Exempt Review Categories –
revised Common Rule (1/21/19 effective date)

UCR Research Integrity

The revised Common Rule, effective Jan 21, 2019, has 8 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). UCR, along with other UC's, will adopt exempt categories 1 – 6 for research projects meeting the stipulated requirements. It is up to the UCR IRB to determine if a study meets exemption requirements and which category of exemption applies.

Studies eligible for exempt review are those that do not present more than minimal risk to the participants and meets the criteria for one of the six categories below. Informed consent can be verbal, but participants should be provided with the study information through an information sheet or a written script. The UCR IRB strongly recommends that the consent process is documented.

Exempt Category 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.

Examples:

- Evaluating the use of accepted versus revised standardized tests or curriculum
- Testing or comparing curriculum or lessons delivered via a new novel medium
- Evaluating the impact of rearranging classroom furniture on the learning outcomes of students

Additional guidance on Exempt #1

Exempt Category 2

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria are met, :

(i) Recorded information cannot readily identify the subject (directly or indirectly/linked); Children can be included only when Investigators do **not** participate in observed activities; **OR**

(ii) Any disclosure of responses outside of the research would NOT reasonably place the subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation), children can be included only when Investigators do **not** participate in observed activities; **OR**

(iii) Information is recorded with identifiers & IRB conducts Limited Review, children **cannot** be used as a subject population.

Examples:

- Surveying teachers, nurses, or doctors about a technique or an outcome
- Interviewing managers about a management style or best practice
- Conducting a focus group about an experience or an opinion of a community program

Exempt Category 3

Research involving Benign Behavioral Interventions (BBI) through verbal, written responses, (including data entry or audiovisual recording) from an adult subject who prospectively agrees to said intervention and ONE of the following criteria are met:

(A) Recorded information cannot readily identify the subject (directly or indirectly/linked): **OR**
(B) Any disclosure of responses outside of the research would NOT reasonably place the subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation); **OR**
(C) Information is recorded with identifiers.

Additionally, this category may not include any medical interventions, may not include any children and the subject must prospectively agree to the study. The BBI itself must be:

1. Brief in duration
2. Painless/harmless
3. Not physically invasive
4. Not likely to have a significant adverse lasting impact on subjects
5. Unlikely that subjects will find interventions offensive or embarrassing
6. No deception unless the participant prospectively agrees

Examples:

- Playing economic games
- Being exposed to stimuli such as color, light or sound at safe levels
- Solving puzzles under various acceptable noise conditions

Exempt Category 4

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens that have been or will be collected for another, separate primary or initial activity if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;
(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily 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 by HIPAA for the purposes of "health care operations" or "research" or for "public health activities and purposes"

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information, it is subject to specified federal privacy laws:

i. Section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501
ii. 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,
iii. The information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

Examples:

- Analyzing an existing publicly available data set that includes identifiers
- Obtaining biospecimens for analysis from a clinical pathology laboratory without identifiers, and the researcher will continually obtain samples as they are deposited into the pathology laboratory
- A research study conducted on behalf of the USDA, where previously collected USDA census data on agricultural land ownership, including landowner names and addresses, is being utilized.

Exempt Category 5

Research and demonstration projects supported by a Federal Agency/Dept. and designed to study public benefit or service programs. 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) For federally funded projects, the research or demonstration project must be published on the applicable agencies' research list prior to commencing the research involving human subjects

See OHRP's guidance regarding this category

Exempt Category 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

Examples:

- Evaluating taste and food quality of avocados
- Evaluating pomegranates as a healthy lunch alternative in elementary schools
- Taste-testing of various beef products from cattle that have been given feed with vs. without a chemical additive, if the amount of the additive is at or below the levels approved by the USDA

At this time, federal exempt categories 7 & 8 are not going to be implemented in whole or in part at any UC campus, including UCR. Projects falling into one of those categories will be reviewed through Expedited procedures. Exempt studies approved prior to January 21st, 2019, will remain under the exempt determinations from the previous Common Rule.

For additional information regarding Exempt categories, please see OHRPs Exempt Research Determination FAQs.