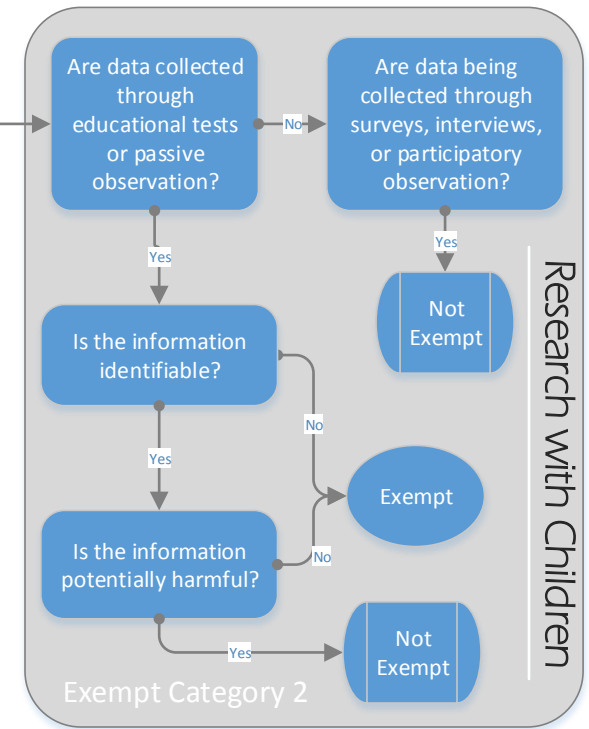
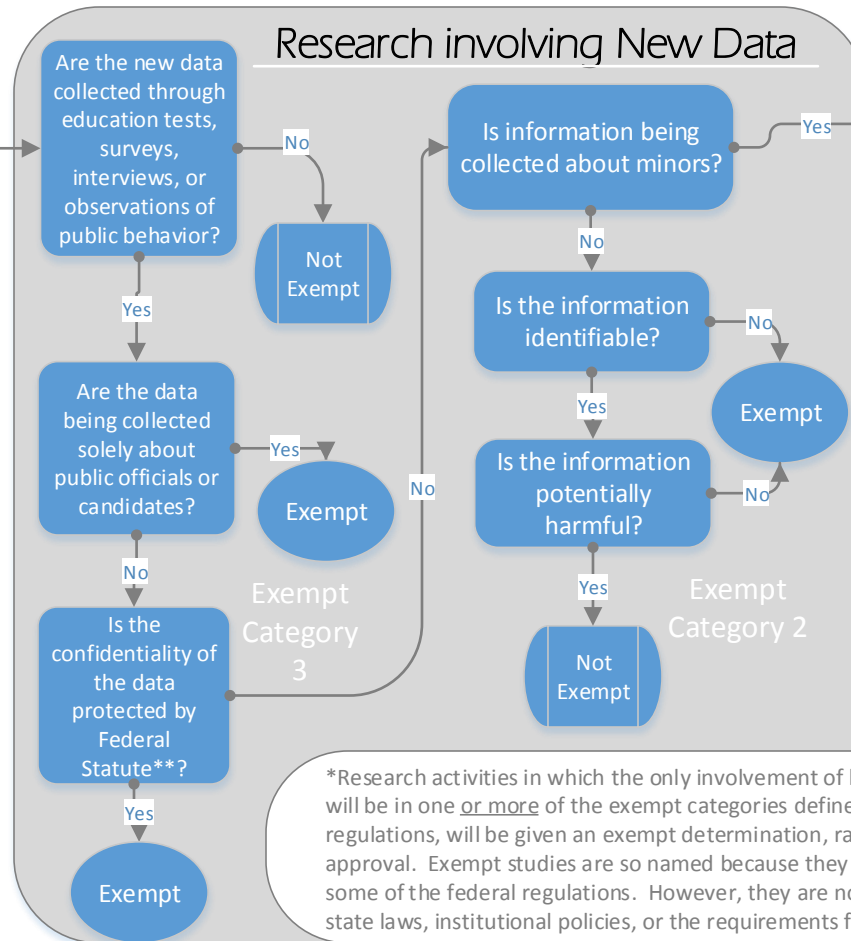
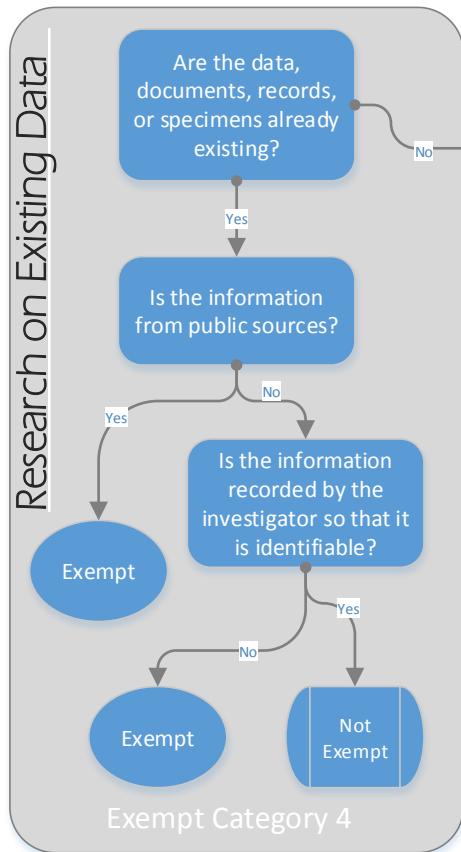
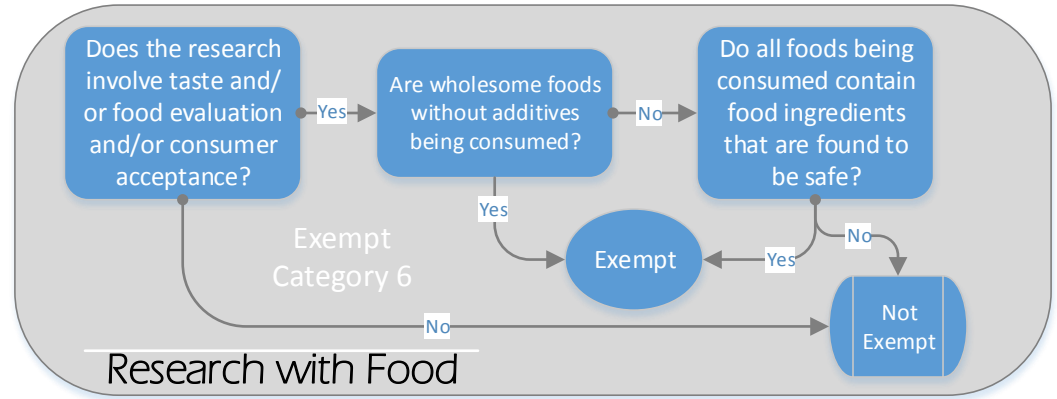
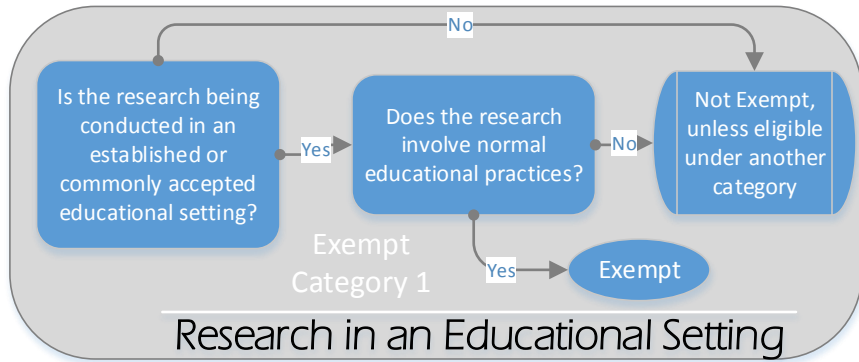


Can My Study be Exempt*?

Find your Area of Research and Start in that Box.

Note: Audio/Video recording does not prevent a study from being exempt



**An example of a Federal Statute protecting confidentiality is the Controlled Substances Act. This category is rarely applicable at OSU.

*Research activities in which the only involvement of human subjects will be in one or more of the exempt categories defined by the federal regulations, will be given an exempt determination, rather than IRB approval. Exempt studies are so named because they are exempt from some of the federal regulations. However, they are not exempt from state laws, institutional policies, or the requirements for ethical research.

Institutional Review Board Office
Office of Research Integrity
Phone: 541-737-8008
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CATEGORIES OF EXEMPTION

Research activities in which the only involvement of human subjects will be in one *or more* of the exempt categories defined by the Federal regulations, will be given an exempt determination, rather than an IRB approval. Exempt studies are so named because they are exempt from some of the Federal regulations. However, they are *not* exempt from state laws, institutional policies, or for the requirements for ethical research.

- Research with prisoners cannot be exempt.
- Audio/video recording is not considered in the application of these exempt categories and is a permitted activity in most cases.

	Federal Definition	Conditions and Examples
Category 1	<p>Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:</p> <p>a) research on regular and special education instructional strategies, OR</p> <p>b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.</p> <p>(45 CFR 46 101 (b)(1))</p>	<p>This category does NOT apply to studies involving surveys, interviews, questionnaires, or focus groups. However, those activities may be covered under category 2 so long as children (under 18 years old) are excluded from those activities.</p> <p>A normal educational setting and practice may include a cooking class in a grocery store, professional development workshops or skills development in children’s summer camps, etc. It is not necessary limited to primary and secondary public/private educational settings.</p> <p>“A study that involves evaluation of radically new instructional strategies or use of random assignment of subjects to different instructional methods is usually not exempt because the methods employed in the studies deviate from normal educational practice” (Prentice & Oki, 2006).</p> <p>This category may NOT apply to research on physical education on exercises that have been significantly altered or pose a level of risk to participants (Prentice & Oki, 2006).</p>
Category 2	<p>Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:</p> <p>a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND</p> <p>b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.</p>	<p>This category does NOT apply if the research involves surveys or interviews with minors (under 18 years old).</p> <p>This category only applies to observations of public behavior involving children if study team members do NOT participate in the activities being observed.</p> <p>Observations must be of a public behavior <i>and</i> in a public setting. Classrooms and medical settings are not considered public.</p> <p>If any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation AND the data are completely anonymous, this category may apply. A determination for a higher level of review may be made at the discretion of the OSU IRB on a case-by-case basis.</p>

CATEGORIES OF EXEMPTION

		<p>At the discretion of the IRB, studies qualifying for an exemption in this category may include activities that supplement or help to inform procedures in this category. Additional activities must be without risk and <i>passive</i> in nature, such as watching a video, looking at pictures, or listening to an audio file. The inclusion of additional activities that are <i>active</i> in nature, such as performing a task, will generally result in the study being reviewed by an expedited procedure.</p>
<p>Category 3</p>	<p>Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category 2 (above), if:</p> <ul style="list-style-type: none"> a) the human subjects are elected or appointed public officials or candidates for public office; OR b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. 	<p>This category does NOT apply in general to government employees.</p> <p>One of the differences between category 2 and 3 is that “exemption 3 effectively holds public officials who become research subjects to a different standard by providing less protection of their rights than for other members of society” (Prentice & Oki, 2006). Regardless, ethical principles should continue to apply for public officials as well.</p> <p>This category also differs from category 2 in that it allows for there to be the types of risks listed in category 2 (i.e. risks to employability, criminal liability, etc.) AND identifiable information provided that there is a federal statute in place that requires confidentiality of the personally identifiable information.</p> <p>An example of a federal statute requiring confidentiality is the Controlled Substance Act (21 CFR 1316.23) which allows researchers to petition the U.S. Attorney General for a grant of confidentiality to protect the identity of human subjects.</p> <p>Rarely applicable to research at OSU</p>
<p>Category 4</p>	<p>Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.</p>	<p>The data and/or samples must already exist (on the shelf) at the time the PI submits the research protocol. This category does NOT apply to data or materials that will be gathered as they become available.</p> <p>This exemption does NOT apply to data that are linked or coded to an individual. In this cases, the identity may be confidential, but it is not anonymous. It would be reviewed at the expedited or full board levels of review.</p>
<p>Category 5</p>	<p>Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine the following:</p> <ul style="list-style-type: none"> a) public benefit or service programs; b) procedures for obtaining benefits or services under those programs; c) possible changes in or alternatives 	<p>A program must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).</p> <p>The research or demonstration project must be conducted pursuant to specific statutory authority.</p> <p>There must be no statutory requirement that the project be reviewed by an IRB.</p>

CATEGORIES OF EXEMPTION

	<p>to those programs or procedures; or</p> <p>d) possible changes in methods or levels of payment for benefits or services under those programs.</p>	<p>Rarely applicable to research at OSU.</p>
<p>Category 6</p>	<p>Taste and food quality evaluation and consumer acceptance studies, if:</p> <p>a) wholesome foods without additives are consumed, OR</p> <p>b) 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.</p>	<p>The food must be wholesome with no additives, OR</p> <p>The consumed food ingredients must meet federal agency safety standards for amount and type.</p> <p>Research under this category must be evaluating taste, food quality, or consumer acceptance. Other types of research involving food will be reviewed by the expedited or full board procedure.</p>

Adopted from Colorado State University's Exemption Criteria. (2013)

<http://ricro.colostate.edu/IRB/Documents/Exempt.Criteria.July.2013.pdf>

Prentice, E. D. & Oki, G. S. F. (2006). Exempt from Institutional Review Board Review. E. A. Bankert & R. J. Amdur. *Institutional Review Board: Management and Function*. (pp. 93-97) Sudbury, MA: Jones & Bartlett Learning

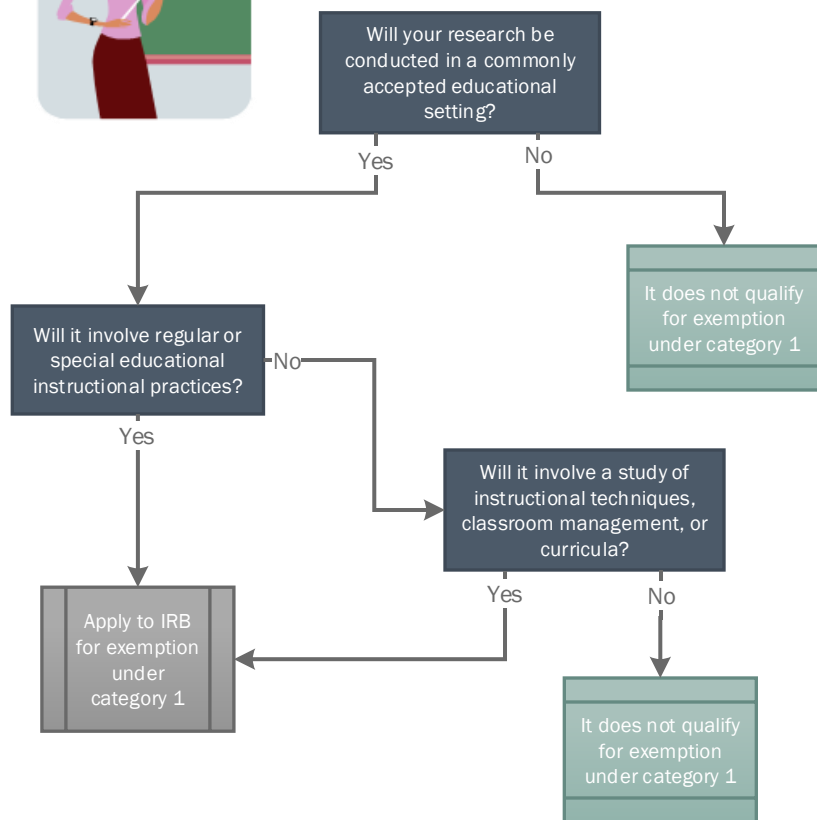
Research activities in which the only involvement of human subjects will be in one or more of the exempt categories defined by the federal regulations, will be given an exempt determination, rather than IRB approval. If your study doesn't fit into one of the category, it may fit into one of the other categories. If all activities involving human subjects don't fit into one or more of the categories, it will need to be reviewed at a higher level.

DESCRIPTION OF CATEGORY 1:

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (1) research on regular and special education instructional strategies; **or** (2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.



EXEMPTION CATEGORY 1



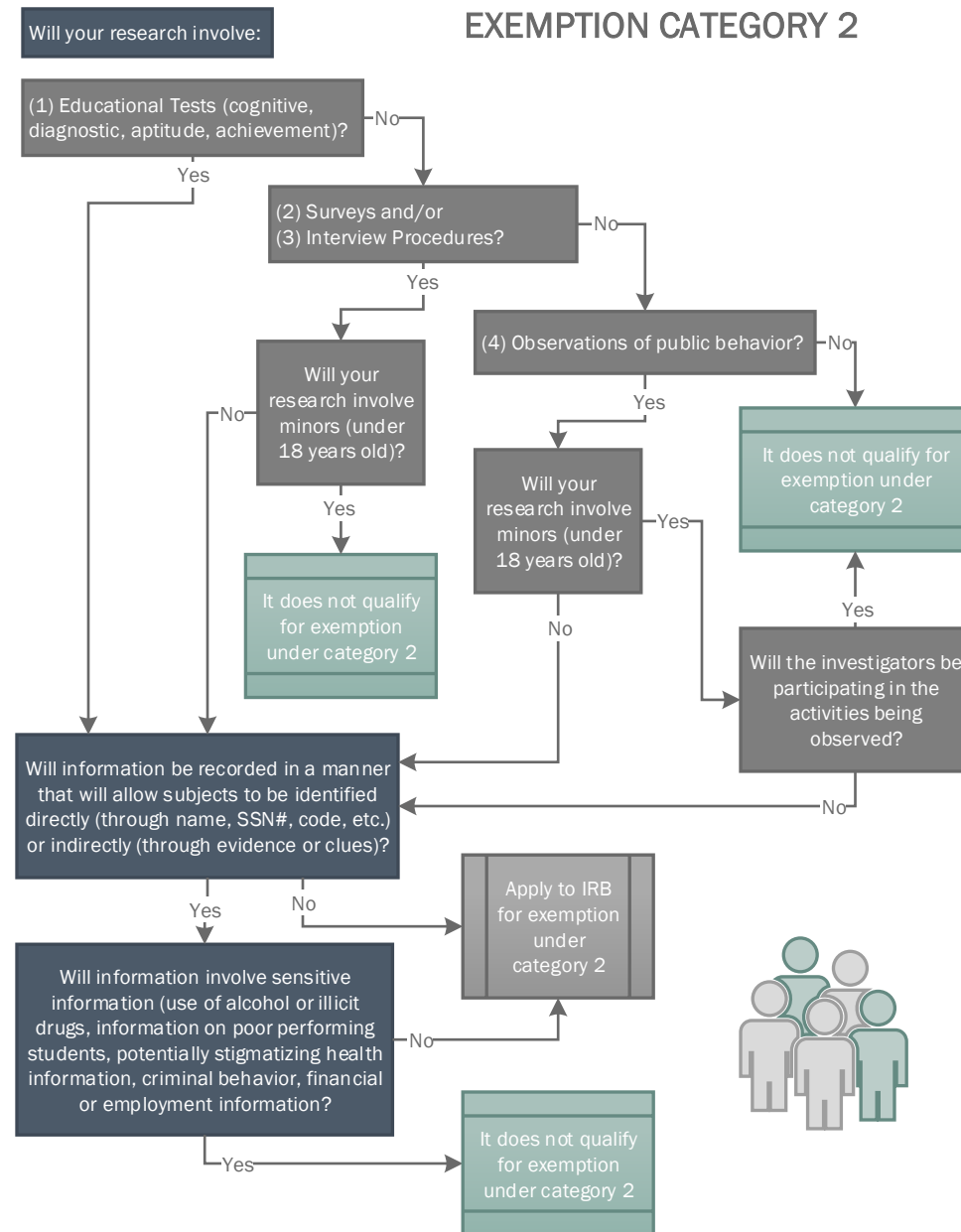
For More Information, Please Contact:
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DESCRIPTION OF CATEGORY 2:

Research involving the use of education tests (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures, observations of public behavior, **unless** the information is obtained and recorded in such a manner that human subjects can be identified, directly or through identifies linked to the subjects; **and** any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

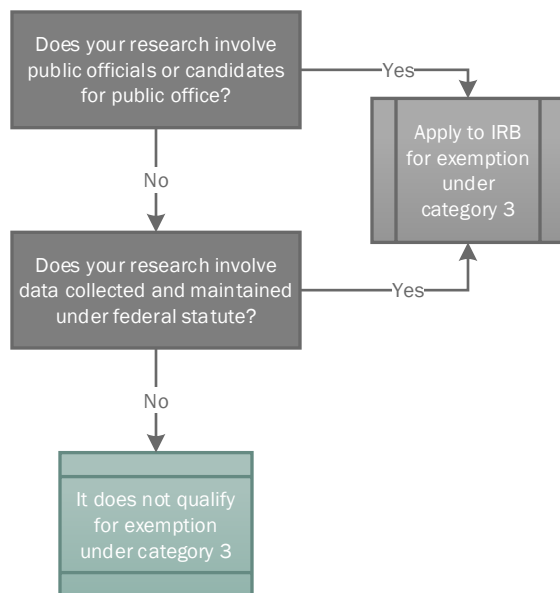
EXEMPTION CATEGORY 2



DESCRIPTION OF CATEGORY 3:

Research involving the use of education tests (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures, observations of public behavior, that is not exempt under category 2 **if** the human subjects are elected or appointed public officials or candidates for public office, **or** federal statute(s) require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

EXEMPTION CATEGORY 3



Note: Rarely applicable to research at OSU

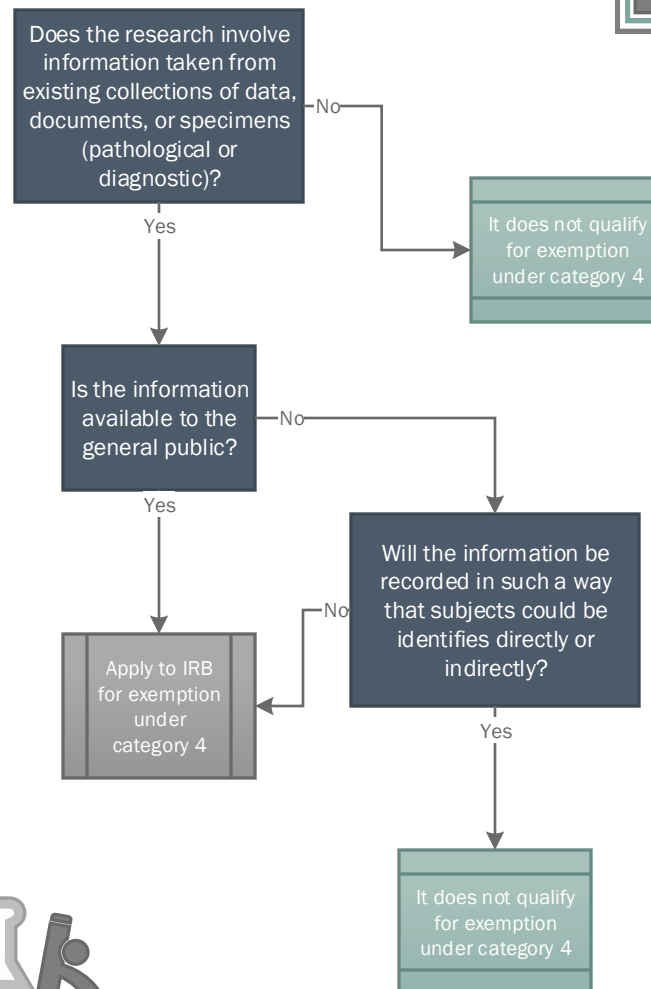
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DESCRIPTION OF CATEGORY 4:

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, **if** these sources are publicly available, **or** if the information is recorded by the investigator in such a manner that the subjects cannot be identified directly or through identifiers linked to the subjects.

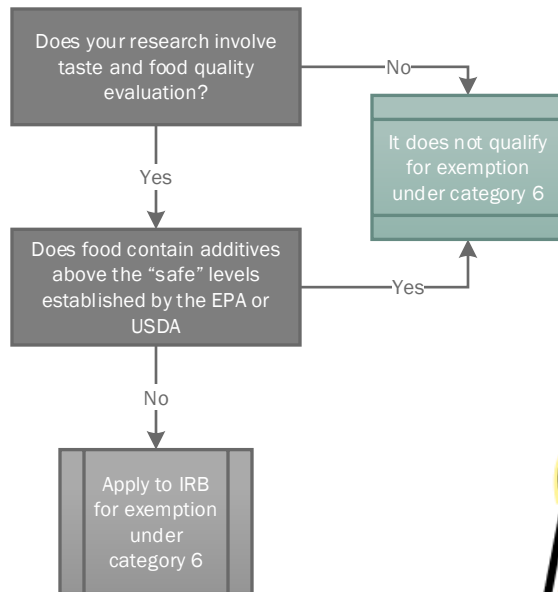
EXEMPTION CATEGORY 4



DESCRIPTION OF CATEGORY 6:

Taste and food quality evaluation and consumer acceptance studies, **if** wholesome foods without additives are consumed, **or** a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or an 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 U.S. Department of Agriculture.

EXEMPTION CATEGORY 6



NOTE: If your research DOES NOT QUALIFY for exemption under ANY CATEGORY identified in these diagrams then it must be submitted to the IRB for approval via the Expedited or Full Board levels of review.

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Frequently Asked Questions

1) Does audio/video recording of interviews mean that my study cannot be exempt? No. Audio/video recording is not considered in the application of these exempt categories and is a permitted activity in most cases. However, if audio/video recording increases risk, it may be reviewed at the Expedited level of review. An example of audio/video recording increasing risk would be an interview in which employees disclose negative opinions of their supervisors.

2) Can I have prisoners as participants in my Exempt research? No. Research involving prisoners must be reviewed by the full board.

3) What does "normal education practice" mean? A normal educational setting and practice may include a class in a grocery store, professional development workshops, or skills development in children's summer camps. It is not necessarily limited to primary and secondary public/private educational settings. However, studies that involve new experimental educational practices or settings may not fit into this category and may need to be reviewed at a higher level.

4) Are observations in public schools considered public observations? No. Classrooms, hospitals, and other similar settings are not considered public.

5) If my survey is completely anonymous but may pose a risk to participants, can it still be exempt? Maybe. In the event that a disclosure of a human subject's responses outside the research could reasonably place them at risk but the data are completely anonymous, exempt category 2 may apply. A determination for a higher level of review may be made at the discretion of the OSU IRB on a case-by-case basis. However, even when responses are anonymous, if the study presents a risk of causing distress to the subject, the IRB may determine that review of the study by an expedited or full board procedure is appropriate. Example: An anonymous online survey about suicidal ideation.

6) Can my study be exempt in more than one category? Yes. All research activities that involve human subjects must fit within one or more of the exempt categories in order to be given an exempt determination.

7) Do "exempt" studies have to be reviewed by the IRB? Yes. Exempt studies are so named because they are exempt from some, *but not all*, of the federal regulations. However, they are not exempt from state laws, institutional policies, or for the requirements for ethical research.

8) Can my study be exempt if it involves documents, records, or biological specimens that do not yet exist and will be collected as they become available? No. In order for a research study to be exempt, all data, documents, specimens, and records must already exist at the time the PI submits the research protocol. Prospective data collection, i.e. data collected as they become available, will need to be reviewed at the expedited or full board level.

9) Why is there no Category 5? Category 5 is for research involving public benefit programs. This category is rarely applicable to OSU and the federal body that regulates research with human subjects has recommended against its use.

10) What is the OSU Express Review Process? OSU has a review process for exempt studies which allows researchers to make an appointment with an IRB Coordinator to review and revise their study in person. Provided that all revisions can be made during the appointment, exemptions can be issued at the end of the meeting. See the IRB Website for more information about this process.



PROJECT REVISIONS FOR EXEMPT STUDIES

If the Project Revision involves...	Do Submit	Don't Submit	No Longer Exempt
1. Adding vulnerable populations, such as prisoners; children; pregnant women; non-English speakers; OSU Students or employees; individuals with diminished capacity to consent; prisoners; people living in poverty; people who are illiterate; and/or international populations, as participants.	X		It depends
2. Adding a survey or interview that involves children (i.e. individuals under the age of 18)	X		X
3. Revising survey/interview questions to make substantive changes, adding items, or revising content	X		It depends
4. Revising surveys/interviews to make minor edits that do not alter the nature of the questions being asked (fixing typos/grammatical errors, restating the same questions for clarity, reordering the questions, splitting one question into multiple questions)		X	
5. Revising interview/focus group questions to include additional planned initial or follow-up questions (i.e. any question that is known in advance to the researcher is a planned question).	X		It depends
6. Revising interview/focus group questions to include follow-up clarifying questions (i.e. questions that cannot be known to the researcher in advance because they are based on the individual responses of the participants).		X	
7. Adding observational research with children that involves participation by the researchers. For example: changing procedures from observing children playing with toys to add researchers entering the room and leading the activity.	X		X
8. Add research procedures that are subject to the FDA Regulations	X		X
9. Revising study procedures such that data samples will be individually identifiable when previously, they were not	X		It depends
10. Adding a new cohort of participants that are similar in age and type as the previously acknowledged cohort (i.e. adding a new group of students to existing pool of students)	X		
11. Increasing the enrollment number		X	
12. Replacing the Principal Investigator	X		
13. Adding External Collaborators	X		
14. Adding a student researcher, if this research will be used for their thesis or dissertation	X		



15. Adding or removing study personnel, not otherwise listed in # 12, 13, or 14 above. Note: Only listed personnel can/will be copied on correspondence with the IRB. The PI is responsible for ensuring that all study staff have completed the appropriate online ethics training .		X	
16. Adding research activities that change the risk to participants	X		
17. Adding or removing funding	X		It depends
18. Adding additional types or varieties of food for tasting or consumer preference tests	X		It depends
19. Revising recruitment materials so long as the 4 required elements are still present and they conform to the OSU policy: http://oregonstate.edu/research/irb/recruitment-research-participants		X	
20. Adding compensation for participants (unless compensation is \$600+ per participant in a year and/or compensation will now be paid via check)	Only if \$600+ or check	X	
21. Adding extra credit as compensation in a manner that conforms to the OSU policy: http://oregonstate.edu/research/irb/recruitment-students-and-employees-research-subjects		X	
22. Revisions to the consent/assent/parental consent form or process. These documents are stamped so even minor revisions must be submitted to a new stamped version can be submitted.	X		It depends
23. Revisions involving changes to, or additions of, conflicts of interest declarations or disclosures for study team members (including those not listed on the application).	X		