COLORADO SCHOOL OF MINES	**Human Subjects Research Protection Policy**	
	Responsible Administrative Unit: Vice President for Research and Technology Transfer	**Policy Contact:** Stefanie Tompkins, Vice President for Research and Technology Transfer *humansubjects@mines.edu

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

Human Subjects Research is broad and includes any Research with individuals that require surveys or interviews, manipulation of the subject's physical environment, and analysis of behavior or characteristics. This policy applies to all Mines employees and students performing Research involving Human Subjects, and to third parties desiring to perform Research involving Mines' employees or students.

Exempt Human Subjects Research is a specific sub-set of Human Subjects Research *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 Institutional Review Board (IRB) oversight. There are several exempt categories of Human Subjects Research defined in the "Common Rule".

Human Subjects Research activities and Exempt Human Subject Research activities conducted or supported by Mines must provide basic ethical protections to all Human Subject participants and must comply with all applicable Mines policies and State and Federal regulations. In particular, all Human Subjects Research activities must provide appropriate protections for human participants, including at a minimum:

- adequate safeguards for minimizing risks to the participants;
- obtaining and documenting the informed consent of the participants;
- protecting the privacy of the participants; and,
- maintaining the confidentiality of data collected.

Specific examples of Human Subjects Research (exempt and not exempt) may include, but are not limited, to Research regarding or involving:

- education instructional strategies;
- effectiveness of instructional techniques;
- comparison among instructional techniques;
- curricula, or classroom management methods;
- interviews;
- physical procedures, such as venipuncture;
- the effects of changes in a subject's environment; or
- data collected under a previously approved Human Subjects Research study.

Additional examples can be found on the Human Subjects Research website.

Human Subjects Research does not include quality assurance and quality improvement activities where data is collected solely with the limited intent of evaluating and improving existing services and programs or for developing new services or programs. Examples include teaching evaluations or customer service surveys.

3.0 PROCEDURES

3.1 Review and Approval of Human Subjects Research.

All exempt Research activities involving Human Subjects or data containing Private Information must be reviewed in advance by the Mines Human Subjects Committee and must be approved in advance by the Mines Human Subjects Administrator, or in their absence, the Vice President for Research and Technology Transfer (VPRTT). This is true whether an investigator believes his or her Human Subjects Research project qualifies for exemption under the Common Rule. Mines can only approve Exempt Human Subjects Research. Mines is not registered with the Office of Human Research Protection (OHRP) for a full internal IRB. Human Subjects Research protocols requiring an expedited approval or full board approval must be sent to an external IRB in good standing with OHRP.

All non-exempt Research activities involving Human Subjects or data containing Private Information must be approved in advance by an authorized external IRB.

3.1.1 Mines employees and students desiring to conduct Human Subjects Research must submit an Application for 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

3.1.2 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.

3.1.3 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.

3.1.4 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.

3.2 Required Training.

All Mines employees and students must complete online training on Social & Behavioral Research 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.

3.3 Responsible Conduct of Research.

Mines employees and students engaged in approved Human Subjects Research are responsible for conducting the Research in accordance with the approved Research protocol, and in compliance with all applicable Mines policies and State and Federal regulations governing Human Subjects Research.

3.4 Unanticipated 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. 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.

3.5 Additional Information.

Details to these procedures may be found on the Human Subjects Research Website.

4.0 COMPLIANCE

The President delegates authority to develop, administer, and maintain appropriate procedures and resources to implement this policy to the Vice President for Research and Technology Transfer. 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 HISTORY AND REVIEW CYCLE

The policy will be reviewed at least every 2 years, or as needed by the Vice President for Research and Technology Transfer
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6.0 DEFINITIONS

- **The Belmont Report,** written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 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.
- **COMIRB (Colorado Multiple Institutional Review Board)** is an 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** is a specific sub-set of “Research involving Human Subjects” that 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,"** is 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** is 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,** as defined by the Common Rule, means a living individual about whom an investigator (whether profession 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)** is 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** includes 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** includes communication or interpersonal contact between investigator and subject.
- **Private Information,** as defined by the Common Rule, includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, 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.
- **Research,** as defined by the Common Rule, is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR 46.102(d)).

7.0 Resources

Mines resources:

- Human Subjects Research website
- Office of the VPRTT, 303-273-3327
- SpeakUp@mines (Violations)

Federal resources:

- Office for Human Research Protections (OHRP)
- Human Subject Regulations Decision Charts
- Code of Federal Regulations, Title 45: Public Welfare, Department of Health and Human Services, Part 46: Protection of Human Subjects (45 CFR 46)

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