



Human Subjects Research Determination

Deciding if an activity is considered Human Subject Research

Investigators are advised to consult with COMIRB to determine whether their activity is considered human subject research. Informal inquiries can be made by telephone, email or through a written communication with the Expedited/Exempt Coordinator, Expedited/Exempt Manager, Chairs, or Directors.

Human Subject Research is based on the definitions of **human subject** and **research** as set forth in the Department of Health and Human Service (DHHS) regulations [45 CFR 46.102(d)] and the Food and Drug (FDA) Regulations [21 CFR 50, 21 CFR 56, 21 CFR 312 and 21 CFR 812].

Results from human subject research may not be published unless Colorado Multiple Institutional Review Board (COMIRB) approval was obtained prior to the conduct of the research. If an Investigator begins a project and later finds that the data gathered could contribute to existing knowledge or that he or she may wish to publish the results, the Investigator should submit a proposal to COMIRB for review as soon as possible. COMIRB does not grant retrospective approvals of human subjects research activities- if COMIRB does not approve the research, the data cannot be used as part of a thesis, dissertation, or publication.

The responsibility for the determination as to whether an activity constitutes human subjects research lies with the investigator. Since the COMIRB will hold the investigator responsible if the determination is incorrect, investigators are advised to consult with the COMIRB Administrative Office.

The investigator can use the “**Decision Tree for Determination of Human Subject Research**” to decide whether a project needs to be submitted to the COMIRB for review. Further guidance is available in the COMIRB brochure **NAVIGATING HUMAN SUBJECT RESEARCH REGULATIONS: Is it human subject research?**

Examples of Activities that are Not Considered Human Subject Research

1. Activities are not research if they are not generalizable or do not use a systematic or ‘step-by-step’ approach that is organized according to a set of interrelated ideas or principles.

Examples include:

- **Medical Case Histories** describing the clinical features or outcome of a single unidentifiable patient that is not generalizable beyond that person, even if the case is published and/or presented at meetings.
- **Course-Related Activities** designed to teach proficiency on a topic. This includes human subject data collection as part of a class assignment that is not intended for



use outside of the classroom. Masters and doctoral level thesis or dissertations do not meet these criteria and will require COMIRB review and approval. Example: classroom exercise on research survey techniques.

- **Data Gathering Activities for Operational Purposes** not intended to create generalizable knowledge. This would include surveys by professional societies or University consortia. Examples: teaching evaluations, customer service questionnaires, JCAHO surveys.
 - **Biography or Oral Histories** involving a living individual that is not generalizable beyond that individual.
 - **Innovative Medical Therapies** designed solely to improve the health of an individual patient, not provide generalizable information. The purpose of the intervention is to provide diagnosis, preventative treatment, or therapy to a particular individual. Please note, emergency use of an investigational product, while not considered human subject research, requires COMIRB review and approval.
 - **Quality Improvement** that meets the following criteria:
 - program initiated by an institution to compare performance to established standards or measure the value of a program to its participants
- AND**
- information will only be distributed to those directly involved in its planning, management and implementation

2. Activities do not involve human subjects if the investigator does not obtain data about a living individual.

Examples include:

- **Research Involving the Deceased** cadavers, autopsy specimens or data/information on deceased individuals do not qualify as human subjects. If the research requires the collection of Private Health Information (PHI), the researcher must obtain clearance from the Privacy Officer via a decedent form.
- **Research Involving Animals** research involving animals, animal tissue, or animal cell lines are not human subject research. These projects are submitted to the Institutional Animal Care and Use Committee (IACUC) for review and approval.
- **Interviews or Surveys that Focus on Things, Processes, or Policies** rather than people or their thoughts regarding themselves. Example: canvassing librarians about inter-library loan policies or rising journal costs.

3. Activities are not considered human subject research if an investigator conducting research is not obtaining (1) data through intervention or interaction with the individual or (2) identifiable private information.*

Examples include:

- **Research on Publicly Available Information** This includes non-identifiable and publicly available data or specimens. However, the term 'publicly available' refers to record sets that are readily available to the general public, such as census data, crime statistics, or election returns. A researcher should not assume that



information is 'publicly available' because it has been posted on a website or that specimens are 'publicly available' because they can be purchased through a repository.

■ **Research on human cells lines about which all information has been published** (e.g. HeLa cell lines)

* Please note, in research involving devices, unidentified tissue specimens are human subjects- when the research is to determine the safety or effectiveness of the device and the data will be submitted to or held for inspection by the FDA.

Submitting to COMIRB for a Human Subject Research Determination

For those cases in which a determination cannot be clearly made or the funding agency is requiring a written IRB determination, the Investigator can submit an Exempt application to COMIRB.

Investigators can submit one copy of 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. Indicate that the project has been submitted for a "*Not Human Subjects Research*" determination
6. Supporting information and materials such as:

- A copy of any data collection instruments, surveys/questionnaires, etc.
- If the project involves the collection of publicly available information, the source of the data and data elements.
- If the project involves laboratory analysis of discarded specimens, the original purpose of collection, who collected the specimens, whether clinical consent included a release for research, how the investigator will obtain specimens, and what data or links, if any, will accompany the specimens.
- If the project involves coded information or specimens, a copy of the written agreement that prohibits the release of identifiers. A template 'Coded Information Agreement' is available from the Expedited/Exempt team.

All requests must include sufficient detail of the activity to support the determination. The application must be signed and dated by the Responsible Principal Investigator.

COMIRB Not Human Subject Review Process

Exempt applications will be reviewed by the Chairs, Expedited/Exempt Manager or designated member of the IRB. 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.

Determinations are made according to whether the activity meets the definition of “research” and involves “human subjects” using the **COMIRB REVIEWER PROTOCOL CHECKLIST- EXEMPT and NOT HUMAN RESEARCH.**

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