IRB Decision Tree #1

Colorado Mesa University

Does my project require IRB approval?

Will you, a member of your research team or, a collaborator <u>observe, interact with, or intervene with living individuals to gather information</u> that will be used for research?
Examples:

- Surveys, questionnaires, focus groups, interviews
- Physical/Electronic games, experiments, or tasks
- Biomedical/Physical procedures, e.g. imagine, scanning, blood collection, exercise, etc.
- Diet or nutrition studies, taste tests
- Studies on effectiveness of educational strategies, teaching methods, curricula
- Use of instruments, sensors, electronic devices, apps, software, or recording mechanisms (e.g., video, screen capture, key logging, etc.) to collect data or monitor or influence behavior
- Passive observation of private behavior (in physical/online environments, incl. social media)
- Studies examining individuals' responses to manipulation of their physical/online environment
- Any other activity that involves observation of, or interaction with, individuals to gather information for research (in physical or online environments, including social media)

Adapted from Iowa State University, Office of Research Ethics.

YES

NO *i*

Refer to IRB Decision Tree #2 (Secondary Use of Data) and/or Non-human Subject Research guidance, as applicable.

Is the information being collected 'about' individuals?

YES *i*

NO *i*

This is <u>not</u> human subjects research. IRB review/approval is NOT required.

Refer to the "Request for Waiver IRB Application for Class Projects" form. *i*

Is this a class assignment or project?

NO

YES

Is the sole intent of the project to meet course requirements, **and the results <u>will not</u> be used for something other than the course assignment?**

YES

NO *i*

Is the project an **oral history, ethnography, or journalistic piece**?

YES

NO

Is this a **quality assurance / quality improvement / organizational effectiveness study**?

This project is research with human subjects and IRB approval OR determination of exemption IS REQUIRED before the study may begin. Questions? Contact irb@coloradomesa.edu

NO

YES

Will information be used by the researchers to **draw broad conclusions about a population, culture, or norms and practices** even if no research hypothesis is being tested or validated?

YES

Is there **intent to generalize outcomes** for other organizations, programs, or services?

NO *i*

This is <u>not</u> human subjects research. IRB review/approval is NOT required.

NO *i*

YES

YES

(HOVER OVER INFO ICON *i* TO SEE HELP/ADDITIONAL GUIDANCE)

Does My Project Require IRB Approval?

(Adapted from Iowa State University, Office of Research Ethics)

Step 1 – Interaction with Living Individuals

- Question: Will you, a member of your research team, or a collaborator *observe, interact with, or intervene with living individuals* to gather information for research purposes?
- Examples of activities:
    - Surveys, questionnaires, focus groups, interviews
    - Physical/electronic games, experiments, or task
    - Biomedical/physical procedures (e.g., imaging, scanning, blood collection, exercise)
    - Diet or nutrition studies, taste tests
    - Studies on teaching methods, educational strategies, curricula
    - Use of instruments, sensors, apps, or recording devices (video, screen capture, key logging, etc.)
    - Passive observation of private behavior (in physical or online environments, including social media)
    - Studies examining individuals' responses to manipulation of their environment (physical or online)
    - Any other activity that involves observation or interaction with individuals to collect research data
- If *NO*: Refer to *IRB Decision Tree #2* for Secondary Use of Data or Non-Human Subjects guidance.
- If *YES*: Proceed to Step 2.

Step 2 – Is the Information 'About' Individuals?

- If *NO*: This is not human subjects research. IRB review/approval is NOT required.
- If *YES*: Proceed to Step 3.

Step 3 – Is this a Class Assignment or Project?

- If *YES*:
    - Is the sole intent of the project to meet course requirements, and results will not be used for anything beyond the class assignment?

        - If *YES*: Not human subjects research. IRB review not required.
        - If *NO*: Proceed to Step 4.
        - If *NO*: Proceed to Step 4

Step 4 – Oral History, Ethnography, or Journalism?

- If *YES*:
- Will information be used to draw broad conclusions about a population, culture, or norms/practices (even if no formal hypothesis)?
    - If *NO*: Not human subjects research. IRB review not required
    - If *YES*: Proceed to Step 6.
- If *NO*: Proceed to Step 5.

Step 5 – Quality Assurance/Quality Improvement (QA/QI) or Organization Effectiveness Study?

- If *YES*:
- Is there intent to generalize outcomes for other organizations, programs, or services?
    - If *NO*: Not human subjects research. IRB review not required
    - If *YES*: Proceed to Step 6.
- If *NO*: Proceed to Step 6.

Step 6 – Determination of Human Subjects Research

- If you answered *YES* in previous steps:
    - This project involves research with human subjects.
    - IRB approval OR a determination of exemption is required before starting the study.
    - Questions? Contact irb@coloradomesa.edu

Additional Notes

1. If no interaction with living individuals occurs, your project may involve secondary use of information or specimens.
2. Information about people includes their behaviors, attitudes, opinions, personal characteristics, demographics, decisions, reactions, biological specimens, and physiological responses.

3. Data limited to factual information (not opinions or attitudes) about products, methods, policies, procedures, or organizations may not qualify as human subjects research.
4. The CMU IRB reviews all projects involving human participants.
5. If results may be shared outside the classroom (e.g., publication, conference, thesis), the project may require IRB approval.
6. QA/QI studies specific to one organization, program, or service may not need IRB review unless intended to be generalized.
7. Published materials limited to specific events, policies, or institutions without intent to generalize may not need IRB approval.