

IRB Decision Tree #1

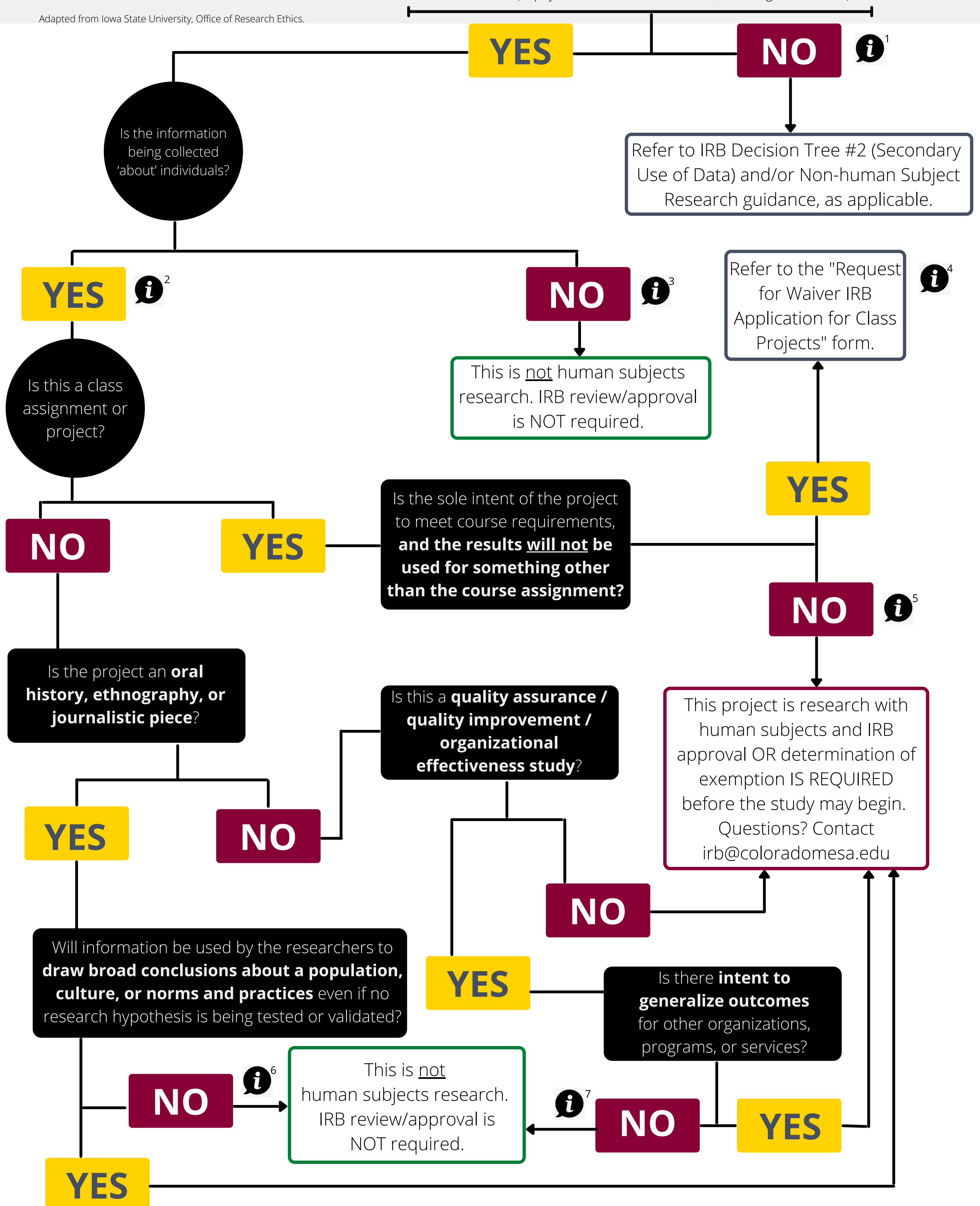
Does my project require IRB approval?

Will you, a member of your research team or, a collaborator observe, interact with, or intervene with living individuals to gather information 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.



Note 1: If you, a member of your research team or, a collaborator are not *observing, interacting with, or intervening with living individuals to gather information* that will be used for research, then you are doing research involving secondary use of information/specimens.

Note 2: The project gathers information about people (their behaviors, attitudes, opinions, personal characteristics, demographics, decisions, reactions to stimuli, biological specimens, physical or physiological responses, etc.).

Note 3: Data will involve only factual information (not opinions, attitudes, beliefs, etc.) on products, methods, policies, procedures, or organizations (e.g., interviewing school staff about school policies or factual information).

Note 4: The Colorado Mesa University (CMU) Institutional Review Board (IRB) must review all projects that involve human participants. Student projects conducted within an academic course may be categorized as either a course assignment or disseminated research. Course Assignment/Project includes human participant data collected during or outside of class by students enrolled in an official course, as well as activities for a course that involve persons not part of the course. Course assignments involving research activities are considered educational in nature and not subject to IRB review. This Request for Waiver Form must be submitted to the IRB. Disseminated Research includes human participant data that are formally presented to any audience beyond the course (e.g., poster, oral presentation, written paper, seminar, Show Case etc.). In this case, contact the IRB to complete the appropriate protocol and the project will need to be approved.

Note 5: The results of the project may be shared outside of the classroom (e.g., for publication, presentation at academic conferences, in a thesis/dissertation/graduate creative component, etc.) or departmental/interdepartmental seminars designed to exhibit coursework. A prime example of this would be sharing results, data, etc., at Student Showcase.

Note 6: Outcomes will remain specific to the organization, programs, or services, although other organizations may use the results for their own programs.

Note 7: Published materials will be limited to only documenting or reporting on specific events, situations, policies, institutions or systems without the intent to generalize the outcomes for other organizations, programs, or services.

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.