responsibility of the Course Instructor

The course instructor is responsible for working with the IRB to determine whether or not a project requires IRB review. The instructor is also responsible for communicating to the students the ethics of human subjects research, for ensuring the protection of human subjects (including a process is in place for obtaining voluntary informed consent from research subjects when appropriate), and for monitoring the students' adherence to an approved protocol.

When designing a project, students should be instructed on the ethical conduct of research and on the preparation of the IRB application when such is required. In particular, instructors and students should:

- Understand the elements of informed consent
- Develop appropriate consent documents
- Plan appropriate strategies for recruiting subjects
- Identify and minimize potential risks to subjects
- Assess the risk-benefit ratio for the project
- Establish and maintain strict guidelines for protecting confidentiality
- Allow sufficient time for IRB review (if necessary) and completion of the project

13.6.2 Theses and Dissertations

Human subjects research activities that will contribute to part or all of a thesis, dissertation, or other type of publication or presentation must go through the IRB review process prior to enrolling subjects and collecting data. These research activities are considered to meet the federal definition of human subjects research and must be submitted to the IRB. When students conduct research as part of a course of study, a faculty member ultimately is responsible for the protection of the subjects, even if the student directs the project.

Students may not serve as Principal Investigators. They must have a faculty sponsor who fulfills the principal investigator eligibility criteria and who will serve as PI and faculty advisor on the study. The PI must be qualified and available to provide the appropriate training and oversight, and to ensure both protocol adherence and the responsible conduct of research from initiation of the study through reporting of results.

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11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016

13.7 Genetic and Genomic Studies

The Genetic Information Nondiscrimination Act of 2008 (GINA) prohibits discrimination in health coverage and employment based on genetic information. Researchers who conduct studies using genetic information are responsible for becoming familiar with the provisions of the law, both to implement measures to protect that information from inappropriate disclosures and to inform potential research participants about their rights under the law.

The IRB will determine (to the best of their ability) whether the genetic information can be linked to the individuals from whom the information was, or will be, collected. Although genetic studies may be limited to a collection of family histories or blood draws, the IRB will not necessarily consider these studies to be minimal risk if a link between the subject and the information or genetic material exists.

References and Resources

The Genetic Information Nondiscrimination Act of 2008 Information for Researchers and Health Care Professionals (2009)

<https://www.genome.gov/pages/policyethics/geneticdiscrimination/ginainfodoc.pdf>

OHRP's Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards (2009)

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-genetic-information-nondiscrimination-act/index.html>

13.7.1 Data Sharing

Researchers proposing to submit data to the NIH database of Genotypes and Phenotypes (dbGaP), or other genomic data sharing repository will first need IRB approval and an institutional certification. The certification must be signed by an institutional official, not a study team member. When data sharing is a term of the funding award, the signatory official should be the appropriate representative from OSRAA.

References and Resources

[Study Registration and Data Submission to an NIH-Designated Controlled-Access Data Repository](#)

[NIH Guidance on Consent for Future Research Use and Broad Sharing of Human Genomic and Phenotypic Data Subject to the NIH Genomic Data Sharing Policy](#)

[Information regarding institutional certifications](#)

Ohio State University, Office of Responsible Research Practices, [Submission of Data to dbGaP and Other Requests for Data Sharing](#)

Revision Dates			
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11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
11-13-2018	12-21-2018	01-10-2019	01-20-2019

13.8 Research Involving Coded Private Information or Biological Specimens

The HRPP policy is based on the OHRP guidance document entitled, [Guidance on Research Involving Coded Private Information or Biological Specimens](#) (October 16, 2008). This document:

1. Provides guidance as to when research involving coded private information or specimens is or is not research involving human subjects, as defined under HHS regulations for the protection of human research subjects (45 CFR part 46).
2. Reaffirms OHRP policy that, under certain limited conditions, research involving only coded private information or specimens is not human subjects research.
3. Provides guidance on who should determine whether human subjects are involved in research.

For purposes of this policy, *coded* means that: (1) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and (2) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Under the definition of “human subject,” obtaining identifiable private information or identifiable specimens for research purposes constitutes human subjects research. *Obtaining* means receiving or accessing identifiable private information or identifiable specimens for research purposes. This includes an investigator’s use, study, or analysis for research purposes of identifiable private information or identifiable specimens already in the possession of the investigator.

In general, private information or specimens are considered to be individually identifiable when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

Research involving **only** coded private information or specimens do **not** involve human subjects if the following conditions are both met:

1. the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and
2. the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:
 - a. the key to decipher the code is destroyed before the research begins;

- b. the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that the HHS regulations do not require the IRB to review and approve this agreement);
- c. there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or
- d. there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

In some cases an investigator who obtains coded private information or specimens about living individuals under one of the conditions cited in 2(a)-(d) above may (1) unexpectedly learn the identity of one or more living individuals, or (2) for previously unforeseen reasons now believe that it is important to identify the individual(s). If, as a result, the investigator knows, or may be able to readily ascertain, the identity of the individuals to whom the previously obtained private information or specimens pertain, then the research activity now would involve human subjects. IRB review of the research would be required. Informed consent of the subjects also would be required unless the IRB approved a waiver of informed consent.

Investigators are advised to submit a Determination Form to the HRPP office prior to initiating work with coded or de-identified samples.

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11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
07-27-2016	N/A	N/A	07-29-2016
11-20-2018	N/A	N/A	N/A

13.9 Case Reports Requiring IRB Review

In general, an anecdotal report of a single individual and a comparison of this individual to existing reports in the literature is not research and would not require IRB approval. A case series will be considered systematic and potentially generalizable and require IRB review.

13.9.1 Definitions

Case Study: External reporting (e.g., publication or poster/verbal presentation) about a single case or individual. Case reports normally contain detailed information about an individual and may include demographic information, as well as a discussion of existing relevant literature. The individual’s information used in the report must have been originally collected solely for non-research purposes.

Case Series: External reporting (e.g., publication or poster/verbal presentation) about a series of individuals (i.e., more than one person). Case series usually contain detailed information about each person and may include demographic information, as well as a discussion of existing relevant literature. The information used in the report must have been originally collected solely for non-research purposes.

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11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
05-02-2018	N/A	01-10-2019	01-20-2019

13.10 International Research

The IRB will review all international research utilizing human participants to assure adequate provisions are in place to protect the rights and welfare of the participants.

Approval of research is permitted if the procedures prescribed by the foreign Institution afford protections that are at least equivalent to those provided in 45 CFR 46.

The IRB must receive and review the foreign Institution or site's IRB review and approval of each study prior to the commencement of the research at the foreign Institution or site.

From the April 2014 CITI training module:

If research funded by Department of Health and Human Services (DHHS) involves collaboration with an organization that is "engaged" in research in a foreign country, the organization will need to have an assurance filed with the DHHS Office for Human Research Protections. The assurance, called an International (Non U.S.) Federalwide Assurance, commits the organization to having procedures in place that ensure that subjects will be protected in a manner commensurate with the Subpart A of 45 CFR 46 (the "Common Rule").

Other federal agencies sponsoring international research may use the DHHS assurance process, but they may also choose alternate assurance processes. Foreign collaborators may have their own IRBs or comparable review committees. The International Assurance allows for the designation of another IRB, such as the U.S. investigator's IRB or another IRB in the foreign country, to serve as its IRB.

Some international research is carried out without the involvement of collaborators. For example, political scientists from the U.S. may interview people on the street in Germany or U.S. environmental scientists may interview fishermen in Panama. Federal regulations do not require onsite, local review in such cases; however, the researcher and the IRB that reviews the activity should be mindful of foreign regulations or other requirements that govern research on the local population.

Approval of research for foreign Institutions or sites "not engaged" in research is only permitted if one or more of the following circumstances exist:

- When the foreign Institution or site has an established IRB/IEC (institutional ethics committee), the Investigator must obtain approval to conduct the research at the "not engaged" site from the site's IRB/IEC or provide documentation that the site's IRB/IEC has determined that approval is not necessary for the Investigator to conduct the proposed research at the site.
- When the foreign Institution or site does not have an established IRB/IEC, a letter of cooperation must be obtained demonstrating that the appropriate Institutional or oversight officials are permitting the research to be conducted at the performance site.

- IRB approval to conduct research at the foreign Institution or site is contingent upon receiving documentation of the performance site’s IRB/IEC determination, or letter of cooperation, as applicable.
- It is the responsibility of the OSU Investigator and the foreign Institution or site to assure that the resources and facilities are appropriate for the nature of the research.
- It is the responsibility of the OSU Investigator and the foreign Institution or site to notify the IRB promptly if a change in research activities alters the performance site’s engagement in the research (e.g., performance site “not engaged” begins consenting research participants, etc.).
- The IRB will consider local research context when reviewing international studies to assure protections are in place that are appropriate to the setting in which the research will be conducted.
- In the case where there is no local ethics review the IRB may require a letter of support or a review from a consultant. In either case, the individual must have expertise or knowledge required to adequately evaluate the risk and the cultural appropriateness of the proposed research
- The informed consent documents must be in a language understandable to the proposed participants. Therefore, the IRB will review the document and a back translation of the exact content contained in the foreign language informed consent document which must be provided by the Investigator, with the credentials of the translator detailed in the IRB application or amendment form. The IRB cannot verify the accuracy of translated documents. Therefore, verification of the back translation must be made available before the IRB may approve the translated documents. The requirement for back translation will be waived if the translation is certified by a professional translator, an individual with a master’s degree in languages, or a native speaker of the relevant language(s). Translated documents will be processed in a manner consistent with documents presented in English.

13.10.1 Monitoring of Approved International Research

The IRB is responsible for the ongoing review of international research conducted under its jurisdiction through the continuing review process in accordance with all applicable federal regulations.

13.10.2 Conducting Chart Reviews¹⁵

13.10.2.1 Authorization to conduct chart reviews

Only individuals with existing legal access to the charts may conduct reviews. Depending on the circumstances, written permission from the Institution holding the records, and/or external IRB approval, may be necessary.

13.10.2.2 Determining review level

Exempt Category 4: This level of review is appropriate for secondary analysis of publicly available or de-identified information. Exempt review should only be requested if the information to be collected already exists and is publicly available or data will be recorded in such a manner that subjects cannot be

¹⁵ Guidance adapted, in part, from the Chart Review Protocol Instructions from Northwestern University Office for Research (2009).

identified, either directly or indirectly. As data must exist at the time the project is submitted to the IRB, this limits exempt review to retrospective chart reviews. In the majority of cases, chart reviews do not qualify for exempt status because most investigators need to retain identifiers at least through the data collection process. Even if an investigator plans to eventually discard all identifiers once data collection is complete, this is not sufficient for the project to qualify for exempt review.

Expedited Category 5: An expedited procedure may be used to conduct chart or record reviews when data, documents, records, or specimens have been, or will be, collected solely for non-research purposes. Most chart reviews fall into this category if federally funded.

Full Board: Full board review may be required for retrospective or prospective chart reviews if it involves the collection of sensitive data that can be linked to an individual.

13.10.2.3 Non-exempt Chart Review and Consent

Waiver of Consent: In order for the IRB to approve a waiver of consent, the IRB must be satisfied that the relevant criteria in this policy are met.

Waiver of Documentation of Consent: Under a waiver of documentation of consent, an investigator must still obtain consent from the subject. However, the investigator does not need to obtain a signed consent form from subjects if the relevant criteria in this policy are met.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
05-09-2016	N/A	06-23-2016	06-23-2016
11-13-2017	12-15-2017	12-21-2017	12-21-2017
01-29-2018	02-21-2018	02-22-2018	02-22-2018
11-13-2018	12-21-2018	01-10-2019	01-20-2019
01-02-2022	02-14-2023	03-16-2023	03-16-2023

14 Participant Outreach

14.1 Policy

The IRB strives to connect research participants, prospective research participants, and community members, to information that will enhance their understanding of research involving human participants at OSU.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
01-30-2018	02-21-2018	02-22-2018	02-22-2018
11-13-2018	12-21-2018	01-10-2019	01-20-2019

15 Relevant References

[Food and Drug Administration \(FDA\)](#)

[Federal Food, Drug, and Cosmetic Act 505\(i\) and 520\(g\)](#)

[21 CFR 50 Protection of Human Subject](#)

[21 CFR 54 Financial Disclosure by Clinical Investigators](#)

[21 CFR 56 Institutional Review Boards](#)

[21 CFR 312 Investigational New Drug Application](#)

[21 CFR 807 Establishment Registration And Device Listing For Manufacturers And Initial Importers Of Devices](#)

[21 CFR 809 In Vitro Diagnostic Products For Human Use](#)

[21 CFR 812 Investigational Device Exemptions](#)

[45 CFR 46 Protection of Human Subjects](#)

[Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research](#)

Notice Number: NOT-OD-16-094

[Notice of Changes to NIH Policy for Issuing Certificates of Confidentiality](#)

Notice Number: NOT-OD-17-109

[Federal Policy for the Protection of Human Subjects](#)

01/19/2017

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
11-12-2010	N/A	07-18-2014	07-18-2014
None	N/A	06-23-2016	06-23-2016
12-21-2017	N/A	N/A	N/A
11-20-2018	N/A	01-10-2019	01-20-2019

16 HRPP Operations in Emergency Situations

In the event of an emergency (e.g., public health crisis, natural disaster), the procedures in this manual may be modified as appropriate for the situation. Such modifications may include alternative procedures for:

- Meetings
- Submission and review of project revisions and prompt reporting of events
- Any other changes necessary to ensure appropriate ongoing oversight and conduct of research

Because procedural modifications may vary based on the nature of the event, these cannot be anticipated and described in this manual. Instead, such procedural modifications will be communicated to the research community and documentation of the modifications will be maintained in accordance with applicable record retention requirements.

Revision Dates			
Revised	Reviewed by Ex Comm	Approved by IO	Effective
03-19-2020	03-19-2020	06-23-2021	06-23-2021