

Researchers: Exempt Self-Determination may be done under specific exempt categories and with specific subject populations. Visit the [Levels of Review webpage](#) to learn more about what categories can be confirmed by the Lead Researcher, and those that require UCI IRB review.

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.
2. Research that includes only **interactions involving educational tests** (cognitive, diagnostic, aptitude, achievement), **survey procedures, interview procedures, or observation² of public behavior** (including visual or auditory recording) **if at least one of the following criteria are 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; **OR**
 - iii. The information obtained is recorded by the investigator in such a manner that the **identity of human subjects can readily be ascertained**, directly or through identifiers linked to the subjects, **and an IRB conducts a limited review to make the determination required by 45 CFR 46.111(a)(7)**

Note: For Category 2iii, any disclosure of the human subjects' responses outside the research *would* reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.
- 3i. 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 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; **OR**
 - 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 subject, **and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7)**

¹ Research funded/supported by the Department of Justice is not currently eligible for the 2018 Exempt Categories.

² Children may be included if procedures include educational tests or observation of public behavior only and the researcher does not participate in the activities being observed.

Note: For Category 3iC, any disclosure of the human subjects' responses outside the research *would* reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

- 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.

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**;

Note: Category 4i applies to secondary research use of archives in a public library, for example, or to government or other institutional records where public access is provided on request, or from a commercial entity if the information is provided to members of the public on request or if the only requirement for obtaining the information is paying a user fee, registering or signing in as a visitor to an archive. It would also apply if a commercial entity made identifiable biospecimens publicly available to anyone on request or for a fee.

- ii. Information, which may include information about the biospecimens, is recorded by the investigator in such a manner that the **identity of 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;

 **Note: Based on recent UC Office of the President guidance, due to HIPAA considerations, 4iii will no longer be used at UCI. Consider Exempt Category 4ii or Expedited 5 instead.**

- 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.

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.

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.

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 45 CFR 46.111(a)(8).

Note: UCI will not adopt the option for broad consent provided in Category 7. UCI's interpretation of Broad consent is that it is a system-wide program that allows institutions to track via a central system biospecimens and data for which individuals provide their broad consent, or decline, as well as the terms of the broad consent to determine which future research uses remain within scope. This interpretation aligns with the Health and Human Services (HHS) Secretary's Advisory Committee on Human Research Protections (SACHRP) interpretation. Consequently, UCI is taking the same position as all UC's, Children's Hospital Orange County, Harvard, and Johns Hopkins and is not implementing Category 7, because UCI currently lacks a system-wide program for collecting broad consent.

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 45 CFR 46.116(a)(1) through (4), (a)(6), and (d);
- ii. **Documentation of informed consent or waiver of documentation of consent was obtained** in accordance with 45 CFR 46.117;
- iii. An **IRB conducts a limited IRB review** and makes the determination required by 45 CFR 46.111(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 results.

Note: UCI will consider Category 8 on a case by case basis. Researchers interested in Category 8 should contact HRP Staff for more information OR consider Expedited Review under Category 5.