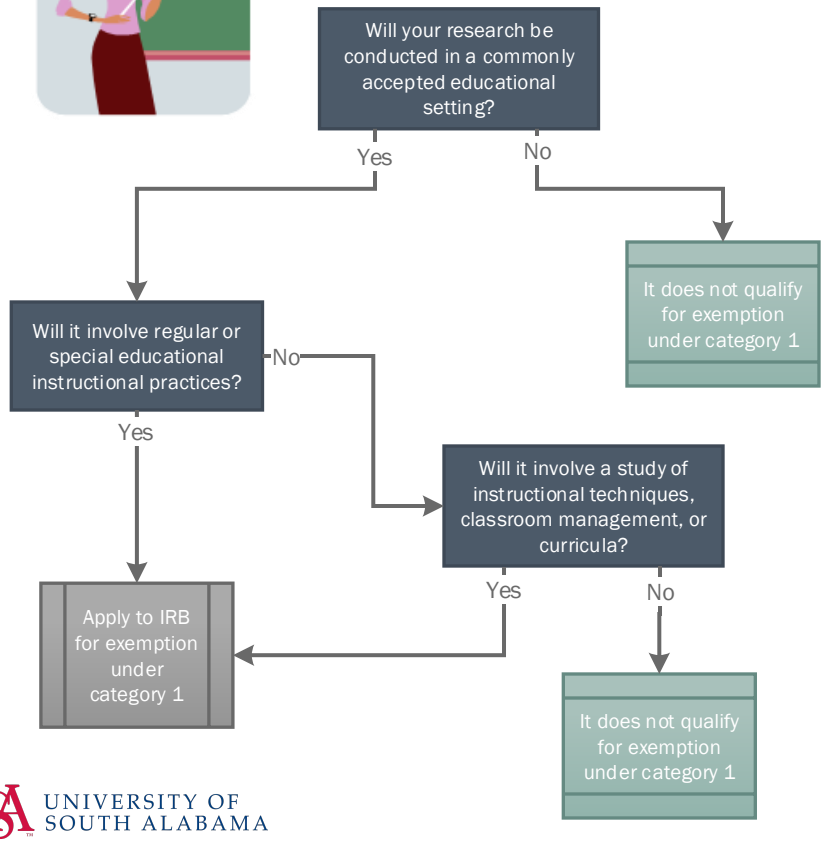
Research activities in which the only involvement of human participants will be in one or more of the exempt categories defined by the federal regulations, will be given an exempt determination, rather than IRB approval. If all activities involving human participants do not fit into one or more of the 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



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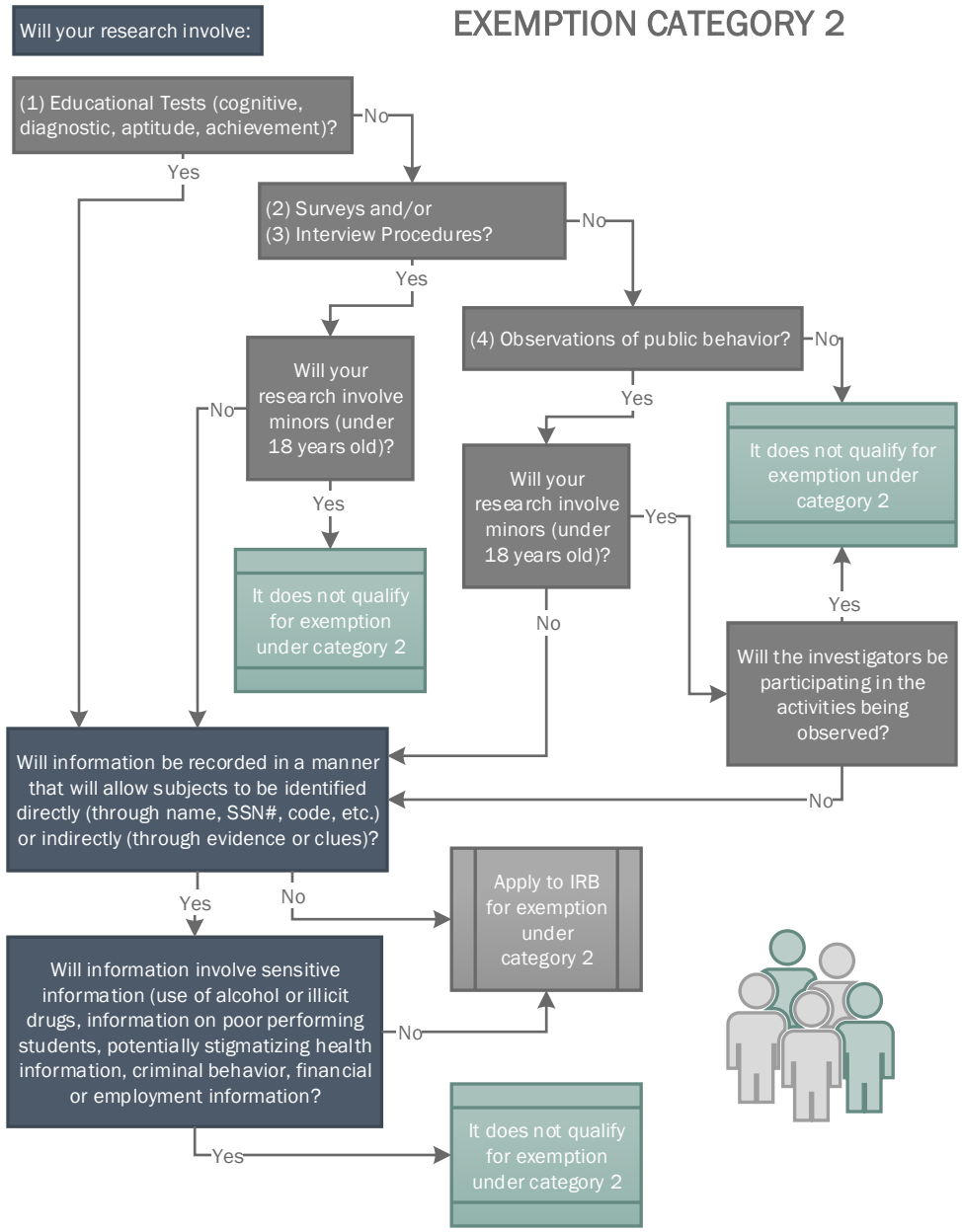
For More Information, Please Contact:
Institutional Review Board Office
Phone: 251-460-6308
Email: irb@southalabama.edu
Website: southalabama.edu/departments/research/compliance/humansubjects

Adopted and modified from Oregon State University

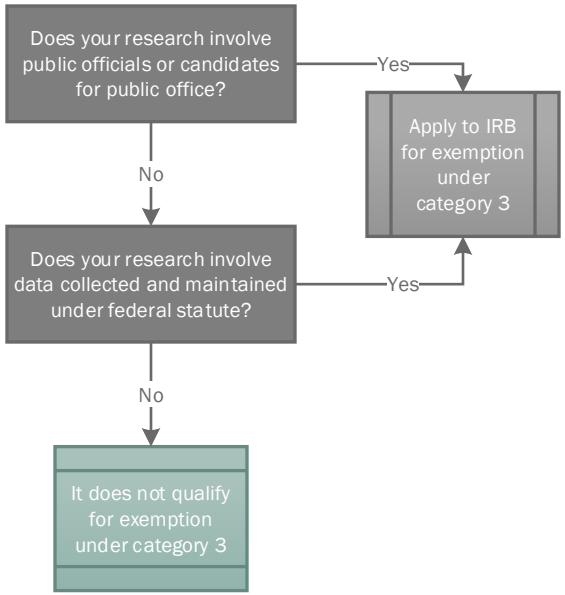
DESCRIPTION OF CATEGORY 2:
Research involving the use of education tests (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures, observations of public behavior, **unless** the information is obtained and recorded in such a manner that human subjects can be identified, 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



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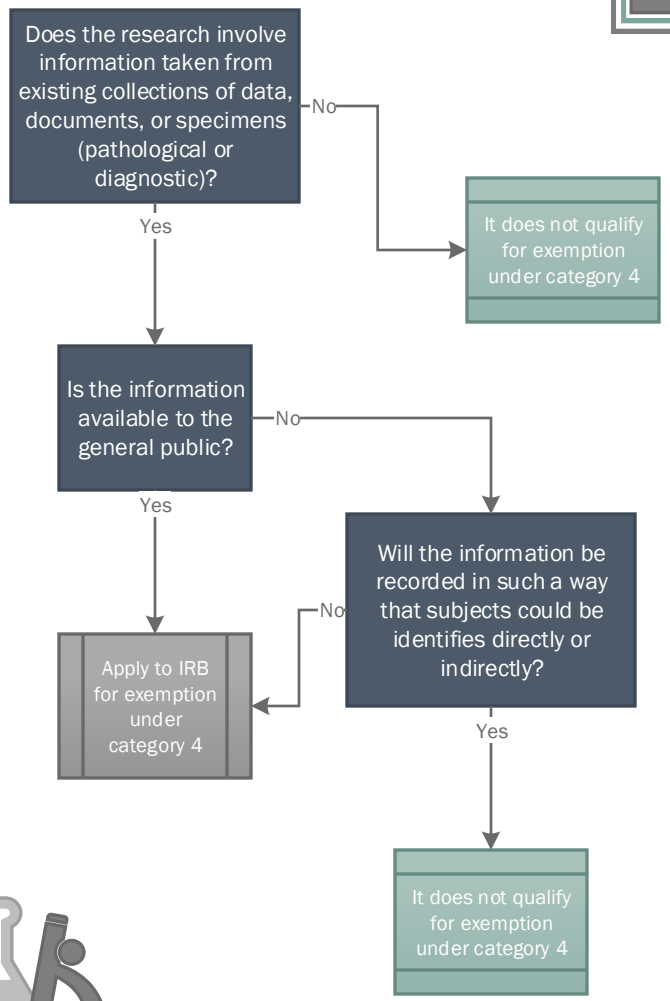
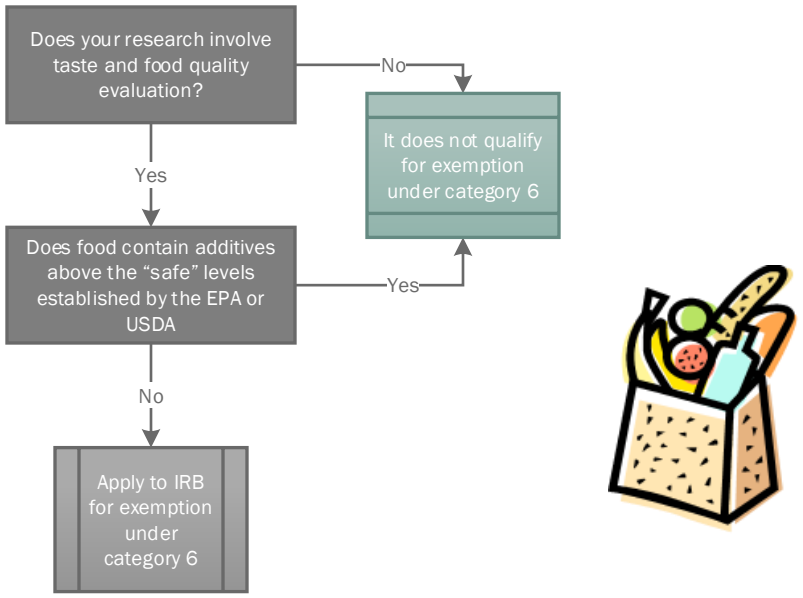
DESCRIPTION OF CATEGORY 4:
Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, **if** these sources are publicly available, **or** if the information is recorded by the investigator in such a manner that the subjects cannot 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 humans 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 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 and the federal body that regulates research with human subjects has recommended against its use.