Investigator Responsibilities

Institutional Guidelines

The IRB reviews research to ensure that the federal regulations for protecting human research subjects outlined in IRB policy, local policy, the Department of Health and Human Services (DHHS) regulations (45 CFR 46) and the Food and Drug Administration (FDA) regulations (21 CFR Parts 50 & 56) as well as other requirements are met.

The University of Colorado Denver (UCD) Federal wide Assurance (FWA # 00005070) awarded by the Office for Human Research Protections (OHRP) at DHHS, is a written commitment to follow federal regulations at 45 CFR 46 for protecting human research subjects. The following principles and policy apply must be upheld by investigators conducting research approved by COMIRB or any other IRB that may be responsible for the review and approval of your research:

1. Conducting the Research. You are responsible for assuring that the research is conducted according to the IRB approved research protocol. As the Principal Investigator, you may delegate the authority to make decisions about the study but may not delegate the responsibility for proper conduct of the study. You are responsible for the actions of all your co-investigators and research staff involved with this research.

2. Conflict of Interest. The PI, investigators and research team must disclose any existing conflicts of interest and follow any management plan agreed to by all interested parties and approved by the University of Colorado, Denver and the IRB. Any new conflicts of interest must be reported to the COI Officer and IRB within 30 days of identification of the new COI.

3. Denver VA Medical Center (VAMC). Research may not be initiated at Denver VAMC until after Denver VAMC Research & Development (R&D) Committee approval. Therefore, upon initial approval, the COMIRB Office will forward the stamped, COMIRB- approved VA consent documents to the Denver VAMC R&D Office for release.

4. University of Colorado Hospital (UCH). Research may not be initiated at University of Colorado Health until after UCH Research Administration has reviewed and approved the research.

5. Sufficient Resources. Ensure that you have sufficient resources to conduct your study properly, including:
   - Access to a population that will allow you to recruit the required number of subjects
   - Sufficient time to conduct and complete your research
   - Adequate staff to carry out, monitor, and compile your research
   - Adequate facilities for the type of research you are doing

Office of Regulatory Compliance
Version: 04
Effective date: 05.17.16
• A process to check that all staff assisting you fully understand the protocol and their duties in the research

• Available medical or psychological resources that subjects may need if they suffer consequences from your research, as appropriate.

6. Subject Enrollment. You may not recruit or enroll subjects prior to the IRB approval date or after the expiration date of IRB approval. Only the IRB-approved format and text of the recruitment materials may be utilized. If you need to recruit more subjects than was noted in your IRB approval, you must submit an amendment requesting an increase in the number of subjects and obtain IRB approval prior to enrolling additional subjects.

7. Finder’s Fee / Enrollment Incentive. Refuse any payment to you or your research staff for referring or recruiting prospective subjects. Such finder’s fees include any payment or gift to an individual who identifies a prospective subject.

8. Informed Consent. You are responsible for obtaining and documenting effective informed consent using only copies of the stamped, IRB-approved consent documents, and for ensuring that no human subjects are involved in research prior to obtaining their informed consent. Unless consent is waived by the IRB, a copy of the signed consent form should be provided to the research subject. Keep the originals in your secured research files for at least seven (7) years. Place a copy of the informed consent document in the subject’s medical record, when appropriate, for example no consent forms are placed in the medical record when there is a Certificate of Confidentiality related to the specific study.

9. HIPAA Authorizations for Research. If the research involves the use or disclosure of protected health information from a covered entity, unless otherwise noted, you are responsible for obtaining an authorization from prospective subjects. All research authorization documents must be reviewed and noted by COMIRB acting as the privacy board. All subjects must be given signed and dated copies of the authorization. Maintain the originals in your secured research files for at least seven (7) years. Place a copy of the informed consent document in the subject’s medical record, when appropriate, for example no consent forms are placed in the medical record when there is a Certificate of Confidentiality related to the specific study.

10. Continuing Review. The IRB must review and approve all IRB-approved research protocols at intervals appropriate to the degree of risk but not less than once per year. There is no grace period. Prior to the date on which the IRB approval of the research expires, the IRB Office will send you a reminder to submit a continuing review materials. Although the IRB sends reminders, it is ultimately your responsibility to submit the continuing review report in a timely manner to ensure a lapse in IRB approval does not occur. If IRB approval of your research lapses, you must stop new subject enrollment, and contact IRB immediately. It is suggested that the continuing review be submitted approximately 45 days prior to expiration of IRB approval.

11. Amendments and Changes. If you wish to amend or change any aspect of your research (such as research design, interventions or procedures, number of subjects, subject population, informed consent document, instruments, surveys or recruiting material), you must submit the
amendment to the IRB for review and consideration. You may not initiate any amendments or changes to your research without first obtaining written IRB approval. The only exception is when it is necessary to eliminate apparent immediate hazards to subjects. Once the change has been made, the IRB must be immediately informed of the event that required this emergent change.

13. Data Safety Monitoring. All research must have a data and monitoring plan that is appropriate to the type of research. This should include a plan for monitoring subject reactions and reporting any unanticipated problems or adverse events.

14. Unanticipated Problems / Adverse Events. Any reportable events must be reported to the COMIRB within five (5) days of discovery of the incident as outlined in the COMIRB Policies and Procedures. When using an external IRB it is important that you have read and understand their expectations with regard to reporting these events. For purposes of the COMIRB, these events include:

- An actual unforeseen harmful or unfavorable occurrence to participants or others that relates to the research protocol (injuries, psychological events, drug errors).
- Adverse events which in the opinion of the principal investigator are both unexpected and probably related to the intervention/ drug or device.
- An unforeseen development that potentially increases the likelihood of harm to participants or others in the future.
  - Information that indicates a change to the risks or potential benefits of the research.
    - An interim analysis or safety monitoring report indicates that frequency or magnitude of harms or benefits may be different than initially presented to the COMIRB or
    - A paper is published from another study that shows that the risks or potential benefits of your research may be different than initially presented to the COMIRB.
- A problem involving data collection, data storage, privacy or confidentiality. 
  - Incarceration of a participant in a protocol not approved to enroll prisoners.
- Pregnancy of a participant or spouse in a protocol that specifically excludes pregnancy due to the potential risks of the intervention or treatment on the fetus.
- Change to the protocol taken without prior COMIRB review to eliminate an apparent immediate hazard to a research participant.
- Complaint of a participant when the complaint indicates unexpected risks or cannot be resolved by the research team.
- Protocol violation (meaning an accidental or unintentional change to the COMIRB approved protocol) that harmed participants or others or that indicates participants or others may be at increased risk of harm.
- Study related event that requires prompt reporting to the sponsor.
- Sponsor imposed suspension for risk.
• Non-compliance by the PI or research team
• Any other problem that caused a risk to the participant or others

15. You must also report any instances of serious or continuing non-compliance with the COMIRB’s requirements for protecting human research subjects as identified by you and/or your team. All reportable events should be submitted to the COMIRB using the Unanticipated Problem / Adverse Event Report Form available at http://www.ucdenver.edu/comirb

16. Research Record Keeping. You must keep original copies of the following research related records in a secure location for a minimum of seven (7) years (longer is dictated by a sponsor, funding agency or external IRB) after study completion: the IRB approved research protocol and amendments; IRB approved and signed (when required) informed consent documents; recruitment materials; continuing review reports; adverse or unanticipated event reports; and all correspondence from the IRB. All HIPAA research-related documentation (including research authorizations, waiver of authorization, accounting of individuals’ records accessed through a waiver, etc.) must be kept for a minimum of seven (7) years.

17. Reports to Sponsor. You must also comply with your obligations to Sponsor in fulfillment of your contractual obligations.

18. Provision of Experimental (not FDA approved) Emergency -Use of a Test Article. When a physician provides an unapproved test article via emergency care to a subject without prior COMIRB review and approval, to the extent permitted by law, such activities will not be recognized as research nor may the data be used in support of research. “Emergency” and “one-time use” of unapproved drugs and devices require timely reporting to the FDA and to the COMIRB.

19. On-Site Evaluations, FDA Inspections, or Audits. If you are notified that your research will be reviewed or audited by the FDA, the Sponsor, any other external agency, you must inform the COMIRB Office immediately of the impending audit/evaluation.

20. Change in PI. If you are unable to continue as the PI on the study then ensure that an appropriate person takes over. This needs to be done in writing using a change form submitted by you as the original PI. In some cases, changes in PI must also be approved by the sponsor.

21. Final Reports. When you have completed or stopped work on your research (no further subject enrollment, interactions, interventions or data analysis), you must close the study with COMIRB by submitting a final continuing review form with a closure letter.

If you have any questions or need assistance, please contact the COMIRB Help Desk for Anschutz Medical Campus and Downtown Campus: COMIRB@ucdenver.edu | 303-724-1055
please contact the UCD Clinical Research Support Center at 303-724-1111

Office of Regulatory Compliance
Version: 04
Effective date: 05.17.16