Exempt Research
(excerpt from section 9 of COMIRB Policies and Procedures)

Certain categories of research, exempt research, are not subject to federal regulations and do not require convened Institutional Review Board (IRB) review and approval.

Research activities that meet the criteria set forth by the federal regulations [45 CFR 46.101(b) or 21 CFR 56.104 (c)(d)] that involve minimal risk may qualify for exemption.

Investigators cannot self-exempt from review. Exempt research is subject to Institutional Review as determined and approved by the COMIRB. Although exempt research is not covered by the federal regulations, this research is not exempt from UCD or the appropriate Affiliate's policies on responsible conduct of research or the ethical guidelines of the Belmont Report.

Exemption of Eastern Colorado Health Care System Research
Projects that are exempt from COMIRB review must be reviewed by the Eastern Colorado Health Care System R&D Committee prior to initiation and then they must be included in its annual review of research projects. For questions contact the VA Research Office.

Limitations on Exemptions:
Research Involving Vulnerable Populations:

- **Children** [45 CFR 46.401(b) (2)]: Exemptions apply to children as research subjects with the exception of:
    - Exempt Category (2). This category only permits exemptions if the project involves educational tests or the observations of public behavior when the investigator does not participate in the activities being observed. Also the provision for exemption with limited IRB review may not be used for research involving children.

      In other words, research involving children cannot be classified as exempt if the research involves:
        - Survey
        - Interview Procedures
        - Observations of public behavior when the investigator participates in the activities being observed.

    - Exempt Category (3). This category may not be used for research involving children.

- **Prisoners** [45 CFR 46.301(a)]: **Exemptions do NOT apply**, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

- **Other vulnerable populations**: Persons who are cognitively impaired, economically/educationally disadvantaged, pregnant, or are fetuses will be reviewed in consideration of their vulnerable status to determine eligibility for exempt status.

Eligible Categories for Exemption

Except for the limitations described above, the following categories are eligible for exemption:

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.

- "Commonly accepted settings" usually involve schools but also includes non-academic settings where education of patients, professionals, clients or other populations is commonly conducted.
- Participation in research should not be a required part of the curricula. Students should be able to refuse participation without penalty.

Educational research protocols are exempt providing all of the following conditions are met:

1. It is conducted in a commonly accepted education setting. "Commonly accepted settings" usually involve public schools, but can include other non-traditional settings such as an automotive garage (e.g. how to do preventative maintenance on a car) or a kitchen where developmentally delayed adults are learning to cook. An educational program that is well established in one area, such as suburban Denver, that is extended to a different area, such as rural Colorado, should not necessarily be considered established or commonly accepted in the new setting.

2. It involves normal educational practices.

   It is important for the reviewer to determine whether the procedures change or alter the educational practices for the location.

3. It does not increase the level of risk or discomfort attendant to normal, routine educational practices.

4. Provisions are made to ensure a non-coercive environment for students who choose not to participate.

   Research should not be a required part of the curricula. Students should be able to refuse participation. Instructor-researchers should minimize the potential for coercion through the anonymous return of data collection instruments. This can be done by the involvement of a neutral third party, a drop box, and other mechanisms.

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 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 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
(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 subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

Category 3: 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 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
(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 subjects, and an IRB conducts a limited IRB review to make the determination required by §ll.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.

Examples of benign behavioral interventions eligible for exemption include having participants 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.

If the research involves deceiving the participants 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.

The reviewer may request that the Investigator provide an "Invitation to Participate" to potential participants when appropriate. The Invitation is an explanatory letter that may include: an explanation of the research project; the duration of participation time; information on how to contact the investigator; a statement indicating anonymity or confidentiality; and an indication that the return of the questionnaire will constitute the subject's consent to participate (a statement of voluntariness).

Category 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:

(A) The identifiable private information or identifiable biospecimens are publicly available;
(B) Information, which may include information about biospecimens, 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, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
(C) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA (i.e., 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
(D) 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, and conducted in compliance with 45 CFR 46.104(d)(4)(iv).

Category 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;
- 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.

Category 6: Taste and food quality evaluation and consumer acceptance studies,

- if wholesome foods without additives are consumed; or
- 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 (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA).

This category applies to two different criteria:

1) Applies to research involving wholesome food without any additives. An example would be a taste-test on different types of oranges from different parts of the country, using normal agricultural practices that do not involve the addition of food additives or chemicals.

2) Applies to research on human subjects who consume plants or animals raised for food products. The FDA has determined levels of safety for various agricultural chemicals, referred to as GRAS (generally recognized as safe) and GRAE (generally recognized as effective) additives which are fed to animals raised for food production. If these additives are given to animals at or below the levels found to be safe by the FDA, the research is eligible for exemption. There are also approved levels for environmental contaminants set forth by the FDA, EPA, or the Food Safety and Inspection Service.