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| Submission Type | **RESEARCH and ENGAGEMENT DETERMINATION WORKSHEET** | | |
| Title |  | | |
| Principal Investigator |  | | |
| Funding Source |  | Proposal # |  |
| PI on Grant or Contract |  | | |

This form is intended to assist researchers and the IRB in determining whether or not a project involves research with human subjects and whether or not OSU is engaged in research. The IRB will make the final determination. Submit this form to the IRB only if think that your project does not require IRB review.  **If your study will involve interviews, focus groups, surveys, questionnaires, etc., please provide a copy of all planned questions.**



**BRIEFLY DESCRIBE THE PROJECT:**

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| **SECTION 1a: RESEARCH WITH HUMAN SUBJECTS** [§46.102] | **Yes** | **No** |
| Does the activity involve **RESEARCH**?  **Definition**: *Research* is defined by the Federal Regulations as a systematic investigation (including research development, testing and evaluation), designed to develop or contribute to generalizable knowledge. In order to be considered research the project must meet each of the components of the definition.  ***Systematic:*** The implementation or utilization of specific methods of inquiry or data collection that is repeated with multiple participants. An activity that involves a prospective plan to incorporate data collection and data analysis to answer a question. Methodology alone does not determine the need for IRB review. More often than not, methods used in research (such as interviews or blood draws) are employed for reasons having nothing to do with research.  ***Designed to develop or contribute:*** Intent to disseminate results to those outside of the University via the web, poster presentations, conferences, library placement, or publication. 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.  ***Generalizable knowledge:*** Designed to draw conclusions from the data; results are analyzed for predictive value; results can be applied to a larger population (i.e., applicability is not limited to the participants) or inform policy. |  |  |
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| |  |  | | --- | --- | | ***If Yes****:* | *If “yes” to each component above, the activity is research. Proceed to section 1b.* | | ***If No****:* | *Elaborate on the “no” answers. Proceed to section 2.* | | ***Explanation of “no” answers:*** | | | | |

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| **SECTION 1b: RESEARCH WITH HUMAN SUBJECTS (DHHS)** [§46.102] | **Yes** | **No** |
| Does the activity involve **HUMAN SUBJECTS**?  **Definition**: *Human subject* means a living individual about\* whom an investigator conducting research obtains: (1) Data through intervention or interaction with the individual, **OR** (2) Identifiable private information.   * *Intervention* includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. * *Interaction* includes communication or interpersonal contact between investigator and subject. * *Identifiable 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 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. Identifiable individuals may include third parties.   \*Information is about an individual whenever the answer involves demographic information (e.g., age, gender, etc.) or requests that individual to provide information based in opinion, attitude, or perception. |  |  |
| |  |  |  | | --- | --- | --- | | ***If Yes****:* | *If project is research* ***AND*** *involves human subjects, this activity may require IRB review. Proceed to section 3.* | | | ***If No****:* | *Elaborate on the “no” answer(s). Proceed to the section 2.* | | ***Explanation of “no” answers:*** | | | | | | |

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| **SECTION 2: FDA DETERMINATION** |  |  |
| SECTION 2a: TEST ARTICLE | **Yes** | **No** |
| **Does the activity involve a** DRUGS, BIOLOGICS, OR MEDICAL DEVICES**?**  ***Drug/biologic*: A chemical or biological substance – other than food – that achieves its primary intended purposes through chemical action within or on the body or which is dependent upon being metabolized for the achievement of any of its primary intended purposes.** This may include dietary supplements being studied for their effects on diseases **(i.e., to cure, treat, mitigate, prevent, or diagnose disease including its symptoms) [FDA CDER FAQ].**  ***Medical device*: An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory that is one of the following:**   * The article is recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them * The article is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals * The article is intended to affect the structure or any function of the body |  |  |
| *Proceed to section 2b.* | | |

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| **SECTION 2b: RESEARCH** | **Yes** | **No** |
| Does the activity involve **RESEARCH**, as defined by the FDA?  The activity is an experiment that involves a test article and one or more human subjects.  ***Note:*** *For drugs, an experiment includes any use of a drug other than the use of a marketed (approved) drug in the course of medical practice. For medical devices, it is limited to activities being conducted to determine the safety or effectiveness of a device.* |  |  |
| The activity is subject to requirements for prior submission to the Food and Drug Administration; **OR**  The activity is intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit. |  |  |
| *Proceed to section 2c.* | | |

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| **SECTION 2c: HUMAN SUBJECTS** | **Yes** | **No** |
| Does this project involve **HUMAN SUBJECTS**, as defined by the FDA?   * The research involves one or more individuals who become a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy person or a patient; OR * For medical devices, an individual on whose specimen an investigational device is used |  |  |
| |  |  | | --- | --- | | ***If Yes:*** | *If you answered “yes” to sections 1a-b and/or 2a-c, the activity involves research with human subjects. Proceed to section 3.* | | ***If No:*** | *If you answered “no” to sections 1a-b and 2a-c, do not complete section 3. Submit this form to the IRB Office for a final determination.* | | | |

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| **SECTION 3: INSTITUTIONAL ENGAGEMENT** [OHRP 10/16/2008] | **Yes** | **No** |
| Does conducting this project cause OSU to be **ENGAGED IN RESEARCH?**  The institution is *engaged* in research if any item in the following list is marked “yes”. |  |  |
| * OSU is the primary awardee on the grant or contract. |  |  |
| * OSU is the only site. |  |  |
| * OSU employees, students, or agents are interacting or intervening with human subjects. Examples include obtaining consent, invasive/non-invasive study procedures, manipulating the subject’s environment for research purposes. |  |  |
| * OSU employees, students, or agents are obtaining or receiving identifiable, private information or biological samples. |  |  |
| |  |  | | --- | --- | | ***If yes:*** | *If “yes” to any of the items in section 3, the institution may be engaged in research. Submit a complete application packet to the IRB for review.* | | ***If no****:* | *Elaborate on the “no” answer(s). Submit this form to the IRB Office for a final determination.* | | ***Explanation of “no” answers:*** | | | | |

**THE REMAINDER OF THIS FORM IS FOR IRB USE ONLY**

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| **SECTION 4: IRB REVIEWER DETERMINATION** | **Yes** | **No** |
| Comments: |  |  |
| * Does the activity meet the definition of *research with human subjects* under the Common Rule? |  |  |
| * Does the activity meet the definition of *research with human subjects* under the FDA regulations? |  |  |
| * Is the institution is engaged\* in research under the Common Rule? |  |  |

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| Reviewer: |  | Date of Review: |  |

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| \*Conditions Under Which an Organization is Not Engaged Even Though a Condition in Section 3 is Met: | Yes | No |
| 1. OSU’s employees or agents perform commercial or other services for investigators provided that **ALL** of the following conditions also are met:  * The services performed do not merit professional recognition or publication privileges. * The services performed are typically performed by those organizations for non-research purposes. * OSU’s employees or agents do not administer any study intervention being tested or evaluated under the protocol. |  |  |
| 1. OSU is not selected as a research site but its employees or agents provide clinical trial-related medical services that are dictated by the protocol that would typically be performed as part of routine clinical monitoring or follow-up of subjects enrolled at a study site by clinical trial investigators provided that **ALL** of the following conditions also are met:  * OSU’s employees or agents do not administer the study interventions being tested or evaluated under the protocol. * The clinical trial-related medical services are typically provided by the OSU for clinical purposes (e.g., DEXA Scan). * OSU’s employees or agents do not enroll subjects or obtain the informed consent of any subject for participation in the research. * When appropriate, investigators from an organization engaged in the research retain responsibility for **ALL** of the following:   + Overseeing protocol-related activities.   + Ensuring appropriate arrangements are made for reporting protocol-related data to investigators at an engaged organization, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol. |  |  |
| 1. OSU was not initially selected as a research site but OSU’s employees or agents administer the study interventions being tested or evaluated under the protocol limited to a one-time or short-term basis where an investigator from an organization engaged in the research determines that it would be in the subject’s best interest to receive the study interventions being tested or evaluated under the protocol and **ALL** of the following are true:  * OSU’s employees or agents do not enroll subjects or obtain the informed consent of any subject for participation in the research. * Investigators from the organization engaged in the research retain responsibility for **ALL** of the following:   + Overseeing protocol-related activities.   + Ensuring the study interventions are administered in accordance with the IRB-approved protocol.   + Ensuring appropriate arrangements are made for reporting protocol-related data to investigators at the engaged organization, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol, and * An IRB designated on the engaged organization’s FWA is informed that study interventions being tested or evaluated under the protocol have been administered at an organization not selected as a research site. |  |  |
| 1. OSU’s employees or agents do **ANY** of the following:  * Inform prospective subjects about the availability of the research. * Provide prospective subjects with information about the research but do not obtain subjects’ consent for the research or act as representatives of the investigators. * Provide prospective subjects with information about contacting investigators for information or enrollment. * Seek or obtain the prospective subjects’ permission for investigators to contact them. |  |  |
| 1. OSU is permitting use of its facilities for intervention or interaction with subjects by investigators from another organization. |  |  |
| 1. OSU’s employees or agents release to investigators at another organization identifiable private information or identifiable biological specimens pertaining to the subjects of the research. |  |  |
| 1. OSU’s employees or agents:  * Obtain coded private information or human biological specimens from another organization involved in the research that retains a link to individually identifying information. and * Are unable to readily ascertain the identity of the subjects to whom the coded information or specimens pertain. |  |  |
| 1. OSU’s employees or agents access or utilize individually identifiable private information only while visiting an organization that is engaged in the research, provided their research activities are overseen by the IRB of the organization that is engaged in the research. |  |  |
| 1. OSU’s employees or agents access or review identifiable private information for purposes of study auditing. |  |  |
| 1. OSU’s employees or agents receive identifiable private information for purposes of satisfying U.S. Food and Drug Administration reporting requirements. |  |  |
| 1. OSU’s employees or agents author a paper, journal article, or presentation describing a Human Research study. |  |  |