IRB Operating Principles

Mission

The primary mission of the Institutional Review Board (IRB) at Rocky Mountain College (RMC) is the protection of the rights, welfare and wellbeing of human subjects who participate in research at RMC. The RMC IRB follows the ethical standards described in the Belmont Report, as well as all applicable federal, state and local regulations. In addition to those regulations, the IRB abides by RMC's institutional policies and procedures.

Jurisdiction of the Institutional Review Board

1. All research (except as exempted) conducted by faculty, students and staff of RMC that involves human subjects must be approved by the Institutional Review Board. This requirement applies to unfunded research, research funded by the federal government, and research funded by other sources.

2. Certain kinds of research involving human subjects require limited Institutional Review Board review and approval. These categories of exempt research are described in the Code of Federal Regulations, 45CFR46.104 and in the Types of Research reviewed by the IRB document.
    1. While researchers should note on their application which exemption they believe applies to their research, **researchers can not certify their own projects as exempt**. This determination must be made by the IRB.
    2. Investigators who believe that their research may be exempt should submit the required materials to the IRB using **Track 1 section of the IRB moodle page**.

3. Researchers conducting class-based and program evaluation-style research projects that use human subjects are not systematic or generalizable —i.e. they are not intended to use surveys, tests, or evaluation in order further generalizable knowledge in the field via publication or another form of dissemination outside of the classroom or institutional setting — must request a *non-reviewable determination letter* from the IRB using the **Track 2 submission portal on the IRB moodle page**.

4. Researchers whose projects use involve human subjects but whose focus and methods fit the definition scholarly activities that are exempt from review as spelled out in CFR 45 §46.104 [l] [1] should request from the IRB a determination of *non-reviewable* using the Request for non-reviewable determination letter template on the IRB web page.

> *"Scholarly and journalistic activities (e.g. "oral history, journalism, biography, literary criticism, legal research, or historical scholarship) that focus directly on the specific individuals about whom the information is collected" "oral history, journalism, biography, literary criticism, legal research, or historical scholarship".* *CFR 45 §46.104 [l] [1]*

Rules and Regulations Governing the Institutional Review Board

1. The Board operates under rules defined in the Code of Federal Regulations 45CFR46, March 8, 1983 and The Belmont Report (Ethical Principles and Guidelines for the Protection of Human Subjects of Research) prepared by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

Approval and Disapproval of Proposals

5. Except for research exempted or waived under Section 104 of the Federal Policy, all human subject research will be reviewed, prospectively approved, and subjected to continuing oversight, as applicable. The Institutional Review Board will have authority to approve, require modifications in, or disapprove the covered human subject research. For a proposal to be approved, its benefits must outweigh the risks to the subjects, it must conform to the ethical principles in the Belmont Report and there must be appropriate methods for obtaining informed consent from the subjects. In summary:
    a. The need to do experiments in humans as opposed to experimental animals must be demonstrated.
    b. Risks to subjects must be minimized.
    c. Risks must be reasonable in relation to anticipated benefits of research.
    d. Selection of subjects must be fair.
    e. There must be procedures for obtaining and documenting informed consent.
    f. There must be provisions to protect the privacy of subjects and maintain confidentiality of records.
    g. There must be appropriate additional safeguards to protect the rights of children, economically or educationally disadvantaged persons, severely ill persons, mentally ill persons and prisoners.

6. The RMC IRB operates by consensus. To be approved, a protocol must receive a majority vote (>50%) from the members present in a virtual or physically convened meeting, as long as there is a quorum present at the meeting. To achieve a quorum, at least one more than half the number of regular IRB members (i.e., a majority), including a nonscientist, must be present. The IRB cannot review research if a quorum is not present. The board may lose quorum if members recuse themselves due to a conflict, or if the nonscientist has to leave the meeting. If the quorum is lost, then the protocol being considered will be tabled until it can be reconsidered at a meeting where sufficient members are present to meet a quorum, even with recusals. Any member's request for clarification or revision of an application will be documented in the IRB's final decision. The numbers of members voting For or Against will be recorded in the minutes.

7. Within 10 days of Board review, investigators will receive written notification of approval, disapproval or the changes necessary before approval will be given. Reasons for disapproval will be communicated to the investigator.

8. Approvals are for a period of one year, unless the Board votes to impose a shorter period of approval. Approximately one month prior to expiration of approval, the IRB will send renewal forms to the investigator to be returned for reapproval prior to the expiration date. Protocols can be renewed for up to 5 years.

9. Investigators will be given an opportunity to appeal any disapprovals or unfavorable decisions of the Board.

Meetings

10. The Board will meet monthly, typically on the second Monday of the month, and will consider all proposals submitted one week prior to the meeting. Proposals are due by noon on the first Monday of the month.

11. The Board may convene physically or virtually. The decision about whether/ when to virtually convene the IRB virtual convened meetings will be made on a case-by-case basis and should be one that the IRB members unanimously support as indicated by their responses to an email circulated to all IRB members. Projects may not be disapproved via a virtually convened meeting. To disapprove a project, the IRB must physically convene.
    a. If there is unanimous agreement that the virtually convened meeting is appropriate, the IRB chair emails the group with a "request for feedback". The group then proceeds to use email to "discuss" their views on the project and to voice their thoughts on any aspects of the IRB submission that require attention. After all members have replied to the request for feedback (either with feedback or with an "I have no additional feedback" email), the IRB sends a "call for a vote" email that the group replies to in order approve the project. Quorum status at virtual meetings will be determined by Board members' participation in email strings.

Consultants:

12. The IRB may use non-member consultants for advice and information in specialized areas as needed. These consultants may be RMC faculty, staff, or students, or may be unaffiliated with RMC. The IRB Chair is responsible for arranging for the use of formal consultants. The formal consultants may be asked to present their assessments in writing or to attend IRB meetings in person or by phone. Consultants do not vote during IRB meetings and are bound by the same confidentiality and conflict of interest disclosure requirements as all other attendees at an IRB meeting. In addition, IRB members may directly contact non-member colleagues for information that would be helpful for their reviews; in this case, the IRB member will remind the colleague of confidentiality obligations and will document in the electronic system that an informal consultation took place.