1.0 BACKGROUND AND PURPOSE

The Colorado School of Mines (“Mines”) is committed to ensuring the protection of the rights and welfare of Human Subjects participating in Research activities. As part of this commitment, Mines has promulgated this policy in accordance with the requirements of the Federal Policy for the Protection of Human Subjects (45 CFR part 46), also known as the “Common Rule,” and the ethical principles defined in The Belmont Report.

2.0 POLICY STATEMENT(S)

All Exempt Human Subjects Research, or Research involving Private Information, must be approved in advance through the review and approval process included in Exhibit 1 – Procedures. This is true regardless of whether an investigator believes their Human Subjects Research project qualifies for exemption under the Common Rule. Mines is not registered with the Office of Human Research Protections (OHRP) for full internal Institutional Review Board (IRB); accordingly, Mines can approve only Exempt Human Subjects Research. Mines Human Subjects Research Committee must maintain an active federal wide assurance (FWA) under the Office for Human Research Protections.

All non-exempt Human Subjects Research must be approved by an authorized external IRB.

All Mines employees and students must complete online training on Social & Behavioral Research and any other trainings deemed necessary by the Human Subjects Committee, before beginning any work on an approved Human Subjects Research project. Additional training and review obligations may be necessary for projects requiring expedited or full IRB review.

All Human Subjects Research activities, including Exempt Human Subject Research activities conducted or supported by Mines, must provide basic ethical protections to all Human Subject participants. In particular, all Human Subjects Research activities must at a minimum:

- provide adequate safeguards for minimizing risks to the participants;
- document the fact that informed consent was obtained from the participants;
- protect the privacy of the participants; and,
- maintain the confidentiality of data collected.

3.0 RESPONSIBILITIES
Mines employees and students engaged in approved Human Subjects Research (or third parties desiring to perform Research involving Mines employees or students) are responsible for conducting the Research in accordance with the approved Research protocol, and in compliance with all applicable Mines policies, procedures, and State and Federal regulations governing Human Subjects Research.

Principal investigators are also responsible for ensuring the completion and documentation of required training by all research personnel prior to initiating Research.

Department Heads are responsible for ensuring that the Principal investigators meet all departmental or Mines requirements for review and approval of the Research prior to initiation.

The Mines Human Subjects Committee is responsible for reviewing applications for proposed Research to determine if the Research is exempt or non-exempt.

In close coordination with the Mines Human Subjects Committee, Mines’ Human Subjects Administrator, or their authorized delegate, is responsible for approving Exempt Human Subjects Research (in their absence, the Vice President for Research and Technology Transfer (VPRTT) may also approve Exempt Human Subjects Research).

4.0 COMPLIANCE/ENFORCEMENT

Violators of this policy may be subject to disciplinary action pursuant to Mines policies and procedures, and penalties prescribed by applicable federal and state law.

5.0 EXCLUSIONS/DISCLAIMER

Human Subjects Research generally does not include activities where data is collected solely for the limited intent of evaluating and improving existing Mines services and programs or for developing new Mines services or programs and where such data is not intended for publication. Examples of such activities include teaching or course evaluations used to improve or modify instruction, or internal campus surveys where the data will not be published.

6.0 DEFINITIONS

The Belmont Report means the report written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Report identifies three basic ethical principles in Research involving Human Subjects. These principles are:

- Respecting the personal dignity and autonomy of Human Subjects;
- Minimizing the possible risks of harm to the Human Subjects; and
- Selecting and treating the Human Subjects fairly.
Colorado Multiple Institutional Review Board (COMIRB) means the external Institutional Review Board that Mines contracts with for the review of Mines Human Subjects Research protocol requiring expedited or full board approval.

Exempt Human Subjects Research means a specific sub-set of “Research involving Human Subjects” where the identity of the Human Subjects cannot readily be ascertained and the Research does not place the Human Subject at physical or legal risk. Exempt Human Subjects Research does not require ongoing IRB oversight, because the only involvement of Human Subjects falls into one or more specifically defined exempt categories.

Federal Policy for the Protection of Human Subjects (45 CFR part 46), or the “Common Rule,” means the federal regulation that sets forth the requirements for Human Subject Research conducted or supported by the Department of Health and Human Services. The Common Rule has been adopted in separate regulations by many Federal agencies.

Generalizable Knowledge means scholarly work that is intended to be shared, published, presented to colleagues, and is intended to have an impact (theoretical or practical) on others within one’s discipline. Activities that are disseminated with the intent to influence behavior, practice, theory, future research designs, etc. are contributing to generalizable knowledge.

Human Subject(s) (as defined by the Common Rule) means a living individual about whom an investigator (whether professional or student) conducting Research: (1) Obtains information or bio specimens through Intervention or Interaction with the individual, and uses, studies, or analyzes the information or bio specimens; or (2) Obtains, uses, studies, analyzes, or generates identifiable Private Information or identifiable bio specimens.

Institutional Review Board (IRB) means a federally regulated committee charged with ensuring that Research involving Human Subjects is ethical, equitable, and humane. An IRB conducts an initial review of a proposed Research protocol as well as ongoing reviews of an approved Research project. During the initial review, an IRB will consider whether a proposed Research protocol meets established criteria for minimizing risks to Human Subjects. Based on this consideration, an IRB may approve or deny the protocol, or may alternatively condition approval upon certain changes to the protocol.

Intervention means both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for Research purposes.

Interaction means communication or interpersonal contact between investigator and subject.
Private Information (as defined by the Common Rule) means 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). Collection of Private Information that is individually identifiable for Research purposes (i.e., the identity of the subject is or may be readily ascertained by the investigator or associated with the information) typically constitutes Research involving Human Subjects.

Research (as defined by the Common Rule) means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to Generalizable Knowledge (45 CFR 46.102).

7.0 RESOURCES or ATTACHMENTS

- Human Subjects Research website
- The Belmont Report
- The Common Rule
- Office for Human Research Protections (OHRP)
- Human Subject Regulations Decision Charts

KEY WORDS
human subjects, IRB, OHRP, FWA, private information, COMIRB, Common Rule, Belmont Report, privacy

8.0 HISTORY AND REVIEW CYCLE

The policy will be reviewed at least every 2 years, or as needed by the Responsible Administrative Unit.

Issued: June 26, 2019.
Updated/Amended: September 7, 2021 (formatting and minor clarifications)
EXHIBIT 1 - PROCEDURES

1.0 REVIEW AND APPROVAL OF HUMAN SUBJECTS RESEARCH

Mines employees and students desiring to conduct Human Subjects Research must submit an Application of Exemption describing the proposed Human Subject Research protocol to the Mines Human Subjects Committee for review and approval, prior to beginning the proposed Research activities.

The Mines Human Subjects Committee includes individuals from the following offices:
- VPRTT – Mines Human Subjects Administrator
- Policy and Compliance – member

Applications are reviewed by the Mines Human Subjects Committee to determine if the proposed Research qualifies as exempt under the Common Rule or if the Human Subject Research protocol requires review and approval by an external IRB. Mines currently contracts with the external IRB, COMIRB, to provide external IRB services.

If the Human Subjects Research protocol falls within an exempt category under the Common Rule, the Mines Human Subject Committee will review the protocol to ensure adequate and appropriate protection of participating Human Subjects. The Mines Human Subjects Administrator will send an approval letter to the requestor if the Human Subjects Research protocol is approved as exempt.

If the Mines Human Subjects Committee determines that the Human Subjects Research protocol does not qualify as exempt, the Mines Human Subjects Committee will notify the requestor that Mines cannot approve the protocol as exempt. The Research team may then choose to submit the Human Subjects Research protocol to an external IRB for review and approval.

2.0 UNANTICIPTED PROBLEMS/VIOLATIONS

Any reportable events must be reported to the VPRTT within five (5) business days of discovery of the incident. The VPRTT or authorized delegate will review the reportable event and determine if it warrants further investigation. Reports can be made to the Office of VPRTT at 303-273-3327 or to SpeakUP@mines.edu.

Reportable events may include, but are not limited to:
- An actual unforeseen, harmful or unfavorable occurrence to participants or others that relates to the Research protocol;
- A problem involving data collection, data storage, privacy or confidentiality. (Any violations of privacy or confidentiality also need to be reported to the Privacy Compliance Director.);
- A protocol violation (meaning an accidental or unintentional change to the Mines-approved protocol) that harms participants or others; or that indicates participants or others may be at increased risk of harm;
• Any study related event that requires prompt reporting to the Research sponsor; or
• Any other problem that creates a risk to the participant or others.

3.0 ADDITIONAL INFORMATION

Additional information may be found on the Human Subjects Research Website.