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 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 some of your 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 the research.

2. IRB approval. You are responsible for ensuring that no research activity begins prior to IRB approval. Whether using the COMIRB or an external IRB, you are responsible for reviewing adhering to that IRB's requirements and expectations. When using an external IRB, you are required to inform the External IRB team.

3. Conflict of Interest. The PI, investigators and research team must disclose any existing conflicts of interest (COI) 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.

4. Denver VA Medical Center (VAMC). Research may not be initiated at the Denver VAMC until after Denver VAMC Research & Development (R&D) Committee approval.

5. Research may not be initiated at a hospital site or other facility without the appropriate facility approvals.

6. Sufficient Resources. Ensure that you have sufficient resources to conduct the study properly, including:

- Access to a population that will allow you to recruit the required number of subjects in a reasonable amount of time
- Sufficient time to conduct and complete the research
- Adequate staff to carry out, monitor, and compile the research

- Adequate facilities for the type of research to be conducted
- Education and training for all staff assisting you to fully understand the protocol and their duties in the research
- Appropriate medical or psychological resources as outlined in the data safety and monitoring plan.

7. Subject Enrollment. You may not recruit or enroll subjects prior to the IRB approval date or after IRB approval has expired. Any recruitment materials used must adhere to the expectations of the IRB that reviewed and approved the research.

8. 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.

9. Informed Consent. You are responsible for obtaining and documenting effective informed consent in accordance with IRB's approval 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 required by hospital policy.

- For Denver VAMC research: If the investigator does not personally obtain informed consent, the investigator must delegate this responsibility in writing to research staff sufficiently knowledgeable about the protocol and related concerns to answer questions from prospective participants and about the ethical basis of the informed consent process and protocol.

10. 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 the appropriate privacy board.

11. Continuing Review. You are responsible for submitting your research for continuing review 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. Although the IRB will issue reminders about continuing review, it is ultimately your responsibility to submit the continuing review materials if required. Continuing review might not be required if the IRB reviewed your under the *2018 Requirements* for human subjects protections and the IRB did not require continuing review.

12. 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 in accordance with the IRB's requirements. 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. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. The plan should be 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: You are responsible for reporting unanticipated problems and adverse events to the IRB according to the IRB's Policies and Procedures. In the case of COMIRB, this is within five (5) days.

15. Non-compliance: You are responsible for reporting to the IRB any instances of serious or continuing non-compliance with the IRB's requirements for protecting human research subjects as identified by you and/or your team.

16. Record Retention: You must keep original copies of all research related records in a secure location after study completion as long as required by university policy or longer if required by a sponsor, funding agency or external IRB.

17. Reports to Sponsor. You must comply with your contractual obligations to the Sponsor.

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 IRB.

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

20. Change in PI. If you are unable to continue as the PI on the study you are required to ensure that an appropriate person takes over as PI and that this is reported to and approved by the IRB and 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 IRB by submitting a final continuing review per IRB requirements.

If you have any questions or need assistance, please contact the UCD Clinical Research Support Center at clinicalresearchsupportcenter@ucdenver.edu | 303-724-1111, or

The COMIRB Help Desk for Anschutz Medical Campus and Downtown Campus**:** COMIRB@ucdenver.edu | 303-724-1055.