Responsibilities of Students/Residents/Fellows/Trainees conducting Human Subject Research Conducting Research at the University of Colorado Denver

Institutional Guidelines
The COMIRB reviews research to ensure that the federal regulations for protecting human research subjects outlined in COMIRB policy, University of Colorado Denver 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 pledge to follow federal guidelines for protecting human research subjects in accordance with the principles of the Belmont Report. The Colorado Multiple Institutional Review Board (COMIRB) must review and approve your research before you can begin the study.

All trainees (includes students, residents, fellows, and other trainees) and mentors/advisors must read the Belmont Report and understand their ethical responsibilities in conducting human subject research that are outlined in this document.

The following principles and policy apply must be upheld by investigators conducting research approved by COMIRB:

1. Conducting the Research. You in conjunction with your named mentor/advisor are responsible for making sure that the research is conducted according to the COMIRB 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 COMIRB. Any new conflicts of interest must be reported to the COI Officer and COMIRB within 30 days.

3. 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 facilities for the type of research you are doing
   - A process to check that any 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

4. **Subject Enrollment.** You may not recruit or enroll subjects prior to the COMIRB approval date or after the expiration date of COMIRB approval. All recruitment materials for any form of media must be approved by the COMIRB prior to their use. Only the stamped, COMIRB-approved format and text of the recruitment materials may be utilized. If you need to recruit more subjects than was noted in your COMIRB approval letter, you must submit an amendment requesting an increase in the number of subjects and obtain COMIRB approval prior to enrolling additional subjects.

5. **Informed Consent.** You are responsible for obtaining and documenting effective informed consent using **only** copies of the stamped, COMIRB-approved consent documents, and for ensuring that no human subjects are involved in research prior to obtaining their informed consent. Please give all subjects copies of the signed informed consent documents. Keep the originals in your secured research files for at least five (5) years. When appropriate, you should place a copy of the signed informed consent document in the subject's medical record.

6. **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. You are advised to submit your research for continuing review approximately 45 days prior to expiration of IRB approval. If your research was reviewed under the 2018 Requirements for human subjects protections and the IRB did not require continuing review, then your IRB approval will not have an expiration and continuing review is not necessary. On an annual basis, the IRB Office will send you a reminder to submit a continuing review materials, or a reminder that your study is still active in our records. Although the IRB sends reminders, it is ultimately your responsibility to submit the continuing review materials if required.

7. **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 COMIRB for review using the COMIRB Change Form. You **may not initiate** any amendments or changes to your research without first obtaining written COMIRB review and approval.

8. **Data Safety Monitoring.** All research involving more than minimal risk to subjects must have a data safety monitoring plan to ensure subject safety during the course of the research. You should have a plan for monitoring subject reactions and reporting any unanticipated problems or adverse events.
9. **Unanticipated Problems.** 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. Reportable events include:

- An actual unforeseen harmful or unfavorable occurrence to participants or others that relates to the research protocol (injuries, psychological events).
- Adverse events which in the opinion of the principal investigator are both unexpected and probably related to the intervention.
- 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.
    - For example:
      - 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.
    - Complaint of a participant when the complaint indicates unexpected risks or cannot be resolved by the research team.
    - Any other problem that caused a risk to the participant or others

10. **Serious or Continued Non-Compliance.** You must also self-report any instances of serious or continuing non-compliance with the COMIRB’s requirements for protecting human research subjects, as well. All reportable events should be submitted to the COMIRB using the Unanticipated Problem Form.

11. **Research Record Keeping.** You must keep originals of the following research-related records in a secure location for a minimum of five (5) years after study completion: the COMIRB approved research protocol and amendments; COMIRB-approved and signed (when required) informed consent documents; recruitment materials; continuing review reports; unanticipated event reports; and all correspondence from the COMIRB.

12. **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. Analysis of a stripped anonymous data set with no link to identifiers is not human subject research.

*If you have any questions or need assistance, please contact the UCD Compliance Office at 303-724-1010.*
Responsibilities of Students/Residents/Fellows/Trainees and their Mentors conducting Human Subject Research Conducting Research at the University of Colorado Denver

Note: if you are using a test article under the jurisdiction of the FDA then additional responsibilities will also apply. Please check the COMIRB website for more information at: http://www.ucdenver.edu/academics/research/AboutUs/comirb/Pages/comirb-home.aspx

Responsibilities of Faculty Mentors for students, residents, fellows and other trainees engaged in human subject research

To the Faculty Mentor
Mentorship is a serious responsibility. It is time-consuming and requires an enthusiastic commitment to the students/trainees and to the program. In addition to tangible evidence of your willingness to make a commitment to the students/trainees, mentors must have a demonstrated commitment to scholarship. In all likelihood, it will be your student/trainee’s first experience with formal research. The success of the student/trainee’s experience will be measured not only in the outcome of their projects, but also in what they learn from you as a role model. These experiences will help form their perception of scientific research, and in some cases, determine whether a career in academic research is right for them.

Responsibilities of a Mentor:

1. A mentor should not take on new students/trainees unless he or she has the capacity to effectively mentor them as outlined in this guidance and in accordance with the academic requirements of the respective school.
2. Advise your student/trainee on the selection of a topic.
3. Advise your student/trainee on the content and preparation of his/her research proposal.
4. Assist your student/trainee with the preparation of the IRB application. Complete and sign forms as required.
5. Obtain all necessary approvals (i.e., IRB and FDA) before initiating the project.
6. Ensure on-going compliance with federal regulations and institutional policies and procedures relating to human subject research.
7. Guide and interact with your student/trainee throughout the research period. Both you and your student/trainee must be in regular contact, with the student/trainee receiving on-going guidance during this time. Remember, students/trainees should not be treated as if they were just another pair of hands to put to work. Teach them to think about their projects.
8. Assist the student/trainee to monitor and evaluate the progress of the study and appropriately report any unanticipated problems.
9. Ensure that any continuing reviews are submitted in a timely manner.
10. Complete the student/trainee progress report.
11. Advise and assist your student/trainee with the preparation of the poster presentation and final paper.
12. Ensure that your student/trainee complies with the prescribed deadlines.
13. Encourage your student/trainee to present his/her results at other meetings or to co-publish them, if appropriate.
14. Communicate with the Committee Chair immediately should your student/trainee be unable to fulfill program requirements.

All mentors must be available and actively supporting the student/trainee during the student/trainee’s active research period.

By signing below I acknowledge my responsibilities as a student Principal Investigator or mentor/advisor and agree to take on these responsibilities:

Name of Trainee:____________________________________

Signature of Trainee (electronic signatures not permitted):___________________________________

Date of signature:____________

Name of Mentor/Advisor:___________________________________

Signature of Mentor/Advisor (electronic signatures not permitted): ____________________________

Date of Signature: ___________