

Title: Self Exemption Determination

SOP # 15

Department: Office of Research Compliance & Integrity

Issue Date: December 12, 2022

Subject: Self Exemption Determination

The following is the University of California, Merced (UCM) Institutional Review Board (IRB) Standard Operating Procedure for Self-Exemption Determination. The Self-Exemption Tool will allow UCM researchers to make a self-determination as to whether their human subjects research project fits within Exempt categories 1-4. Some exceptions apply. IRB review is not required and will not be provided for protocols that meet the Exempt definition as defined below. Exempt research activities are subject to the same subject protections and ethical standards outlined in the Belmont Report. All research conducted under exempt review is subject to all UCM and IRB policies and procedures.

Definitions:

Human subjects research as defined in *45 CFR 46.104 Exempt research* categories 1-4 are eligible for self-exemption.

1. **45 CFR 46.104(d)(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. **45 CFR 46.104(d)(2):** Research that includes only interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation¹ 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.
3. **45 CFR 46.104(d)(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:

¹ 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.

- 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)**

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. **45 CFR 46.104(d)(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;
 - 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**
Note: Category 4iii is allowable when a UCI healthcare workforce member uses identifiable health information for research purposes and the information obtained for research will not be disclosed outside of the covered entity (i.e., not outside of UCI Health). **IMPORTANT!**

Disclosure beyond UCI Health for research purposes does not meet category 4iii and the project should be submitted as Expedited Category 5.

- 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.

Exceptions

1. Exempt Categories 5-8
2. The research is regulated by the FDA
3. The research is supported by the Department of Justice (DOJ)
4. The research involves the following:
 - i. The use or disclosure of UCM protected health information (PHI)**²
 - ii. The use of video/audio recordings for publication/presentation (not transcription only)
 - iii. The study requires FERPA authorization
 - iv. A targeted recruitment of children
 - v. A targeted recruitment of adults (age 18 or older) who may not be legally/mentally/cognitively competent to consent
 - vi. A targeted recruitment of prisoners (may include parolees)
 - vii. A targeted recruitment of American Indian/Alaska Native tribes
 - viii. A targeted recruitment of undocumented people
 - ix. A targeted recruitment of pregnant women
 - x. Studies that include the following topics: self harm, suicide or illegal behavior or other sensitive topics
 - xi. International Research
 - xii. A request for UCM to serve as IRB of Record for non-UCI individuals engaged in human subjects research.
 - xiii. A study team member has a Disclosable Financial Interest

Procedures:

Researchers will complete the Self-Exemption submission in Cayuse Human Ethics.

References:

45 CFR 46

² Use is any sharing, employment, application, utilization, examination, or analysis within the entity. Disclosure is any release, transfer, provision of access to, or divulging outside of entity.