



Institutional Review Board (IRB) Manual

Policies and Procedures

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Contents

BACKGROUND.....	5
DEFINITIONS.....	5
APPLICATION OF POLICY	8
STATEMENT OF ETHICAL PRINCIPLES	8
RESPONSIBILITIES OF THE IRB.....	8
HIPAA COMPLIANCE.....	9
Research that is covered by HIPAA	10
Use and Disclosure of PHI for Research.....	10
Authorization of Use	10
Waivers of the Authorization Requirements	11
De-Identified Data.....	11
Limited Data Set with a Data Use Agreement	12
Recruitment of Subjects.....	13
MEMBERSHIP OF THE IRB	13
Member Nomination, Selection and Service	14
Alternate Members.....	14
Responsibilities of IRB Members	14
Additional IRB Member Responsibilities for Research Involving Sharing Data or Specimens.....	15
Responsibilities of IRB Chair and Vice Chair	15
Evaluation of IRB Members	17
MEETINGS AND RECORDS.....	17
The Meeting.....	18
Order of Business.....	18
Actions	18
Conflict of Interest	18
Minutes	19
Attendance by non-IRB members.....	19
IRB Records	19
IRB Related Documents	19
Protocol Related Documents	20
CRITERIA FOR APPROVAL OF RESEARCH.....	20

TRAINING REQUIREMENTS	23
PROTOCOL CRITERIA AND SUBMISSION PROCEDURES	23
Non-Human Subjects Research Activities	23
Quality Improvement / Assurance	24
Program Evaluation.....	24
Activities Defined as Human Subjects Research	25
Criteria for Exempt Review	25
Criteria for Limited Review	28
Criteria for Expedited Review	29
Criteria for Full Review.....	30
REVIEW PROCESSES	30
Non-Human Subjects Research Activities	30
Activities Defined as Human Subjects Research	30
Exempt Review.....	31
Limited Review	31
Expedited Review.....	31
Full Review	31
CONTINUING REVIEW, MINOR CHANGES, AND COOPERATIVE RESEARCH.....	32
Continuing Review	32
Changes to Approved Research	32
Cooperative Research	32
IRB Authorization Agreement	32
PROTOCOL CLOSURE.....	33
PRINCIPAL INVESTIGATOR RESPONSIBILITIES.....	33
Prior to Proposal Submission	33
Following IRB Approval	34
STUDENTS AS RESEARCHERS.....	35
Activities Involving Data Collection.....	35
Student Research Projects	36
STUDENTS AS SUBJECTS.....	36
Underage Students	36
Potential for Coercion.....	36

Requiring Research Participation.....	37
SURVEYS.....	37
CMU TRADEMARKS AND LICENSING	37
Permission for Use of Content.....	37

BACKGROUND

Colorado Mesa University (CMU) has a moral and legal responsibility to safeguard the rights, welfare, and dignity of human subjects involved in research. CMU is committed to the ethical principles for the protection of human subjects in research set forth in the Belmont Report of the National Commission of the Protection of Human Subjects of Biomedical and Behavioral Research (1979) and the Declaration of Helsinki. In addition, CMU is committed to insuring that all human subject research, regardless of funding source, follow the federal requirements as set forth in Title 45 Part 46 of the Code of Federal Regulations [45 CFR 46].

A vital safeguard of the privilege of conducting research involving human subjects is the institutional review of all research projects to minimize the possibility of unacceptable or unnecessary levels of risk to the rights, welfare, and dignity of human subjects. Careful review of this type also enhances the likelihood that any given research project will yield results that are accepted as valid by the scholarly community. Toward this end, and to comply with the requirements of federal law, CMU has created a Human Subjects Committee, known as the Institutional Review Board (IRB). To assist the individual researcher in protecting the rights of human subjects and to minimize the potential legal liability of the investigator and the university should a human being be placed at risk, the IRB is instructed to review all projects involving human subjects. The CMU IRB for Human Subjects is registered with the federal government (IRB00010588).

DEFINITIONS

“Certification” means the official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

“Clinical Trial” means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

“Department Head” or “Agency Head” means the head of any Federal department or agency, for example, the Secretary of HHS, and any other officer or employee of any Federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated.

“Federal Department” or “Federal Agency” refers to a federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (e.g., the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency).

“Federal Policy” and “Common Rule” shall mean the federal regulations in 45 CFR 46.

"Generalizable knowledge" means any activity that would include (1) knowledge that contributes to a theoretical framework of an established body of knowledge, (2) the results are expected to be

generalized to a larger population beyond the site of data collection or population studied, and (3) the results are intended to be replicated in other settings.

“Harm” means injury or damage which can be physical, psychological, and / or social and economic.

“Human Subject” means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

“Interaction” includes communication or interpersonal contact between investigator and subject.

“Intervention” includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

“Identifiable Biospecimen” is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

“Identifiable Private Information” is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

“Institution,” “University,” and “CMU” shall mean Colorado Mesa University.

“Institutional Review Board” and “IRB” shall mean the Human Subjects Committee.

“IRB Approval” means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

“IRB Authorization Agreement (IAA)” refers to a formal, written agreement that allows an institution holding a Federal-Wide Assurance (FWA) to cede / defer IRB review to a second FWA-holding institution.

The “IRB of Record” is responsible for the initial and ongoing review of a human participant research project, as designated by an executed IAA.

“Minimal Risk” 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 the performance of routine physical or psychological examinations or tests.

“Legally Authorized Representative” means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

“Private Information” includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which

has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

“Public Health Authority” means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

“Research” means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

A “Systematic Investigation” involves a predetermined method or plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory. A “systematic Investigation” incorporates collection of data, either quantitative or qualitative, or specimens and analysis, and may involve randomization of individuals to different treatments, regimens, or processes to prove or disprove a hypothesis.

“Written” or “In Writing” refers to writing on a tangible medium (e.g., paper) or in an electronic format.

APPLICATION OF POLICY

This policy applies to all faculty, staff, and students whenever they are supervising or conducting a research activity involving human subjects, regardless of whether the subjects are members of the university community. Both funded and unfunded research activities are covered by this policy [45 CFR 46.103 (b)(1)].

No research involving human subjects may be conducted by CMU faculty, staff, or students prior to approval being granted under the appropriate provisions of this policy. This restriction applies equally to all categories of review. No contact of any kind may be made for purposes of research with actual or prospective subjects until after the appropriate informed consent form has been reviewed and approved or a waiver of informed consent has been granted by the CMU IRB [45 CFR 46.116].

STATEMENT OF ETHICAL PRINCIPLES

The following broad principles are the basis for CMU's policy concerning review of research involving humans:

Whereas, the participation of humans in research projects may raise fundamental ethical and civil rights questions, all such research, funded and unfunded projects, sponsored and unsponsored which is carried out by faculty, students, or other University employees, on or off campus, shall be covered by this policy.

- A. All activities involving humans as subjects must provide for the rights, safety, health, and welfare of each individual.
- B. The direct or potential benefit to the subject and / or the importance of the knowledge gained must outweigh any inherent risk to the individual.
- C. Participation in research must be voluntary and informed consent procedures must conform to this policy and federal regulations.
- D. An individual does not abdicate any rights by consenting to be a research subject. A subject has the right to refuse to participate or may withdraw from research at any time without penalty or loss of benefits to which the subject would otherwise be entitled.
- E. Safeguarding information about an individual that has been obtained in the course of an investigation is a primary obligation of the Principal Investigator.
- F. The primary responsibility for protection of human subjects rests with the Principal Investigator, with support, approval, and monitoring by the University as set forth in this policy.

RESPONSIBILITIES OF THE IRB

Federal and state regulations mandate that research involving human participants must be reviewed and approved by an Institutional Review Board (IRB) provided for in its assurance filed with the Office of Human Research Protections and will be subject to continuing review by the IRB. The IRB is responsible for providing guidance and oversight for the human participant protection program and for helping to maintain compliance with applicable laws, regulations, and policies. The IRB is responsible for the following oversight functions:

- A. Determine what activities constitute human participant research.

- B. Review, approve, require modifications of (to secure approval), or disapprove all research activities covered by this policy prior to the commencement of the research.
- C. Require that information given to participants as part of informed consent is in accordance with appropriate laws, regulations, and international standards. The IRB may require that additional information be given to the participants when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of participants.
- D. Require documentation of informed consent or waive documentation in accordance with federal and state laws and regulations. When research activities are being proposed to be conducted in other states and / or countries by CMU faculty, staff, and / or students, the research activities will be approved in compliance with the regulations for those specific research locations.
- E. Notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
- F. Conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, (unless the research has been classified as "Exempt") and have authority to observe or have a third party observe the consent process and the research.
- G. Suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional official and the department or agency head.

HIPAA COMPLIANCE

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) was written to allow for insurance portability, but also as a Privacy Rule to protect the privacy and security of a person's identifiable health information, and is primarily concerned with information generated in the course of providing health care services, and is not primarily concerned with research. However, HIPAA does recognize and endorse the fact that some research may create, use, and disclose Protected Health Information (PHI).

A person's PHI includes all individually identifiable health information either created or received by a health care entity. This includes information about the past, present or future physical or mental health of a person, and the provision of health care to a person, or payment for care. It also includes information in written, electronic, or oral form, and information created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse.

In order to understand whether HIPAA rules apply to a research project, it is first necessary to determine whether the activity would be considered research. For this, HIPAA uses the same definition as the federal Common Rule [45 CFR 46], which is a systematic investigation designed to contribute to generalizable knowledge.

Research that is covered by HIPAA

HIPAA affects only that research which uses, creates, or discloses PHI. In general, there are two (2) ways a research study would involve PHI:

1. The study involves review of medical records as one (or the only) source of research information. Retrospective studies involve PHI in this way. Prospective studies may do this also, such as when a researcher contacts a participant's physician to obtain or verify some aspect of a person's health history.
2. The study creates new medical records because as part of the research a health-care service is being performed, such as testing of a new way of diagnosing a health condition or a new drug or device for treating a health condition.

Most sponsored clinical trials that submit data to the US Food and Drug Administration (FDA) will involve PHI because study monitors have an obligation to compare research records such as Case Report Forms (CRFs) to the medical records of the persons participating in the study, in order to verify that the information transcribed onto the CRFs is accurate.

Use and Disclosure of PHI for Research

HIPAA permits the use or disclosure of PHI for research under the following circumstances and conditions:

- If the subject of the PHI has granted specific written permission through an Authorization of Use;
- If the IRB has granted a waiver of the authorization requirement;
- If the PHI has been de-identified in accordance with the standards set by HIPAA; or
- If the information is released in the form of a limited data set, with certain identifiers removed, and with a data use agreement between the researcher and the covered entity.

Authorization of Use

The HIPAA equivalent of consent for use or disclosure of a person's PHI required an authorization form to include:

- Specific description of what PHI will be used or disclosed;
- Who may use or disclose PHI;
- Who may receive the PHI;
- Purpose of the use or disclosure;
- Statement of how long the use or disclosure will continue. "No expiration date" is allowed for research purposes;
- Right to revoke authorization;
- Notice that the information may be disclosed to others not subject to the Privacy Rule;
- Right to refuse to sign authorization; and
- The subject must sign the form and receive a signed copy for the authorization to be valid.

The HIPAA authorization can be a separate document from the consent form, or the required elements can be incorporated into the consent form.

Authorization should be obtained in each of the following two (2) circumstances:

1. When requesting permission from a patient to have their name, address and phone number or other health information released to an investigator for recruitment into a research study; or
2. When enrolling a subject into a specific research study to request permission to collect their PHI as related to the research study. This second circumstance occurs simultaneously with the consent process.

Waivers of the Authorization Requirements

For some types of research, it is impracticable for researchers to obtain written Authorization from research participants. To address this type of situation, the Privacy Rule contains criteria for waiver or alteration of the Authorization requirement by an IRB or a Privacy Board. Under the Privacy Rule, either board may waive or alter, in whole or in part, the Privacy Rule's Authorization requirements for the use and disclosure of PHI in connection with a particular research project.

A Waiver of Authorization can be obtained if the following three (3) criteria have been met:

1. The research is no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
 - a. an adequate plan to protect the identifiers from improper use and disclosure;
 - b. an adequate plan to destroy the identifiers at the earliest opportunity;
 - c. adequate written assurances that the PHI will not be reused or disclosed to any other person or entity except;
 - i. as required by law;
 - ii. for authorized oversight of the research study; or
 - iii. for other research for which the use or disclosure of the PHI is permitted by the privacy rule.
2. The research cannot practicably be carried out without a waiver; and
3. The research cannot be done without this specific PHI.

De-Identified Data

Health information is considered de-identified when it does not identify an individual and the health care entity has no reasonable basis to believe that the information can be used to identify an individual.

Research involving de-identified data will not be required to adhere to HIPAA regulations requiring authorization.

De-identified data includes none of these eighteen (18) identifying links:

1. Name;
2. Address including city, county, zip code;
3. all elements of dates (except year) for dates directly linked to an individual (birth date, admission date, discharge date, date of death) [For all subjects over 89 years, all elements of dates including year that are indicative of their age cannot be used; however, age can be aggregated into a category of age 90 or older.];
4. telephone numbers;
5. fax numbers;

6. e-mail addresses;
7. social security numbers;
8. medical record numbers;
9. health plan beneficiary numbers;
10. account numbers;
11. certificate / license number;
12. vehicle identifiers;
13. device identifiers;
14. Web Universal Resource Locators / Identifiers;
15. Internet Protocol address numbers;
16. Biometric identifiers including finger or voice prints;
17. Full face photographs and comparable images; or
18. Any other unique identifying number, characteristic, or code.

Limited Data Set with a Data Use Agreement

Limited Data Sets include research that falls under HIPAA regulations but does not require researchers to obtain authorization or waiver of authorization. Researchers can collect data that retains the following types of identifiers with a data use agreement:

- Admission, discharge and service dates.
- Birth date.
- Date of death.
- Age (including over age 89).
- Geographic information (except street addresses) such as city, state, and five-digit zip code.

Researchers using a limited data set will be able to use the data only for research purposes but may not use the limited data set to contact subjects.

A data use agreement is the means by which covered entities obtain satisfactory assurances that the recipient of the limited data set will use or disclose the PHI in the data set only for specified purposes. Even if the person requesting a limited data set from a covered entity is an employee or otherwise a member of the covered entity's workforce, a written data use agreement meeting the Privacy Rule's requirements must be in place between the covered entity and the limited data set recipient.

The HIPAA Privacy Rule requires a data use agreement to contain the following provisions:

- Specific permitted uses and disclosures of the limited data set by the recipient consistent with the purpose for which it was disclosed (a data use agreement cannot authorize the recipient to use or further disclose the information in a way that, if done by the covered entity, would violate the Privacy Rule).
- Identify who is permitted to use or receive the limited data set.
- Stipulations that the recipient will:
 - Not use or disclose the information other than permitted by the agreement or otherwise required by law.
 - Use appropriate safeguards to prevent the use or disclosure of the information, except as provided for in the agreement, and require the recipient to report to the covered

entity any uses or disclosures in violation of the agreement of which the recipient becomes aware.

- Hold any agent of the recipient (including subcontractors) to the standards, restrictions, and conditions stated in the data use agreement with respect to the information.
- Not identify the information or contact the individuals.

Recruitment of Subjects

No researcher may contact potential subjects with whom the researcher does not have a clinical relationship, without authorization. If a researcher wishes to recruit subjects into a study, then the researcher must request that a physician who does have a clinical relationship with these subjects obtain authorization from the subjects to release information to the researcher. Alternatively, the care-providing physician can give the patient the contact information about the study.

MEMBERSHIP OF THE IRB

Federal regulations [45 CFR 46.107] require that the members of the IRB collectively have sufficiently varying backgrounds to assure that they can promote the complete and adequate review of those types of research activities commonly conducted by CMU. The membership of the IRB must be highly qualified by experience and expertise, and must be sufficiently diverse in terms of race, gender, cultural background, and sensitivity to community attitudes as to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB may not consist entirely of men or entirely of women, or primarily of members of one discipline. Federal policy requires that the IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist, while members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist. In addition, the IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews.

In addition, federal regulations require that each IRB shall include at least one member who is not otherwise affiliated with CMU and who is not part of the immediate family of a person who is affiliated with CMU.

CMU's IRB will consist of at least five members as follows:

- At least three (3) faculty members from different academic departments;
- At least one academic administrator; and
- One community member.

In addition, the Director of Sponsored Programs or his / her designee will serve as an ex-officio member.

Terms of appointment (except for ex-officio members) are for three (3) years.

A Chair and Vice Chair for the IRB will be selected from the appointed board members for each three (3) year term.

Member Nomination, Selection and Service

Members are nominated by various sources including, but not limited to, other IRB members, Department Chairs, or the Vice President of Academic Affairs. Members are nominated based on expertise and experience and chosen to represent the types of research being reviewed by the IRB. The President of CMU gives final approval to an appointment.

Appointments are renewable by mutual agreement, depending on the needs of the IRB and the results of the yearly member evaluations.

Alternate Members

Alternates are designated for specific primary members. Alternate members should have equivalent expertise, including the same scientific or non-scientific status, as the primary member for whom they are substituting.

When an alternate member substitutes for a primary member, the alternate member will receive and review the same material that the primary member received or would have received.

Responsibilities of IRB Members

Primary members attend IRB meetings as voting members. Alternative members attend IRB meetings as voting members only when replacing a specified primary member; when the specified primary member is present at the meeting, alternative members can attend as non-voting members.

IRB members must:

- Execute their responsibilities in accordance with University policies and applicable federal, state, and local laws;
- Complete the required human subjects protection training, as applicable;
- Complete an annual IRB Member Agreement and IRB Member Self-Evaluation;
- Ensure that the seven (7) criteria for IRB approval at 45 CFR 46.111 are met for all review assignments including expedited and full committee reviews;
- When assigned as a reviewer, review and assess recruitment materials and procedures, and use of recruitment incentives when applicable to confirm the equitable selection of participants;
- Complete the relevant review documents when assigned as reviewer for a project;
- Maintain confidentiality for all matters before the IRB, all expedited reviews, and IRB consultations;
- Comply with the University or Affiliate institution's conflict of interest policy;
- Disclose conflict of interests for a project subject to IRB review at a convened meeting; refrain from the discussion except to provide information requested by the IRB, and leave the room during voting; and
- When she / he has a conflict of interest for a project she / he has been asked to review by expedited procedures, disclose the conflict interests and decline the review.

In evaluating the risks and benefits of the study, IRB members have the additional responsibilities to:

- Consider the adequacy of inclusion / exclusion criteria to enroll individuals most likely to benefit from and least likely to be harmed by the research;
- Determine if the inclusion / exclusion criteria have an ethical basis;
- Verify the adequacy of the consent document for informing subjects about the research, including risks and benefits;
- Evaluate the clarity and appropriateness of the information in consent documents with consideration for the sample populations; and
- Verify the consent documents are consistent with IRB protocols.

IRB members are expected to:

- Attend at least 75% of scheduled IRB meetings when a primary member;
- Notify CMU staff in advance if there is a need to be absent from a scheduled meeting;
- Arrive promptly and stay at convened meetings until all committee business and training has been completed;
- Review the complete package (including recruitment and consent materials) for all projects on the agenda for IRB meetings in which she / he is attending as a voting member;
- Participate in IRB discussions of protocols; and
- Complete expedited reviews (including the relevant review worksheets) in a timely manner (i.e., within 10 business days of receipt).

IRB members:

- May act as resources for researchers in the design of human subjects protection aspects of protocol development; and
- Are encouraged to participate in training opportunities offered outside of IRB meetings.

Unaffiliated IRB members (i.e., IRB Community Members) have the particular responsibility of bringing the perspective of research participants to the review process.

[Additional IRB Member Responsibilities for Research Involving Sharing Data or Specimens](#)

When University or Affiliate investigators plan to conduct non-exempt research that involves providing data / specimens to or obtaining data / specimens from an external entity, AND the data-set includes Protected Personally Identifiable Information (PII) or Protected Health Information (PHI) the primary or expedited reviewer must confirm the following before approving the research:

- The submission includes a fully-executed research agreement that specifies the responsibilities of both the Data Provider and the Data Recipient.
- The research agreement confirms that the Data Provider complied with DHHS requirements for informed consent as it relates to the use of the data / specimens as specified in the agreement.

[Responsibilities of IRB Chair and Vice Chair](#)

The IRB Chair and Vice Chair are voting members of the IRB and assume the aforementioned responsibilities of IRB Members. In addition to their responsibilities as voting IRB members, the IRB Chair and Vice Chair oversee IRB meetings to ensure reviews and approvals comply with regulatory

requirements, the Belmont Report, state laws, and University policy. The Chair will not be assigned expedited protocols for review without prior consultation with the IRB Administrator.

The IRB Chair and Vice Chair are authorized to sign all documents relevant to the review and approval of human subject research projects (e.g., waivers of HIPAA authorization) and documents submitted for post-approval monitoring (e.g., safety reports that are not unanticipated problems; acknowledgement of and notifications from external IRBs), except IRB Institutional Agreements, which are signed by the IRB Director.

The IRB Chair and Vice Chair may designate signature authority to qualified IRB members, the IRB Director, and IRB staff who are voting members of the IRB as appropriate. In all cases individuals sign their own name.

The IRB Chair, through annual "Designation of Authority" letters (or more frequently as required by rapid turnover of IRB members or other circumstances) identify members who are qualified to serve in the absence of the Chair / Vice Chair.

The IRB Chair and Vice Chair oversee IRB meetings to ensure reviews and approvals comply with regulatory requirements, the Belmont Report, state laws, and University policy. During IRB meetings, Chairs and Vice Chairs:

- Remind members who have a conflict of interest to leave the room during deliberation and voting;
- Ensure ample time is allowed for discussion for each study;
- Ensure the criteria for IRB approval and other relevant requirements (e.g., consent waivers / alterations, waivers of signed consent, determinations for vulnerable populations) are met before projects / packages are approved; and
- Ensure voting takes place for each action item on the agenda;
- In the event that a majority vote on an action item cannot be obtained, the item will be tabled until a specified future date (i.e., the next available IRB meeting).

For reportable events, the IRB Chair and Vice Chair:

- May review incident reports as identified, to assess for possible noncompliance or unanticipated problem involving risks to participants or others and Full Committee Review;
- Review reports of initial allegations of serious and / or continuing noncompliance to determine whether to refer the incident for Full Committee Review;

The IRB Chair and Vice Chair work with the IRB Administrator to:

- Review IRB policy, documents (e.g., forms and worksheet), and correspondence;
- Provide consultation and guidance to CMU staff;
- Evaluate their IRB members at least once a year by reviewing and providing feedback to members based on observation and completed IRB Member Self-Evaluation Surveys;
- Provide guidance to IRB members during and outside of meetings as appropriate; and
- Consult with the IRB Administrator regarding IRB member performance and needs.

Evaluation of IRB Members

IRB members are evaluated on an ongoing basis by the IRB Chair, Vice Chair and IRB Administrator. However, formal evaluations occur annually. Members complete a self-evaluation, which is reviewed by the IRB Chair, Vice Chair and IRB Administrator. Performance is assessed according to the following criteria:

Attendance

- Voting members of the IRB establish the committee quorum; therefore, primary members are expected to attend at least 75% of convened meetings annually.
- Voting members are expected to arrive promptly and stay at convened meetings until all committee business has been completed, whenever possible.
- When attendance is not possible, IRB members must notify the Chair or Vice Chair of the IRB allowing sufficient time in advance of the meeting to locate an alternate member, if needed, to reach a quorum.

Knowledge of Federal Regulations and University Policies and Procedures

- Participation in initial orientation and ongoing training as provided at the regular IRB meetings.
- Understanding of the three (3) basic ethical principles of the Belmont Report (i.e., Respect for Persons, Beneficence, and Justice).
- Use CMU IRB Reviewer documents.
- Familiarity with the CMU IRB website.
- Familiarity with the seven (7) criteria for IRB approval of research (i.e., 45 CFR 46.111, and 21 CFR 56. 111 when the research is regulated by the Food and Drug Administration).

Meeting Preparation and Review of Protocols

- The ability to conduct a systematic evaluation of the assigned protocols according to:
 - The three (3) principles in the Belmont Report;
 - The federal criteria for IRB approval of research (i.e., 45 CFR 46.111, and 21 CFR 56. 111 when the research is regulated by the Food and Drug Administration);
 - The policies and procedures described on the CMU IRB website.

Maintaining Confidentiality

- Service on the IRB includes the review of documents that contain personal, confidential and proprietary information. Members of the IRB are responsible for maintaining all committee proceedings and documents in confidence. Such information may not be used for any purpose other than the IRB review and may not be disclosed to anyone outside of the IRB.

MEETINGS AND RECORDS

The IRB meetings are generally held monthly during the academic year. Meetings are limited during the summer months. The IRB Chair or Administrator may convene additional meetings as necessary to handle business related to policies and IRB operating procedures.

The Meeting

A majority of IRB members must be present at a formally convened IRB meeting to conduct official IRB business. The IRB cannot act on a submitted protocol unless at least one member whose primary concerns are in a non-scientific area is present. Members present at a formally convened IRB meeting may, via a majority vote, table agenda items if they believe essential members of IRB are not present. If a quorum is not able to be maintained throughout the entirety of a formally convened IRB meeting, the IRB will no longer have the authority to conduct official IRB business.

Order of Business

The agenda for IRB meetings shall be:

- A. Review of and action on minutes of previous meetings;
- B. Old and New Business related to IRB functioning;
- C. Review and discussion of and action (if needed) on;
 - a. protocols;
 - b. continuing protocols;
 - c. modifications or changes to previously approved protocols;
 - d. new protocols; and
- D. Other business.

Actions

Protocols shall be:

- Approved, no additional information required;
- Approved with modifications / revisions. Once the requested information and / or revisions are supplied, the IRB Chair, or his / her designee, is empowered to grant approval without additional review by the Committee;
- Disapproved; or
- Tabled until a specified future date.

The IRB shall notify investigators and the institution in writing (e.g., e-mail) of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

The IRB will conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year, and has the authority to observe or have a third party observe the consent process and the research.

Conflict of Interest

Anyone, including IRB members, must declare any potential conflict of interest in advance of speaking and/or presenting at a formally convened IRB meeting; written documents submitted to the IRB shall explicitly address any conflict of interest or its absence. In addition, members of the IRB are not allowed to;

- vote on their own protocols and/or;
- the protocols of students the IRB member may be advising and/or;
- any protocol in which the IRB member may be a potential participant.

Minutes

The IRB Administrator will keep minutes of all formally convened IRB meetings. The minutes must show:

- Attendance;
- Actions taken by the IRB on each agenda item;
- The vote on the actions taken including;
 - the number of IRB members voting in favor of an action;
 - the number of IRB members voting against an action; and
 - the number of IRB members abstaining from voting on an action.
- The rationale for requiring changes in or disapproving of research; and,
- A brief summary of any discussion of controversial issues associated with an agenda item and the related resolution.

Attendance by non-IRB members

Formally convened IRB meetings are generally open to all members of the University community and the community at large. IRB members may, via a simple majority vote, close meetings for compelling reasons, as long as such closure is not in conflict with 45 CFR Part 46 or other applicable Federal, State, or local law or regulations. Anyone may speak for or against a protocol but remarks must be based only on the Criteria for Approval of Research. The IRB Chair may limit the duration of comments or the number of speakers for and against a protocol to serve the best interest of committee functioning. Written comments received by the IRB Chair prior to the meeting will be read into the minutes or distributed and appended to the minutes, insofar as they address the Criteria for Approval of Research.

IRB Records

The CMU Office of Sponsored Programs (OSP) is the repository for IRB records. The OSP shall keep IRB related documentation of IRB activities and protocol related documents on file for at least three (3) years [45 CFR 46.115 7b]. Protocols that are part of a grant or sponsored project must be kept on file for six (6) years after close of grant award:

IRB Related Documents

- Written procedures for the IRB.
- Minutes of IRB meetings.
- A list of IRB members including;
 - Name;
 - Earned degrees;
 - representative capacity;
 - Indications of experience such as board certifications, licenses, etc., sufficient enough to describe each member's chief anticipated contributions to the IRB deliberations; and
 - Employment or other relationship between each member and the institution.
- Records of continuing review activities

Protocol Related Documents

- Copies of all protocols received;
- Scientific evaluations (if any) that accompany the protocols;
- Copies of all internal and external correspondence related to each submitted protocol;
- Copies of all correspondence between the IRB and the investigator;
- Approved sample consent documents;
- Progress reports submitted by investigators;
- Reports of injuries to subjects (if any) ; and
- Statements of significant new findings provided to subjects as required by the consent documents.

CRITERIA FOR APPROVAL OF RESEARCH

In order to approve research covered by this policy, the IRB shall determine that all of the following requirements [45 CFR 46.111] are satisfied:

1. Risks to subjects are minimized, either by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, or by using procedures which are already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects, and in relation to the importance of the knowledge that may reasonably be expected to result. The IRB does not consider possible long-range effects of applying knowledge gained in the research as a research risk that falls within its purview.
3. The selection of subjects is equitable. The IRB must be particularly cognizant of special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
4. Informed consent will be appropriately documented or appropriately waived in accordance with §46.117. Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator must seek consent under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimizes the possibility of coercion or undue influence.
5. Required elements of informed consent are present. The IRB may waive or modify this requirement under certain circumstances. Any modification to informed consent procedures must be fully justified in writing.

Key information of Informed consent:

- The 'Informed Consent' must begin with a concise and focused presentation of 'Key Information' that is most likely to provide a potential participant, or legally authorized representative, an understanding of the reasons why one may or may not want to participate in the research. The 'key information' must receive priority and appear at

the beginning of the consent document, be organized and presented in a way that facilitates comprehension, and provide sufficient information that a 'reasonable person' would want to have. 'Key Information' should include ALL of the following:

- The fact that the consent is being sought for research and that participation is voluntary:
- Purpose(s) of the research, expected duration of the potential participants participation, and procedures to be followed in the research:
- Reasonably foreseeable risks or discomforts to the potential participant:
- The benefits to the potential participant or others that may reasonably be expected from the research:
- Appropriate alternative procedures or courses of treatment, if any that may be advantageous to the potential participant.

General elements of informed consent:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others that may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights (including a referral to the IRB Chair), and whom to contact in the event of a research-related injury to the subject; and
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- An 'Informed Consent' must include one of two statements about the collection of private identifiable information or identifiable bio-specimens for future research.
 - The data collected may be used for future research or distribute to other researchers without further consent after identifiers have been removed (if this is a possibility in the research).
 - The information or bio-specimens will not be used for future research even if identifiers are removed.

Additional elements of informed consent – when appropriate, one or more of the following elements of information shall also be provided to each subject:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- Any costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- The approximate number of subjects involved in the study.

Broad Consent

- The 'Final Rule' allows for 'Broad Consent' to be obtained as an alternative to traditional informed consent for the non-exempt storage, maintenance, and secondary research use of identifiable private information or identifiable bio-specimens. The 'Final Rule' prescribes the following elements for 'Broad Consent' to be legally effective:
 - A description of any reasonably foreseeable risks or discomforts to the subject;
 - A description of any benefits to the subject or to others that may reasonably be expected from the research;
 - A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
 - A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
 - When appropriate, a statement that the subject's bio-specimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
 - When appropriate, for research involving bio-specimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen);
 - A general description of the types of research that may be conducted with the identifiable private information or identifiable bio-specimens. This description MUST include sufficient information such that a reasonable person would expect that the Broad Consent would permit the types of research conducted;
 - A description of the identifiable private information or identifiable bio-specimens that might be used in research, whether sharing of identifiable

- private information or identifiable bio-specimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable bio-specimens;
- A description of the period of time that the identifiable private information or identifiable bio-specimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable bio-specimens may be used for research purposes (which period of time could be indefinite);
 - Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable bio-specimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;
 - Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and
 - An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable bio-specimens, and whom to contact in the event of a research-related harm.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of the subjects.
 7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
 8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, the IRB should make sure additional safeguards have been included in the study to protect the rights and welfare of these subjects.

TRAINING REQUIREMENTS

Training in human subject protection is required for IRB members, Principal and Co-Principal Investigators, and Faculty Advisors. Training must be completed before a protocol will be reviewed by the IRB. Instructions on how to complete the training are available on the CMU human subjects' website. Individuals shall be required to complete a training review once every three (3) years.

PROTOCOL CRITERIA AND SUBMISSION PROCEDURES

Non-Human Subjects Research Activities

Federal regulations require human subjects research to be reviewed and approved by the IRB, while non-human subjects research do not require IRB oversight. Human subject's research is defined as an activity that meets the definition of research and involves human subjects as defined either by the common rule or by FDA regulations.

Projects that involve quality improvement, case reports, program evaluation, marketing and related business analysis, and surveillance activities may not be considered human subject research, so long as the project does not involve:

- A systematic investigation designed to develop or contribute to generalizable knowledge using human subjects; or
- A clinical investigation.

Additionally, use of existing de-identified or publicly available datasets may not be considered human subject research.

If you begin an activity that is not classified as human subject research with the intent to eventually use the activity or data for research, it is best to submit to the IRB prior to the activity. Also, if after you complete an activity that is not classified as human subject research, and you want to study it further and make it generalizable, then IRB submission and approval is required.

Activities that are not considered human subject research are typically classified as Quality Improvement / Assurance or Program Evaluation Activities (i.e., Non-Human Subjects Research).

Quality Improvement / Assurance

Quality improvement / assurance activities are generally pursued in order to evaluate existing local practices with a goal of documenting and correcting deficiencies. If the goal of a project is to determine success / effectiveness or failure of a given program or process and the information gained from that evaluation is used to improve the program, this is not considered research involving human subjects, even when information is collected in a systematic way, because the results of this type of activity are not considered applicable to population other than those under evaluation. Publication or presentation is allowed but results must not be described as, or inferred to be, generalizable to a broader population; results should not be described as research results.

If the quality improvement activities involving human subjects are used to test novel services or programs for effectiveness and are presented in a more global fashion or applied to a broader population they should be considered research involving human subjects.

If you have questions regarding this category, investigators are encouraged to submit a Non-Human Subjects Research Form to the IRB Administrator at irb@coloradomesa.edu.

Program Evaluation

Program evaluation is the inquiry into past, present, and potential programs to understand or clarify their needs, working processes, or impact. When the purpose of the evaluation is to provide feedback to the program and / or funder to improve that program, the activity is not human subject research and does not need IRB review and / or approval. Presentation of findings to the program and its funders and publication of the results would be acceptable, so long as results are described as program evaluation efforts and are clearly limited to the program to which they apply and are not described as research.

Program evaluation is considered human subjects research when the intent is to contribute to generalizable knowledge. If results are presented or published using language that seeks to generalize

results beyond the program studied, the study would be considered human subject research and would need to be reviewed by the IRB.

If you have questions regarding this category, investigators are encouraged to submit a Non-Human Subjects Research Form to the IRB Administrator at irb@coloradomesa.edu.

Activities Defined as Human Subjects Research

All protocols to conduct research involving human subjects must be submitted to the CMU IRB. The investigator must obtain IRB approval or permission before undertaking the research. Research involving human subjects may not proceed until written approval is received by the investigator from the IRB. Investigators may submit a completed IRB request for review, a research summary, consent document(s), and a copy of the protocol if funding has been applied for or received for your project. The items above must be submitted via email to the IRB Administrator at irb@coloradomesa.edu.

Exempt and Expedited requests for IRB Review are usually processed within 10-15 business days. For research needing Full review, investigators must submit an electronic copy to the IRB Administrator at irb@coloradomesa.edu no later than thirty (30) days before the intended research start date. Typically Full reviews may take more than twenty-five (25) business days to review and approve.

Criteria for Exempt Review

Research in this category involves risks or stressors that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Please note: The researcher is most vulnerable for allegations of scientific misconduct should the exempt status be challenged. If in doubt, request an expedited or full review.

NOTE: The IRB Chair, or designee(s) (e.g., IRB Member, IRB Staff or Designated Reviewer), must determine that a project qualifies for an exempt review.

Research qualifies for exempt if it falls in one of the following eight (8) categories:

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. This applies only to normal educational research in regular educational settings. Surveying or interviewing may apply under this category if the surveying or interviewing participants about education instructional strategies, techniques, curriculum or classroom management methods.

NOTE: In order for a project involving educational research (research conducted in schools / classrooms) to be reviewed under the exempt category, the investigator must supply a letter from the appropriate school district official that certifies that the project meets the following conditions.

The research activities will:

- Not differ in any significant ways from the normal range of activities of the classroom, school, or district;
- Involve only customary and non-controversial instructional goals;
- Not deny any students educational benefits they would otherwise receive;
- Promise direct benefits (at least in the form of evaluative information) to the classroom, school, or district;
- Incorporate adequate safeguards to protect the privacy (i.e., anonymity or confidentiality) of all individuals who might be subjects of the research; or
- Involve only existing data on students which are non-identity specific.

If the investigator cannot provide this documentation it will be necessary for the protocol to be reviewed by the full committee under the regular review process.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
 - The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 - Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
 - The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination.

3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
 - The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 - Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
 - The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination.

NOTE: For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the

subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
 - The identifiable private information or identifiable biospecimens are publicly available;
 - Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
 - The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
 - The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory

requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

NOTE: Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains an ingredient at or below the level and for a use found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes a determination.
8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
 - Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § ll.116(a)(1) through (4), (a)(6), and (d);
 - Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §ll.117;
 - An IRB conducts a limited IRB review and makes the determination required by § ll.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and
 - The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

For research in this category, investigators must submit to the IRB Administrator at irb@coloradomesa.edu an Exempt Protocol Application. The Exempt Protocol Application should include all relevant documents (e.g., protocol summary, consent document(s), etc.). Do not proceed with the research until you have received written IRB approval.

Criteria for Limited Review

For Exempt Categories 2 and 3, a limited IRB review is only required if the research involves identifiable information (i.e., The information obtained is recorded by the investigator in such a manner that the

identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects” [HHS 2017]).

For Exempt Categories 7 and 8, a Limited Review is always required.

Criteria for Expedited Review

Research that poses only minimal risk to adult human subjects and does not deal with sensitive or personal aspects of the subject's behavior may be granted an expedited review under one or more of the conditions listed below (if carried out through standard methods). Research with minors (children aged 17 years and under) may not be reviewed under the expedited category.

1. Collection of hair and nail clippings in a non-disfiguring manner, non-permanent teeth, and permanent teeth if patient care indicates a need for extraction.
2. Collection of excreta and external secretions including perspiration, un-cannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.
3. Recording of data from subjects eighteen (18) years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (e.g., x-rays, microwaves).
4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight (8) week period and no more often than two (2) times per week, from subjects eighteen (18) years of age or older and who are in good health and not pregnant.
5. Collection of both supra- and sub-gingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
6. Voice recordings made for research purposes.
7. Moderate exercise (not including stress testing) by healthy volunteers.
8. The study of existing data, documents, records, pathological specimens, or diagnostic specimens
9. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the research will not involve stress to subjects beyond that routinely experienced in daily life or during the use of noninvasive procedures routinely employed in clinical practice.
10. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

For research in this category, investigators must submit to the IRB Administrator at irb@coloradomesa.edu an Expedited or Full Board Application. The Expedited or Full Board Application should include all relevant documents (e.g., protocol summary, consent document(s), etc.). Do not proceed with the research until you have received written IRB approval.

Criteria for Full Review

Research involving more than minimal risk or vulnerable human subjects who are not specifically meet the criteria for an Exempt Review under this policy must undergo a Full IRB review.

Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. Vulnerable subjects include:

- Children under eighteen (18) years;
- Prisoners;
- Mentally disabled persons, or economically or educationally disadvantaged persons;
- Persons not proficient in the language of the research study; and
- Any subjects likely to be vulnerable to coercion or undue influence.

Examples of research that may involve more than minimal risk (mental or physical) include:

- Surveys or questionnaires that solicit information regarding personal or sensitive aspects of the subjects' behavior, including sexual practices, instances of child or sexual abuse suffered by the subject, criminal activities, drug and alcohol use, or studies of eating disorders.
- Stress testing, drug and alcohol use by the subjects for research purposes, and studies where subjects are asked to do more than moderate physical exercise that could result in injury to the subject.

For research in this category, investigators must submit to the IRB Administrator at irb@coloradomesa.edu an Expedited or Full Board Application. The Expedited or Full Board Application should include all relevant documents (e.g., protocol summary, consent document(s), etc.). Do not proceed with the research until you have received written IRB approval.

REVIEW PROCESSES

Non-Human Subjects Research Activities

If you have questions regarding this category, investigators are encouraged to submit a Non-Human Subjects Research Form to the IRB Administrator at irb@coloradomesa.edu. The IRB Administrator will review the submitted materials and make a determination that:

- The activities as described do not constitute Human Subjects Research. Submission of an IRB Application is not required: or
- The activities as described do constitute Human Subjects Research. Submission of an IRB Application IS REQUIRED. IRB Approval must be obtained before the research can begin.

Activities Defined as Human Subjects Research

All projects that meet the federal definition of research with human subjects [45 CFR 46.102 (f)] must be reviewed and approved, or receive an exempt determination, by an IRB prior to beginning the research. The IRB staff initially screens submissions to determine the completeness and the appropriate type of review. Submissions may be returned to the study team for changes before the review type is assigned. The review type may be reassessed at any time during the review process.

Exempt Review

The IRB Chair or designee(s) (e.g., IRB Member, IRB Staff or Designated Reviewer) will conduct expedited reviews. The IRB Chair or designee(s) reviewing the research may exercise all of the authority of the IRB, except that the reviewer may not disapprove the protocol [45 CFR 46.110]. When reviewers cannot approve the research under exempt review, the study does not qualify for exemption, and the researcher(s) will be notified that they must resubmit their protocol as a non-exempt review (i.e., expedited or full board review). An Exempt reviewer's decisions include:

- Approve the protocol as submitted;
- Approve the protocol with minor modifications;
- Require significant modifications before approval is given; or
- Does not qualify for exemption; researcher(s) instructed to re-submit protocol for non-exempt review (i.e., expedited or full board review).

Limited Review

Limited IRB review is process that must be conducted by an IRB member and is designed to safeguard for activities that fall slightly outside the 'spirit' of the exempt categories. A 'Limited Review' provides the IRB with an opportunity to ensure privacy and confidentiality protections are in place prior to confirming an exempt determination that involves the collection or use of sensitive, identifiable data (exemptions 2, 3 and 8) AND that 'Broad Consent,' if applicable, (exemption 7) was obtained and documented according to an approved protocol.

In limited IRB review, the IRB must determine that certain conditions, which are specified in the regulations, are met. Limited IRB review may be done via the expedited review mechanism, that is, by the Chair or an experienced IRB member designated by the Chair (although it can also be conducted by the full IRB).

Expedited Review

An expedited review will consist of protocol review by two (2) members of the IRB. The IRB members selected to review the expedited protocol can request that the protocol be raised to full review status or reduced to an exempt review. The IRB members reviewing the research may exercise all of the authority of the IRB, except that the reviewers may not disapprove the protocol [45 CFR 46.110]. When reviewers cannot approve the research under expedited review, the study is referred for full board review, with the option for the researcher to present the research at an IRB meeting. Expedited IRB reviewers decisions also include:

- Approve the protocol as submitted;
- Approve the protocol with minor modifications;
- Require significant modifications before approval is given; or
- Does not qualify for expedited review; referred for full board review.

Full Review

Given the authorities that IRBs have under HHS regulations [45 CFR 46.109(a)], when conducting an initial or continuing review of a proposal / research study, or a review of proposed changes to a previously approved research study, an IRB can take any of the following actions:

- Approve the research study or proposed changes as submitted without any conditions;
- Approve the research study or proposed changes with conditions;
- Defer or table the research study or proposed changes for further review at a future date; or
- Disapprove the research study or proposed changes.

CONTINUING REVIEW, MINOR CHANGES, AND COOPERATIVE RESEARCH

Continuing Review

During the initial review of research, the IRB may determine if the research requires continuing review and will set the renewal date. If the research is to continue past the expiration date, then the investigator must submit a Protocol Modification Form to the IRB Administrator at irb@coloradomesa.edu.

If an investigator has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the expiration date specified by the IRB, the research must stop. Enrollment of new subjects cannot occur after the expiration of IRB approval.

Changes to Approved Research

Any changes to approved research that affect the risks to subjects must be approved by the IRB before implementing the changes. To ensure there is not an increase in risk to the subjects, the Principal Investigator should review changes with the IRB Administrator to determine if there is a need to submit a modification request to the IRB. In addition, the IRB must be notified of any changes in Principal Investigator(s) or faculty sponsorship.

Investigators must submit changes in writing to the IRB Administrator (irb@coloradomesa.edu) via the Protocol Modification Form.

Cooperative Research

Cooperative research projects are those projects which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with 45 CFR Part 46. Therefore, investigators seeking a cooperative research agreement must submit, for CMU IRB approval, all research to which this policy is applicable and an IRB Authorization Agreement Request Form.

With the approval of the CMU IRB, the University may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort, unless there is an agreement in writing from a Federal Department or Agency head outlining joint review arrangements.

IRB Authorization Agreement

Research projects involving multiple IRBs may qualify for an IRB Authorization Agreement (IAA). This will allow one IRB to defer review and oversight to another IRB (i.e., Non-CMU IRB).

Requests for IAAs are considered by the CMU IRB on a case-by-case basis and are subject to a Full Review prior to approval by the CMU IRB.

Among the considerations involved in review of a request to cede authority are the following:

- CMU personnel must be listed as study team member on the approved study of the institution willing to accept IRB oversight;
- The reduction of regulatory and administrative burden by ceding review to an external IRB; and
- The appropriateness of external IRB to review local context; qualification of the IRB to which the review will be ceded (with due consideration given to such objective factors as accreditation status); and level of confidence in its review and determinations.

If the CMU IRB approves the ceding request, the IRB Director will arrange for a formal agreement (i.e., IAA) between the University and the entity in which the external may IRB reside, under which the respective responsibilities of the two organizations will be described.

While the CMU IRB will make every effort to ensure IRB review for IAA eligible studies can be ceded to an external IRB, reliance arrangements cannot always be reached with the proposed external IRB and the study will then need to be governed by the CMU IRB. It is recommended that researchers consult with the proposed external IRB to confirm it is willing to accept the responsibility of acting as the reviewing IRB prior to submitting a request to cede IRB review.

Studies for which CMU IRB review will not likely be ceded to an external IRB include:

- Protocols where the funding is coming directly to CMU or where the grant / contract specifies that CMU will act as the reviewing IRB.
- Research where a CMU study team member has a potential financial conflict of interest relevant to the research and the proposed external IRB does not agree to adhere to (or be more strict than) any applicable management plan CMU has issued.

Investigators interested in pursuing an IAA or any other type of cooperative research will need to contact the IRB Administrator (irb@coloradomesa.edu).

PROTOCOL CLOSURE

When a study ends or is closed or canceled for any reason, a Protocol Termination Form must be completed. This form should be completed with as much detail as possible. A distinction is made between a protocol that is closed to accrual and a protocol that is closed to all human subject activity. A protocol that is closed to accrual may still be collecting follow-up data on subjects. Such a protocol must remain open and is subject to continuing review until all follow-up data collection has ceased. A protocol that has been closed may no longer collect data of any kind.

Investigators are required to submit the completed Protocol Termination Form to the IRB Administrator (irb@coloradomesa.edu) as soon as possible after all activity on the protocol has ceased.

PRINCIPAL INVESTIGATOR RESPONSIBILITIES

Prior to Proposal Submission

The Principal Investigator and / or Faculty Advisor needs to ensure research protocol applications are completed per procedure guidelines and that each of the following criteria are met before authorizing their approval for project submission:

- All study team members have completed human subject's protection training within the past three (3) years.
- The protocol includes a clear description of the study's:
 - Objectives;
 - Procedures;
 - Risks;
 - Benefits;
 - Recruitment;
 - Consent processes; and
 - Procedures to maintain confidentiality.
- The proposal and all relevant / required forms associated with the research proposal, have correct grammar and punctuation.
- Attach all relevant / required forms associated with the research proposal. When attaching each file, name the file as you want it to appear in the IRB determination letter. Examples of attachments include:
 - Grant project summaries;
 - Recruitment materials;
 - Collection tools;
 - Consent forms;
 - Survey documents, including electronic links to surveys;
 - Finalized and signed acknowledgement / permission Letters on organizational letterhead; and
 - Finalized and signed contractual agreements on organizational letterhead.

Following IRB Approval

In accordance with federal regulations, the IRB is required to define the researcher's responsibility regarding the use of human subjects in research. These responsibilities apply to all investigators and researchers including faculty, students, and staff involved in human subject research. After IRB approval is obtained, it is the Principal Investigator's responsibility to:

- Ensure all researchers associated with a project will adhere to all policies and procedures set forth by the University and by the IRB as well as all applicable local, state and federal regulations.
- Conduct research in an ethical and appropriate manner, refraining from Scientific Misconduct activities, which include, but are not limited to, plagiarism, falsification, fabrication, and failure to protect the confidentiality of human subjects in research.
- All human subject information (consent forms, data, etc.) are to be maintained in a safe and secured (e.g., locked file cabinet) environment on campus, and kept for at least three (3) years after completion of the study or for a longer period of time in accordance with the audit retention clause of any externally funded project.
- Provide the IRB with all protocol and consent form amendments and revisions, as well as all advertisements recruiting study subjects to the IRB.
- Researchers are responsible for obtaining informed consent of all subjects in accordance with federal regulations. In addition, the researcher must provide each subject with a copy of the IRB

approved consent form and obtain a signed copy of that consent form from each subject or his/her legally authorized representative at the time of consent unless the IRB has specifically waived this requirement.

- Renew all Expedited and Full protocols prior to the expiration date indicated in the Approval Letter from the IRB.
- Report the status of Exempt protocols each year, prior to the anniversary of the original approval date.
- Report any unanticipated and unintentional adverse events to human subjects to the IRB Administrator or designee within five (5) business days via email irb@coloradomesa.edu.
- Report any changes that affect the risks to subjects as well as any changes in Principal Investigator(s) or faculty sponsorship. Changes must be approved by the IRB prior to implementing the changes.
- Report any serious or continuing noncompliance with the requirements of the CMU Human Subjects Policy or any applicable rules and regulations.
- Notify the IRB when the project is complete or canceled.
- Report any Conflict of Interest or Perceived Conflict of Interest to the IRB.
- For more information on Misconduct in Research or Employee Whistleblower Protection, visit the Sponsored Programs Policies and Procedures web page.

Failure to comply with these responsibilities may result in suspension or termination of the protocol.

STUDENTS AS RESEARCHERS

Activities Involving Data Collection

Courses may require students to undertake limited projects in which a student engages in activities involving data collection from other individuals. The purpose of these projects is to provide students with an opportunity to better understand and practice methods of observation and data collection commonly associated with research in various academic disciplines.

These projects are assigned with the goal of developing or contributing to generalizable knowledge and as a result, the IRB does not consider these projects research. These projects do not need IRB review if:

- The objective of the activities associated with the project is to teach research methodology; and
- The activities associated with the project are confined to the students in the classroom; and
- The data generated from the activities associated with the project are destroyed at the end of the course; and
- The Data generated from the activities associated with the project are not used outside the classroom and/or course.

Some classroom projects are designed to research educational practices in a classroom setting such as;

- Research on regular and special education instructional strategies; or
- Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

These types of projects are subject to IRB review.

Instructors need to be familiar with what activities each student may be doing as part of his or her project and is responsible for discussing human subject protection issues with the student. It is the instructor's responsibility to be knowledgeable of human subject protection issues and to protect the individuals who may participate in these types of projects. Any potential risks, which may be incurred by a subject participating in an activity associated with this type of project, are the responsibility of the faculty member.

If there is concern that the activities associated with a classroom project involve more than minimal risk or vulnerable human subjects, faculty are encouraged to contact the IRB Administrator for consultation.

Student Research Projects

Any student data collection activities that use human subjects and are designed to develop or contribute to generalizable knowledge are research and require review and approval by the IRB. This includes:

- Graduate theses;
- Dissertation research; and
- Honors theses.

In order to obtain IRB approval at least one faculty sponsor is required for each student research project and the faculty member must be included as a Co-Principal Investigator; with all undergraduate research projects, a faculty member must be the Principal Investigator. The faculty sponsor shall be responsible for supervising the student research. The faculty sponsor and the student shall be responsible for ensuring adherence to all applicable University policies and procedures.

STUDENTS AS SUBJECTS

While Federal regulations do not provide specific protections to students who are subjects in research, the use of students as subjects may present special concerns to researchers and the IRB.

Underage Students

Minors (students under 18 years of age) attending CMU can be included in the subject pool, as long as the research meets the criteria listed in 45 CFR 46.116, which includes the following:

- The research involves no more than minimal risk to the subjects;
- The research could not practicably be carried out without the requested waiver or alteration;
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

For research involving more than minimal risk, researchers should restrict participation to CMU students eighteen (18) or older, or obtain parental permission and assent from the minor to participate.

Potential for Coercion

To limit coercion, faculty conducting research using student's as subjects should;

1. advertise for subjects generally (e.g., through subject pools or notices posted at the school) rather than recruit individual students or students enrolled in their classes; and
2. will need take special precautions to protect students from adverse consequences of declining or withdrawing from participation.

Requiring Research Participation

To diminish or eliminate the coercive aspect of student participation in faculty research for course credit and/or extra credit, students shall be given the choice of several equitable and alternative activities (e.g., write a literary criticism, legal research, historical scholarship, etc.) to choose from. In addition, faculty research with student subjects must not involve more than minimal risk and students should be able to withdraw from the study at any time without losing the course credit and/or extra credit.

SURVEYS

Researcher(s) planning to include a survey tool(s) for distribution on campus to CMU faculty, staff and/or students as part of their protocol are subject to review by the Office of Institutional Research, Planning and Decision Support.

The IRB Administrator will contact and inform the researcher(s) of any issues that the Office of Institutional Research, Planning and Decision Support may have with a protocol.

CMU TRADEMARKS AND LICENSING

The trademark licensing program promotes and protects the Colorado Mesa University brand and ensures the public can properly identify and associate CMU's name and logos with officially licensed products and/or communications bearing the university's marks.

All campus departments, clubs and organizations producing products using the name or marks of Colorado Mesa University must use a vendor that is a licensee of Colorado Mesa University.

Protected university content, representing intellectual property and registered federal trademarks owned by Colorado Mesa University, includes: names, logos, marks, nicknames, letter(s), word(s), seal, stories, websites, photography, videos, images and symbols. Any combination of these that can be associated with the University qualifies as a trademark and is vigorously protected by CMU.

Permission for Use of Content

Any use of the university's content for commercial purposes or by any person or organization is prohibited without the express permission of the university. This applies to use in all forms of communications.

All individuals, third parties, entities and organizations wishing to use or reproduce university content must contact Marketing and Communications. Once approval has been given, users are forbidden to alter, distort or deface any element of the university content.

Proposals submitted to the IRB, which intend to use data collection tools that utilize CMU names, logos, marks, nicknames, letter(s), word(s), seal, stories, websites, photography, videos, images and symbols or other protected content must have approval from CMU Marketing and Communications. Copies of the

approved data collection tools and notice of approval from CMU Marketing and Communications must be included with the IRB proposal.