

Responsibilities when Conducting Human Subjects Research

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1. Principal Investigator (PI)

The PI is ultimately responsible for the conduct of their research. Though research responsibility may be delegated to research staff, PIs must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibility. CU-Boulder IRB recognizes faculty/staff members with University-paid appointments or students (under the direction of a faculty advisor) as PIs. Protocols that require skills beyond those held by the PI must be modified to meet the investigator's skills or have one or more additional qualified faculty as Co-investigator(s). PIs are required to:

- Acknowledge and accept responsibility for protecting the rights and welfare of human research participants, including the equitable selection of research participants, ensuring that risks to participants are minimized, and that the risks are reasonable in relation to anticipated benefits,
- Fulfill the training requirement for the protection of human participants in research (CITI on-line training modules, www.citiprogram.org), and to understand the ethical standards and regulatory requirements governing research activities with human participants,
- Supervise all study personnel and ensure that all personnel abide by the ethical principles of respect for persons, beneficence and justice, as outlined in the Belmont Report,
- Ensure that all study personnel are knowledgeable of, and conduct the study in accordance with the approved protocol (including approved amendments),
- Ensure that all research activities have IRB approval and other approvals required by the institution before human participants are involved, and implement the research activity as it was approved by the IRB,
- Report any real or potential conflicts of interests of the PI or any study personnel in compliance with conflict of interest policies and management plans,
- Obtain informed consent from participants before participants are involved in the research, and document consent as approved by the IRB. A copy of the IRB-approved informed consent document must be used. Participants must be provided with a copy of the form after it has been signed, unless the IRB has specifically waived this requirement. Documented evidence of informed consent of the participants or their legally authorized representative is to be retained in a manner approved by the IRB,
- Maintain written records of IRB reviews, decisions, research records and informed consent documents,
- Obtain IRB approval for and notify the sponsor (if applicable) of any proposed change to the research protocol *prior to* its implementation, except when necessary to eliminate apparent immediate hazards to the participants,

- Obtain re-approval by reporting progress of approved research to the IRB, in the manner prescribed by the IRB, but not less than once per year,
- Promptly report to the IRB any reportable events, protocol deviations or other unanticipated problems involving risks to participants or others,
- Verify that IRB approval has been obtained from all participating institutions in collaborative activities with other institutions, and that continuing review by other institutions is maintained,
- Ensure the confidentiality and security of all information obtained from and about human participants, and the privacy of participants is maintained,
- Use the most current version of IRB forms and document templates, which can be downloaded from the IRB website
<http://humanresearch.colorado.edu/forms-templates>
- Oversee the budget and expenditures related to the study to ensure that adequate resources are available, including staff, equipment supplies, storage space etc., to conduct the study at the University and any other performance site for which the PI is responsible,
- Provide the IRB with audit or inspection reports or findings issued by regulatory agencies, cooperative research groups, contract research organizations, the sponsor or the funding agency,
- Maintain, when applicable, accurate records on the receipt, use and disposition of excess drugs/devices,
- Conduct the study in compliance with internal policies and applicable federal regulations including 45 CFR 46 and 21 CFR 50 – Protection of Human Participants, 21 CFR 312 – Investigational New Drug Application and 21 CFR 812 – Investigational Device Exemptions.

2. **Key Personnel**

The IRB holds all study personnel (including PI and Co-investigators) responsible for meeting certain obligations. Study personnel are required to:

- Fulfill the training requirement for the protection of human participants in research (CITI on-line training modules, www.citiprogram.org), and understand the ethical standards and regulatory requirements governing research activities with human participants,
- Comply with applicable IRB policies and procedures,
- Document contact with participants, e.g., obtaining informed consent or informing participants of changes that may affect their willingness to continue participating,
- Provide a thorough explanation of the study in lay terms to the participant during the consent process,
- Provide the participant with an opportunity to ask questions and have them answered when obtaining informed consent and throughout their participation,
- Understand the appropriate use of an investigational intervention (drug or device) as described in the protocol, investigator brochures, product information/drug labeling, and various other available sources such as newsletters, safety alerts, or communications from sponsors, if applicable,
- Be familiar with and follow the reportable event and protocol deviation reporting requirements.

3. **Faculty Advisors**

CU-Boulder students (graduate or undergraduate) may conduct research involving human participants only under the direction of a CU-Boulder faculty advisor. Faculty advisors play an important role in students' design and development of human participant research projects. When submitting their study for IRB review, the student is responsible for completing all eRA applications and identifying their faculty advisor. Faculty advisors are ultimately responsible for the protection of the subjects, even if it is the student who actually directs the project. Faculty advisors are required to:

- Accept responsibility for monitoring all aspects of the student's research,
- Fulfill the training requirement for the protection of human participants in research (CITI on-line training modules, www.citiprogram.org), and understand the ethical standards and regulatory requirements governing research activities with human participants,
- Prior to IRB review, the faculty advisor must review the student's submission and acknowledge his or her responsibilities as advisor,
- [Detailed Instructions](#) for completing this process are included in the eRA training documents located on the IRB website.