EXEMPT RESEARCH

This guidance document is intended for researchers planning to carry out minimal-risk activities with human subjects, which may qualify as "exempt" from federal regulatory requirements. Should you need additional assistance, please contact OPHS at 510-642-7461 or ophs@berkeley.edu.

Table of Contents:

A. General Information

"Exempt" research are human subjects studies that present no greater than minimal risk to subjects ***and*** fit into one or more exempt categories (as described below). Exempt research applications are reviewed by Office for Protection of Human Subjects (OPHS) staff, and involve a shorter application form and generally a faster review process than non-exempt studies.

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, 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. See also Part D, Respect for Persons and Informed Consent, below.

Note: Before applying for exempt status, investigators should confirm that their study is considered research on human subjects. For example, some research involving the use of coded private information or specimens does not require CPHS or OPHS review at all. See What Needs CPHS/OPHS Review for more information.

B. Research That Is Not Exempt

Research that involves greater than minimal risk: Research eligible for exemption usually involves negligible risks to subjects. When reviewing an application for exempt status, OPHS staff apply the "minimal risk" standard. As defined in the federal regulations, *minimal risk* means, "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily

encountered in daily life or during the performance of routine physical or psychological examinations or tests." *Research that involves greater than minimal risk will not qualify for exempt status.*

Research with vulnerable populations: Certain research activities are not eligible for exempt status because additional protection has been required by federal regulations for vulnerable populations. Specifically, the following do not qualify for exempt status: (1) survey or interview of children; (2) observation of the public behavior of children when investigators interact with the children; (3) interactions with children; and (4) research involving prisoners except for research aimed at involving a broader subject population that only incidentally includes prisoners.

Research regulated by the Food and Drug Administration (FDA): With the exception of Category 6, FDA-regulated research does not qualify for exempt status. In addition, research does 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.

Research using UC Berkeley protected health information (PHI): Research involving use of protected health information from UC system covered entities does not qualify for exempt status except in cases where a limited data set is being used. See E below for more information.

C. Federal Exemption Categories 1-6 (per 45 CFR 46.104(d)) and Examples

1. Educational Practices: Research conducted in established or commonly accepted educational settings, involving normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or assessment of educators who provide instruction such as:

(i) research on regular and special education instructional strategies; *or*

(ii) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

As noted above, research must be conducted in "established or commonly accepted educational settings" and involve "normal educational practices" to be exempt under this category.

Commonly accepted educational settings include but are not limited to K-12 schools and college classrooms. They may also include after-school programs, preschools, vocational schools, alternative education programs, and other sites where educational activities regularly occur.

Normal educational practices include established teaching methods, curriculum content, commonly accepted classroom management techniques that are planned and implemented by the classroom teacher, and, on a case-by-case basis, projects conducted with teachers for professional development purposes. Normal educational practices are activities that would occur regardless of whether the research is conducted. Thus, a study that evaluates a radically new instructional strategy or curriculum, or that randomly assigns students to different instructional strategies/curricula for comparison, would probably not be exempt, since these are not "normal educational practices." Studies that involve surveys and interviews with minors that are outside of "normal education practices" also do not qualify for exemption.

Examples of Research Exempt under Category 1:

- A study evaluating the effectiveness of a commonly accepted science curriculum. For the study, researchers will observe classroom instruction and collect quizzes and class evaluations that are part of the curriculum and classroom practices.
- A study comparing two curricula that are currently being implemented in a school.

Researchers will observe classrooms as well as interview instructors about their experiences implementing the instructional materials (but not about specific students).

- A study comparing driver's education curricula offered by area driving schools. The researcher will observe classes and compare group driving test scores at the end of the courses.

2. Educational Tests (Cognitive, Diagnostic, Aptitude, Achievement), Survey Procedures, Interview Procedures, or Observation of Public Behavior: 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 could 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) data collection is not anonymous and potentially sensitive or harmful information is collected from subjects. Studies only qualify for this exemption category if CPHS conducts a limited IRB review and determines that there are adequate provisions for protecting subject privacy and maintaining confidentiality.

This exempt category applies only to interactions involving the activities listed above (research involving interventions may not be reviewed under this category). **Public behavior** refers to behavior taking place in a publicly accessible location in which the subject does not have an expectation of privacy (e.g., a public plaza or park, a street, a building lobby, a government building). If subjects have a reasonable expectation of privacy at the location where the researcher is conducting the observation, the project may not be considered exempt.

Note: Research involving surveys or interviews with children or observation of public behavior when investigators interact with the children does not qualify for exemption.

The research must meet ***one*** of the following three conditions to qualify under Category 2:

(1) The data is collected anonymously (which means that no identifiers can be connected to the data, either directly or through a coding system). In addition to videotapes and photographs, audio recordings are considered identifiable; therefore, any data collection that involves audio recordings, video recordings, or photographs of subjects would not be considered anonymous. It is also possible that multiple pieces of information, none of which are identifiable on their own, may uniquely identify a person when brought together; in this case, the data would be identifiable and would not be considered anonymous.

(2) The information collected is not anonymous (because, for example, the researcher has a key linking respondents' names to coded identifiers), but the information is so innocuous that, in the event of disclosure outside of the research, there would be no significant detrimental consequences to the subject. The significance of "detrimental consequences" depends in part on context. For example, including a question about sexual identity in an interview study that investigates adults' plans to change careers could be non- controversial – and exempt – in some locales, but highly sensitive – and non-exempt – in other places.

(3) Data collection is not anonymous and potentially sensitive or harmful information is collected from subjects. Studies only qualify for this exemption category if CPHS conducts a limited IRB review and determines that there are adequate provisions for protecting subject privacy and maintaining confidentiality.

Examples of Research Exempt under Category 2:

- A study involving an anonymous survey regarding workplace satisfaction at area firms.
- An observational study of pedestrians crossing a street; the researcher takes notes of what occurs, recording sex, race, and type of clothing of pedestrians, but does not interact with subjects.
- A study involving interviews with college seniors (age 18 and older) about their plans after graduation. The answers to questions asked would present no risks to subjects if divulged outside the research.
- A study involving focus groups with expectant mothers regarding their perceptions of parenting education.

3. Benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses or audiovisual recording if the subjects prospectively agrees 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) data collection is not anonymous and potentially sensitive or harmful information is collected from subjects. Studies only qualify for this exemption category if CPHS conducts a limited IRB review and determines that there are adequate provisions for protecting subject privacy and maintaining confidentiality.

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.

Brief in duration is intended to refer to the intervention as opposed to the intervention and the data collection activities together. Thus, the data collection activities could proceed over a longer period of time without precluding the applicability of this exemption. If the intervention and the data collection are intertwined or difficult to separate, the entirety of the activity should be brief in duration. To meet the requirement of brief in duration, the benign behavioral intervention should last a few minutes to a few hours.

Examples of Research Exempt under Category 3:

- A study that involves asking subjects to play an online game that takes 30 minutes to complete.
- A study that involves asking subjects to solve puzzles under various noise conditions. Study procedures take about 2 hours.
- Healthy adult subjects are asked to take part in two 2 hour-long assessments of memory, attention and information processing speed before and after 1 hour of cognitive enhancement exercise using specially designed computer software.

<u>Incomplete disclosure/deception under category 3:</u>

If the research involves deceiving 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 s/he will be unaware of or misled regarding the nature or purpose 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) these sources 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 information is collected by or on behalf of the federal government using government generated or collected information obtained for non-research activities.

Note: Many projects involving the secondary use data/specimens do not meet the threshold definition of "human subjects research." See What Needs CPHS/OPHS Review for more information.

Research can be exempted if the data are publicly available (the general public can obtain the data/biological specimens and they are available to anyone regardless of occupation, purpose, or affiliation). Research can also be exempted if the investigators initially have access to identifiable private information but abstract the data needed for the research in such a way that the information can no longer be connected to the identity of the subjects. This means that the abstracted data set does not include direct identifiers (names, social security numbers, addresses, phone numbers, etc.) *or* indirect identifiers (codes or pseudonyms that are linked to the subject's identity). Note that data need not be currently in existence (i.e. "on the shelf") to qualify for exemption under this category.

Examples of Research Exempt under Category 4:

- A research study of treatment outcomes for a certain drug that involves the review of patient charts at a non-UCB medical facility. The researcher records patient age, sex, diagnosis, and treatment outcome in such a way that the information cannot be linked back to the patient.

- Student B will be given access to data from her faculty advisor's health survey research project. The data consists of coded survey responses, and the advisor will retain a key that would link the data to identifiers. The student will extract the information she needs for her project without including any identifying information and without retaining the code. The use of the data does constitute research with human subjects because the initial data set is identifiable (albeit through a coding system); however, it would qualify for exempt status.

  See CPHS Guidelines on Secondary Data Analysis of Existing Data for more information and examples.

5. Research and Demonstration Projects Conducted or Supported by a Federal Department or Agency, or otherwise Subject to the Approval of Department or Agency Heads: This research is exempt if it is designed to study, evaluate, improve, or otherwise examine:

(i) public benefit or service programs; *or*

(ii) procedures for obtaining benefits or services under those programs; *or*

(iii) possible changes in methods or alternatives to those programs or procedures; *or*

(iv) possible changes in methods or levels of payment for benefits or services under those programs.

Exemption Category 5 only applies to research on public benefit programs (such as Social Security) conducted or supported by the federal government and therefore is rarely, if ever, applied to research at UC Berkeley. Research and demonstration projects in general (e.g., state or city funded public service programs) do not fit under this exempt category. Exempt category 5 projects include, but are not limited to, internal studies by Federal employees, and studies under contracts of consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 115A of the Social Security Act, as amended.

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; *or*

(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.

Taste and food quality evaluation studies conducted under this exemption may not involve the consumption of any type or volume of food that would present any risk to the subjects and should fall into what would be considered reasonable eating behaviors by the subject.

The food must be "wholesome" (no additives), or if it involves plants or animals raised for food products, the level of chemical additives or environmental contaminants must be at or below the levels approved by the FDA, EPA, or USDA. Studies involving the consumption of alcohol, vitamins, and other supplements do not qualify for exempt status.

Examples of Research Exempt under Category 6:

- A taste-test on different varieties of a fruit to determine consumer preference, when the fruits do not have any additives and subjects are asked to indicate which fruit they prefer.
- A study that involves taste-testing of various beef products from cattle that have been given feed

with a chemical additive. If the researcher can document that the amount of the additive was at or below the levels approved by the USDA, the research may qualify for an exemption.

D. UCB Exemption Category 70 and Examples

7. UCB Exempt Category 70: Research that involves no greater than minimal risk to subjects, but does not entirely conform to a specific exempt category under 45 CFR 46.104(d) (i.e., categories 1-6 above) and does not fall within the exclusions listed under B. above or in the list below. For example, activities not consistent with the requirement that data may only be collected using verbal or written responses or audiovisual recording *and* are brief in duration would not qualify for review under category 3 above, but might qualify under category 70.

Category 70 minimal risk 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.
- Secondary use of private, identifiable data. When disclosure of the data outside of the research has the potential to 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, a non-exempt application may be required.

When the following procedures are not brief in duration or do not involve the collection of data through verbal or written responses or audiovisual recording (otherwise, category #3 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.

Exclusions:
In addition to the exclusions listed under B. above, specific exclusions apply under Category 70. The research will NOT qualify for Category 70 if any of the following are involved:

1. **Federally funded research, or funding from non-Public Health Service (PHS) agencies that adhere to federal regulations in their award contracts** (investigators should check with the funding agency if unsure)**.**
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. Use of data regulated by HIPAA or by FERPA.
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.

E. Limited Data Sets

A limited data set is protected health information (PHI) under the HIPAA Privacy Rule that excludes 16 of the 18 HIPAA identifiers, as outlined in the CPHS HIPAA Guidelines. A CPHS Biomedical Exempt Application must be submitted for review of research involving limited data sets at the Exempt level.

The researcher must also execute a Data Use Agreement (DUA) with the data holder prior to release of the limited data set. Generally, the researcher will obtain a DUA from the data holder and contact the UCB Industry Alliance Office (IAO) to have them review and sign the agreement before the researcher signs it. Although the researcher should not attach the DUA in the Attachments section of their CPHS Biomedical Exempt Application, s/he must provide a statement in the Study Procedures section confirming that they will contact/have contacted IAO regarding the DUA. In addition, the Confidentiality section of the researcher's application, where data storage and security for the incoming data is described, should match what is written in the DUA.

F. Respect for Persons and Informed Consent

The Belmont principle of Respect for Persons generally requires that subjects be given the opportunity to choose whether or not to participate in research. For this reason, voluntary informed consent should be obtained from participants for any exempt research where the investigator will be collecting data through interaction with the participant. OPHS does not review consent materials for exempt research but recommends that researchers provide participants with, at a minimum, the information listed below during the consent process and before any data collection begins. In some cases, researchers may find it necessary or appropriate to provide more information or to include a Media Release form.

Minimum Consent Information:

1. The identity/affiliation of the researcher.
2. A clear description of the study procedures and how data will be used in the future.
3. A statement that participation in the research is voluntary.
4. Contact information for questions about the research.
5. The CPHS protocol ID number.

See CPHS FAQ on Informed Consent in Exempt Level Research for more information.

G. Changes/Modifications to Exempt Research

All modifications to a project previously deemed exempt must be submitted to OPHS for review and certification of exemption *prior to implementation*. In some circumstances, proposed changes to the protocol may disqualify the project from exempt status, in which case non-exempt review will be required as appropriate to the level of risk.

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 other exclusion factors under B. above, the researcher must immediately cease research activities until IRB approval is obtained. ***This will require submission of a new application***.

H. Determination Period

Exempt determinations are good for ten years. If the study continues beyond the ten-year period, the protocol must be cloned and re-submitted for an updated exempt determination.