

Exempt Research

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 UCDHSC 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.

Categories of Research Permissible for Exemption

Limitations on Exemptions:

1. 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.

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.

- **Prisoners** [45 CFR 46.301(a)]: **Exemptions do NOT apply.** Convened full board IRB review is required.

- **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.

2. Food and Drug Administration (FDA) Regulated Research Exemptions



The following categories of clinical investigations are exempt from the requirements of COMIRB review:

1. Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review. [21 CFR 56.104(c)]
2. Taste and food quality evaluations 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 or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. [21 CFR 56.104(d)]

Eligible Categories

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

- 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as**
 - a) Research on regular and special education instructional strategies,**

OR

 - b) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods**

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 mentally retarded 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 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.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

a) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects;

AND

b) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

The Colorado Multiple IRB (COMIRB) include loss of insurability in this category.

A study cannot be exempt if both (a) and (b) exist. If there is no risk associated with a subject's response being disclosed, having identifiers will not disqualify a study from exemption. The reviewer will determine whether or not risks exist that would be jeopardizing to the individual if discovered AND if identifying information or linking codes exist.

Please refer to Exempt Category #4 for more information on identifiers.

Oftentimes, the reviewer will request that the Investigator provide an "Invitation to Participate" to potential participants. The Invitation is an explanatory letter 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).

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2), if:

a) the human subjects are elected or appointed public officials or candidates for public office

OR

b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. (Example: research conducted by the Census Bureau).

This category applies to two very different criteria.

The first criterion applies to research subjects who are public officials. Personal identifiers can be collected and published. Subjects that are public officials or candidates give up their right to privacy and confidentiality in lieu of the public's "right to know".

The second criterion applies to research for specific federal programs. Personal identifiers can be collected in this category, but the data is protected by law from being accessed by anyone other than those federal agencies. An example is when an investigator is issued a grant to conduct research by the Department of Justice or the National Center for Educational Statistics. Communication from the sponsoring/funding agency will be used to confirm eligibility for exempt status under this category.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Data becomes identifiable when one or more data elements can be combined with other reasonably available information to identify the person. Identifying information may be linked to specific individuals either directly or indirectly through coding systems.

Existing Data, Document, Records

Existing data refers to records that are 'on the shelf' at the time of the IRB application. This means that exempt research can only be approved if the existing records pre-date the application. Once the project is approved, investigators cannot amend the project to include records that were collected after initial COMIRB approval.

Publicly available data that is identifiable is eligible for exempt review. However, the term 'publicly available' refers to record sets that are readily available to the general public, such as death certificates or legal verdicts.

Records that are not publicly available, such as educational records cannot contain identifying information or maintain links for tracking purposes.

To track data extraction, investigators may keep a list of the records (and cross them off the list after the data has been obtained). For example:

~~John Smith Record #909090~~

~~Mary Jones Record #787878~~

Investigator **cannot** track individual subjects to research records through coding systems. This would establish a link. For example:

John Smith, Record #909090, Research ID- 001

Mary Jones, Record #787878, Research ID- 002

5. **Research and demonstration projects which are conducted by or subject to the approval of Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:**
- a) **public benefit or service programs;**
 - b) **procedures for obtaining benefits or services under those programs;**
 - c) **possible changes in or alternatives to those programs or procedures; or**
 - d) **possible changes in methods or levels of payment for benefits or services under those programs.**

In general, research and demonstration project (e.g. state funded public service programs) do not meet these criteria. This category applies to research examining public benefit programs such as Social Security, Medicaid, Unemployment, and Welfare. The project cannot involve significant physical invasions or intrusions on the privacy and there must be no statutory requirement that an IRB review the project.

This exemption must be specifically invoked only with the authorization of the Department of Health and Human Services or the Secretary of one of the other Federal Departments.

6. **Taste and food quality evaluation and consumer acceptance studies,**
- a) **if wholesome foods without additives are consumed; or**
 - b) **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.

The first criterion 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.

The second criterion 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 that may affect the grass



or grain consumed by grazing food animals such as pesticides sprayed on a field. If the research involves taste testing of food products that come from animals exposed to contaminants and the investigator can demonstrate that the level of contaminants is at or below the approved levels, then the research can be exempt. Research that is subject to FDA regulations must be submitted to the COMIRB for a biomedical review.

How to Submit an Exempt Application

Investigators must submit the COMIRB Exempt Application [F-002] that includes the following information:

1. Problem to be studied
2. Description of the research methods
3. Description of the subject population
4. Expected date of completion
5. Plan for protecting privacy and confidentiality
6. A copy of the proposal if the research is externally funded
7. Supporting documents such as data collection tools, surveys, consents, and Invitation to Participate.

Investigators will submit the Exempt Application to COMIRB to determine whether the protocol meets the criteria for exemption. The application must be signed and dated by the Responsible Principal Investigator.

COMIRB Exempt Review Process

The Exempt Application will be reviewed by one of the IRB Chairs, Expedited/Exempt Manager or designated IRB member. Designated members of the IRB must be sufficiently experienced. They must have at least one year of IRB review experience and have undergone COMIRB Expedited/Exempt training procedures.

Reviewers may confirm the determination, request clarifications/ modifications, or refer the project for review in another research category.

The reviewer will determine whether additional measures are needed to protect the rights and welfare of the research participants. Although there is no regulation requiring informed consent for exempt research, all or some of the elements of informed consent may be required by the reviewer.

Exempt Application determinations are usually returned within 7-14 days. COMIRB will respond in email and writing with the reviewer's determination.

Investigators are responsible for informing the IRB immediately of any unexpected events or changes to the project that could impact the exemption status.

All requests for exemption must include a termination date. The exemption applies until that date or three years, whichever comes first. If the research extends beyond three years then COMIRB will issue a status report to the investigator, the investigator must respond to maintain eligibility for exemption.