Individual Investigator Agreement

**Name of Institution providing IRB review: University of Colorado Denver**

**OHRP Federalwide Assurance#: 00005070**

**Name of IRB: Colorado Multiple Institutional Review Board (COMIRB)**

**Individual Investigator’s Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Specify Research Covered by this Agreement (COMIRB #s):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. The above-named Individual Investigator has reviewed: 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*; 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46; and 3) COMIRB Policies and Procedures.
2. The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.
3. If the Investigator is a student at another institution with an IRB, the investigator is required to notify their IRB office about their involvement in this research before they begin work in this research and comply with the requirements of their IRB.
4. The Investigator will abide by all determinations of COMIRB and will accept the final authority and decisions of COMIRB, including but not limited to directives to terminate participation in designated research activities.
5. The Investigator shall not remove any Protected Health Information (PHI) from the university, or store any PHI on their personal devices or on any systems of their employer or school, unless such use is explicitly approved by COMIRB for the research identified above, and appropriate legal agreements are in place to share PHI.
6. The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.
7. The Investigator will complete any educational training and financial interest reporting required by COMIRB, the University and involved affiliates prior to participating in research covered under this Agreement.
8. The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by COMIRB.
9. The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject’s legally authorized representative as required under HHS regulations at 45 CFR part 46 and stipulated by COMIRB.
10. The investigator will not initiate changes in the research without prior COMIRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
11. The Investigator acknowledges and agrees to cooperate in COMIRB’s responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by COMIRB in a timely fashion.
12. The Investigator will report immediately to COMIRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.
13. Emergency medical care may be delivered to subjects without COMIRB review and approval to the extent permitted under applicable federal regulations and state law.
14. This Agreement does not preclude the Investigator from taking part in research not covered by this Agreement.
15. The Investigator acknowledges that they are primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject’s rights and welfare must take precedence over the goals and requirements of the research.

**Investigator Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Degree(s): \_\_\_\_\_\_\_\_\_\_\_\_\_

 (*Last*) (*First*) *(Middle Initial)*

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ phone #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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 (*City*) (*State/Province*) (*Zip/Country*)

**FWA Institutional Official (or Designee)**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_

Alison Lakin, RN, LLB, LLM, PhD

Associate Vice Chancellor for Regulatory Compliance

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