STEP DEFINITION GUIDE

Step by Step Guide to Apply to the Institutional Review Board

The Institutional Review Board (IRB) is a federally mandated committee that provides oversight for all research activities with the aim to protect the rights and welfare of the human subjects recruited to participate in research. In the United States, the Food and Drug Administration (FDA) and Department of Health and Human Services (specifically Office for Human Research Protections) regulations have empowered IRBs to approve, monitor, and review biomedical and behavioral research.

Research, whether funded or unfunded, involving human subjects conducted by any member (faculty, staff or student) of Colorado Mountain College (CMC) or anyone using CMC facilities must go through the IRB review process. The IRB will ensure that research is conducted in a manner that does not infringe on the subjects' safety, health, welfare or well being and ensures institutional compliance with related federal regulations. Title 45 CFR (Code of Federal Regulations) Part 46 provides a guideline for the protection of human subjects involved in research.

The purpose of this document is to provide a step by step guide for faculty, staff and students of Colorado Mountain College who plan to do research that involves human subjects. Please review the following steps to determine if you need to apply to the IRB before conducting your research.

Step 1

First determine if the work that you are doing is research as defined below.

Research as defined by the Code 45 CFR 46.102 (d) is a "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

Examples of systematic investigation include:

- Surveys and questionnaires
- Interviews and focus groups
- Analyses of existing data or biological specimens
- Epidemiological studies
- Evaluation of social or educational programs
- Cognitive and perceptual experiments

Contributing to Generalizable Knowledge means that your research will be published in some form (e.g. thesis or journal article or presentation at conferences).

*If **"yes"** your activity is considered research, then refer to the definition of a human subject to determine if human subjects are involved in your research.*

Human Subject as defined by the Code 45 CFR 46.102 (f) is "a living individual about whom an investigator (whether professional or student) conducting research obtains:

1. Data through intervention or interaction with the individual, or
2. Identifiable private information

*If "**yes**" your activity involves human subjects and identifiable information is obtained from those individuals, then you need to seek IRB approval prior to data collection. NO activity may begin prior to receiving IRB approval.*

*If "**no**" your activity is not considered research and does not involve human subjects, then you may stop here and you do not need to submit your application to IRB.*

Once you determine that your work is research involving human subjects, please precede to Step 2.

Step 2

Completion of Mandatory On-line Training

Anyone who is planning to submit an application to the IRB will be required to go through free on-line research ethics training from the Department of Health and Human Resources. Human Protection Research Training: HHS

You need to complete the registration process before you can start your training. Please make sure that you have included the certificate of completion with your application.

To determine which review process your research needs to go through, please read the detailed information about different types of review processes in Step 3.

Step 3

There are three types of reviews:

1. **Exempt**
2. **Expedited**
3. **Full Board**

1. EXEMPT REVIEW

Types of research projects eligible for exempt review include:

- Research conducted in established or commonly accepted educational setting, involving normal educational practices. (e.g. classroom activities that are solely instructional).

- Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior if there is no identifiable information and the topic is non sensitive.
- Research involving elected or appointed public officials or candidates for public office.
- Research involving the collection of existing data or documents, if publicly available or subjects are unidentifiable.
- Research or evaluation involving public benefit or service programs.
- Taste and food quality evaluation and consumer acceptance studies.
- Research that has been already been approved by another IRB. Identify institution where research has been approved. A letter of approval must be attached to application.

Classroom activities that may qualify for an Exempt Review includes student course work supervised by faculty with the purpose of developing students' research skills, does not involve sensitive subject matter and will not be disseminated publicly or published.

Even though your research falls into one of the seven categories mentioned above, you will still need to submit an application to the IRB. Please remember that **only** the IRB can make this decision and can provide you with proof that your research has been granted Exempt Status.

For more details on exempt criteria, please refer to the appropriate section in CMC IRB Policies and Procedures Manual.

Form Required For Exempt Research: ***Exempt Application Form***

Exempt Review Process: The IRB Chair or a person designated by the IRB Chair will review the proposal once it is received by the Office of Institutional Research.

- Once the proposal is reviewed, you will be notified via email/letter about the recommendation.
- The recommendation will be either:
    a) approved as an exemption
    b) approved with condition
    c) resubmit for expedited review
- If your proposal is approved, then you may begin your research.
- If your proposal is conditionally approved as exempt, then you will be asked to make revisions or provide additional documents for approval.
- After you make your revisions or provide additional documents and resubmit your proposal, it will be reviewed again and will be either approved as exempt or you will be asked to resubmit for expedited review.

If your proposal is recommended to be reviewed through the expedited process, then please read the expedited review process for more information.

Exempt Review Process Timeline: The exempt review can take 1 to 2 weeks depending on the recommendation of the reviewer. Updates about the application will be communicated via email/letter.

2. EXPEDITED REVIEW

If your research involves human subjects and does not qualify for exemption, then you must apply for an expedited review.

Types of research projects eligible for an expedited review include:

- No more than minimal risk according to the federal guidelines.
- Minor changes in previously approved research during the period (one year or less) for which approval was granted.
- Any proposal that was reviewed before as exempt and was recommended by a reviewer to be reviewed as expedited.

"Minimal Risk" as defined by CFR 46.102 (i) means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during performance of routine physical or psychological examination or tests.

Form Required For Expedited Research: ***Expedited and Full Board Application Forms***

Expedited Review Process: The expedited application will be initially reviewed by two different IRB board members once it is received by the Office of Institutional Research.

- Each member will make a recommendation. Recommendation will either be:
    a) approval
    b) conditional approval or
    c) resubmit as a full board review
- If you get an email/letter that states that your proposal is approved by the IRB, then you can begin your research.
- Conditional approval means that you must make some revisions or provide additional documents and resubmit the proposal for approval.
- Upon resubmission, your proposal will be reviewed again and recommendation will either be approved, or you will be asked to submit for full board review.
- If your proposal is recommended for full board review, then you will be provided with additional information about the full board meeting dates and an invitation to attend the meeting.

Expedited Review Process Timeline: The expedited process can take from 1to 3 weeks, depending on the recommendation of the reviewers. Updates about the application will be communicated via email/letter.

3. FULL BOARD REVIEW

If your research is not covered by either an exempt review or an expedited review, or if your research involves more than a "minimal risk," then you must apply for a full-board review. Usually proposals involving vulnerable populations or collecting blood samples, human tissues or any other bodily fluids must be reviewed by full committee.

Form Required For Full Board Research: ***Expedited and Full Board Application Forms***.

Full Board Review Process: When a proposal is reviewed by the full-board

- Each committee member will review your research, discuss and provide recommendation at the convened IRB meeting.
- After that meeting, you will be notified via email/letter about the recommendations.
- If you receive an email/letter that states your proposal is approved then you may begin your research.
- But if it is conditionally approved then you will be asked to make some revisions and resubmit your proposal for approval.
- In order to have your proposal reviewed at the next IRB meeting, you must submit your application by the deadline for that meeting.
- If your proposal is going to be reviewed as full board, then you will also be notified with the meeting date and an invitation to attend the meeting.

Full Board Review Process Timeline: The full board review will take at least 4 weeks, depending on the date when the next IRB meeting is scheduled.

Step 4

Required Documents to Submit Your Application

- Completed Exempt Application Questionnaire or Expedited/ Full Board Application Forms
- Final version of Informed Consent document (if participant s are minor, parental consent or minor consent is required)
- Additional documents used in research (e.g. surveys, flyers, etc.)
- Submit Human Protection Research Ethics Training Certificate from HSS

For more details on informed consent, please refer to the appropriate section in CMC IRB Policies and Procedures Manual.

Once you determine that your research requires IRB approval, you need to submit your application to the IRB through the Office of Institutional Research

Step 5 Await decision of the IRB.