

Unaffiliated Investigator Agreement and Privacy Practices Agreement for Non-SCDMH Employees

All Principal Investigators who are not employees of the South Carolina Department of Mental Health and are seeking approval to conduct research under the authority of the SCDMH Institutional Review Board (IRB) are required to sign an **“Unaffiliated Investigator Agreement and Privacy Practices Acknowledgment for Non-SCDMH Employees: Signature Page.”**

Unaffiliated Investigator Agreement

- (1) The Investigator has reviewed: 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent; <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report> 2) the U.S. Department of Health and Human Services (DHHS) regulations for the protection of human subjects at [45 CFR 46](#) (or other internationally recognized equivalent; and 3) the relevant SCDMH institutional directives for the protection of human subjects.
- (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) The Investigator will comply with all other National, State, or local laws or regulations that may provide additional protection for human subjects.
- (4) The Investigator will abide by all determinations of the IRB designated under the above Assurance and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.
- (5) The Investigator will complete any educational training required by the Institution and/or the IRB prior to initiating research covered under this Agreement.
- (6) The Investigator will report promptly to the IRB any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
- (7) The Investigator will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.
- (8) The Investigator will obtain, document, and maintain records of informed consent from each subject or the subject's legally authorized representative

as required under DHHS and FDA regulations (or other international or national equivalent) and stipulated by the IRB.

- (9) The Investigator acknowledges and agrees to cooperate in the IRB's responsibility for initial and continuing review, record keeping, reporting, and certification. The Investigator will provide all information requested by the IRB in a timely fashion.
- (10) In conducting research involving FDA-regulated products, the Investigator will comply with all applicable FDA regulations and fulfill all investigator responsibilities (or investigator-sponsor responsibilities, where appropriate), including those described at **21 CFR 312** and **812**.
<https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2012-march-30-letter-attachment-a>
- (11) The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB.
- (12) Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable Federal regulations and State law. However, data and information obtained as a result of emergency medical care may not be included as part of federally-supported or –conducted research.
- (13) This Agreement does not preclude the Investigator from taking part in research not covered by the Agreement.
- (14) The Investigator acknowledges that he/she is 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.

Privacy Practices Agreement

The Investigator has reviewed and agrees to comply with the South Carolina Department of Mental Health's (SCDMH) **Privacy Practices Directive**, which incorporates the SCDMH Notice of Privacy Practices, and protects the privacy of SCDMH Consumer information and also provides for Consumer rights regarding a Consumer's control over his or her individually identifiable Protected Health Information (PHI).

The Investigator understands that any unauthorized use or disclosure of PHI or violations of any Consumer rights afforded by the Directive, Notice of Privacy Practices and applicable law, may result in applicable fines, penalties, imprisonment and/or civil suit to be brought against me.

Please sign the Unaffiliated Investigator Agreement and Privacy Practices Agreement for Non –SCDMH Employees: **Signature Page** and submit with the completed **Project Application**.