

P&P: FO 302 Version No: 1.4 Effective Date: 1/21/2019	DETERMINATION OF EXEMPTION	Supersedes: CPHS Policies and Procedures 3/24/2015
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1. POLICY

There are eight federal categories of research activities involving human subjects that may be *exempt* from the requirements of the Policy for the Protection of Human Subjects (45 CFR 46). Categories 1-6 are in use at UC Berkeley (UCB). In keeping with CPHS' efforts to minimize research compliance burden, an additional UCB-defined category of exempt research activities is available as permitted by UCB's Federalwide Assurance: Category #70 (formally #7 from 2015-2018).

Individual investigators do not have the authority to determine that a research project qualifies as exempt. This determination must be made by the OPHS staff, upon review of a Request for Determination of Exempt Status application submitted by the investigator. OPHS cannot exempt parts of the research project. If research is found to be exempt, it need not receive full or subcommittee (expedited) review.

The research may not begin until the investigator has received notification by a formal determination letter that the research qualified for exemption. In order to be eligible for exempt status, all of the proposed research activities of a study must fit in one or more of the six federal exemption categories or UCB's category #70 listed below (formerly category #7).

Although studies that qualify for exempt status do not have the same federal requirements for research involving human subjects as non-exempt studies, investigators still have a responsibility to protect the rights and welfare of their subjects. They are expected to adhere to UCB policies and conduct their research in accordance with the ethical principles of Justice, Beneficence, and Respect for Persons as described in the [Belmont Report](#).

Specific Policies

1.1 Research That Is Not Exempt

The federal exemption categories 1 through 6 (45 CFR 46.104(d)) listed in section 1.2 do NOT apply to the following:

- Research that involves greater than [minimal risk](#).
- Survey or interview of children vis-à-vis Category 2.
- Observation of the public behavior of children when investigators interact with the children vis-à-vis Category 2.
- Benign behavioral interventions with children vis-à-vis Category 3.
- Research involving prisoners except for research aimed at involving a broader subject population that only incidentally includes prisoners.
- Research involving use of protected health information from [UC system covered entities](#) except in cases where a limited data set is being used.
- Research regulated by the Food and Drug Administration (FDA). With the exception of Category 6, FDA-regulated research does not qualify for exempt status. Research will not

qualify for exempt status under Category 6 if there have been food and color additives incorporated into the food product and these additives are used in research with the intent to apply to the FDA for marketing of the additive.

1.2 Federal Exempt Categories 1-6

1. Educational Practices. 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. Educational Tests (Cognitive, Diagnostic, Aptitude, Achievement), Survey Procedures, Interview Procedures, or Observation of Public Behavior (including visual or auditory recording). Research involving these procedures is exempt if:
 - i. the information obtained is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects; *or*
 - ii. any disclosure of the subject's responses outside of the research would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's 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 the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and CPHS conducts a limited IRB review to make the determination required by §46.111(a)(7).
3. 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:
 - i. the information obtained is recorded in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to subjects; *or*
 - ii. any disclosure of the human subjects' responses outside the research would not reasonably place them 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 the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and CPHS conducts a limited IRB review to make the determination required by §46.111(a)(7).
 - 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.
 - 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; *or*
 - ii. the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects, and the investigator does not contact or re-identify subjects; *or*
 - iii. *exempt category 4iii is not in use at UC Berkeley*
 - 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. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.
- i. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.
6. Taste and Food Quality Evaluation and Consumer Acceptance Studies: This research is exempt if:
- i. wholesome foods without additives are consumed;
 - ii. a food is consumed that contains a food ingredient at or below the level and for a use found to be safe by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service (FSIS) of the US Department of Agriculture (USDA); *or*
 - iii. a food is consumed that contains an agricultural chemical or environmental contaminant at or below the level found to be safe by the FDA or approved by the EPA or the FSIS of the USDA.

1.3 UCB Exempt Category 70: Research that involves no greater than minimal risk to subjects, but does not conform to a specific exempt category under 45 CFR 46.104(d), and does not fall within the exclusions listed above under 1.1 or below under 1.3.1.

1.3.1 Such research is NOT exempt if it involves any of the following:

1. **Federal funding or personnel supported by federal training, center, or program grants; or funding from non-Public Health Service (PHS) agencies that adhere to federal regulations in their award contracts.**
2. Prisoners as subjects.
3. Children/minors as subjects.
4. Federal personnel or the Department of Veterans Affairs.
5. Procedures, devices, or drugs subject to FDA oversight.
6. Collection of biospecimens.
7. Invasive biomedical procedures.
8. Clinical interventions.
9. Sponsor or other contractual restrictions.
10. An NIH-issued Certificate of Confidentiality to protect identifiable research data.
11. Deception.
12. Identifiable, private existing data.
13. The information obtained is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects, **and** any disclosure of the subject's responses outside of the research could reasonably place the subject at risk of criminal or civil liability, be damaging to the subject's financial standing, employability, insurability, or reputation, or be stigmatizing in any other way.

1.3.2 Category 70 [minimal risk](#) (46.102(j)) exempt research activities that will not induce distress beyond that of daily life may include (but are not limited to) non-physically invasive interventions or performance of tasks such as:

- Physical activities such as walking, sitting, or manipulating an object.
- Height/weight measurements.
- Collection of non-invasive, non-sensitive health data, such body temperature or lung capacity.
- Use of an activity tracker such as a Fitbit.
- Use of incomplete disclosure (in certain circumstances)
- Passive monitoring of space (environment) with sensors.

The following procedures may qualify for review under exempt category 3. However, when they are not brief in duration or do not involve the collection of data through verbal or written responses or audiovisual recording, exempt category 70 may apply:

- Computer tasks and/or Internet searches.
- Talking and/or listening to words, then making selections, or “think-aloud” exercises.
- Viewing media.
- Role-playing.
- Completing a specific physical or mental action (“imagining”).
- Playing a game.

1.3.3 If the research is determined to qualify for Category 70 Exempt status and later becomes federally funded, supported, or regulated, or changes so that it includes any of the exclusion factors in 1.1 or 1.3.1 above, the researcher must immediately cease research activities until IRB approval is obtained. ***This will require submission of a new application.***

1.4 Action Taken If Proposed Research Does Not Meet Criteria for Exemption

If OPHS staff determines that the proposed research does not meet the criteria for exempt status, the investigator will be notified in writing and asked to submit the appropriate application materials for non-exempt review.

1.5 Modifications to an Exempt Protocol

All modifications to a project previously deemed exempt from IRB review must be submitted to the IRB for prospective review and determination of exemption prior to implementation. In some circumstances, proposed changes to the protocol may disqualify the project from exempt status, in which case either expedited or full committee review would be required, as appropriate.

2. SCOPE

These policies and procedures apply to investigator claims for exemption from 45 CFR 46 requirements and for Category 70 Exemption claims under UCB's Federalwide Assurance.

3. RESPONSIBILITY

OPHS staff are responsible for reviewing and making a determination regarding research applications that claim exemption from 45 CFR 46 under federal categories 1-6 or UCB's Category 70 Exempt Research.

OPHS staff are responsible for providing consultation in the review of claims of exemption. The OPHS Director or her/his designee has final authority to determine a finding of exempt status, or to revoke determinations granted by OPHS staff.

4. PROCESS OVERVIEW

The investigator submits to the IRB an application for determination of exempt status and any additional required information/documentation (e.g., copy of survey instrument).

An IRB administrative staff member reviews the application to determine if the investigator has submitted all of the necessary documentation and supporting materials for exempt review and ensures that all required elements are complete and in proper format. The staff member, in consultation with the OPHS Director or her/his designee as appropriate, evaluates the exemption request for (1) level of risk; (2) category of activity; and (3) other relevant considerations.

Limited review: Research for which limited IRB review is a condition of exemption under §46.104(d)(2)(iii) or (d)(3)(i)(C): The IRB Chair/Designee must determine that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data (§46.111(a)(7)). OPHS staff will conduct Limited IRB Review, if required, as the Director's designated alternate.

If the research qualifies as exempt, the staff member provides the investigator with a letter confirming exempt status.

If the research does not qualify for exemption, the staff member contacts the investigator to request a non-exempt application for expedited or full committee review.

Investigators are not permitted to make the determination of exempt status on their own. Exemption can only be granted by the OPHS staff.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.104

21 CFR 56.104

21 CFR 56.105

[CPHS Exempt Guidelines](#)