COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF MENTAL HEALTH
INSTITUTIONAL REVIEW BOARD
(DMH IRB)
UNAFFILIATED RESEARCH INVESTIGATOR AGREEMENT

Name of Institution Providing IRB Oversight: ***Massachusetts Department of Mental Health***
OHRP Federal wide Assurance Number: ***FWA00000324***

Name of Unaffiliated Investigator:
Protocol Title:
DMH IRB#:

(1) The above-named Unaffiliated Investigator has reviewed *the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects Research*; the U.S. Department of Health and Human Services (DHHS) regulations for the protection of human subjects at 45 CFR 46, and relevant Commonwealth of Massachusetts Department of Mental Health (DMH) regulations, policies, guidelines, and procedures for the protection of human subjects; including but not limited to, 104 CMR 31.00.

(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 DMH's Institutional Review Board designated under the above Assurance and will accept the final authority and decisions of DMH's Institutional Review Board, including but not limited to directives to terminate participation in designated research activities.

(5) The Investigator will complete any training required by DMH or DMH's Institutional Review Board prior to initiating research covered under this Agreement.

(6) The Investigator will report promptly to the Chair of DMH's Institutional Review Board proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior Institutional Review Board review and approval, except when necessary to eliminate immediate hazards to subjects.

(7) The Investigator will report immediately to the Chair of DMH's Institutional Review Board any unanticipated problems in research covered under this Agreement that involves risks to subjects or others.

(8) The Investigator will seek, document, and maintain records of informed consent from each subject or the subject's legally authorized representative as required under HHS and Department regulations and as stipulated by the DMH's Institutional Review Board.

(9) The Investigator acknowledges and agrees to cooperate in the Department's and the DMH's Institutional Review Board's responsibility for initial and continuing review, record keeping, reporting, and certification. The Investigator will provide all information requested by the Department and DMH's Institutional Review Board 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.

(11) The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by DMH's Institutional Review Board.

(12) Emergency medical care may be delivered without the Institutional Review Board's review and approval to the extent permitted under applicable Federal regulations and State law. However, such medical care may not be included as part of Federally-supported research.

(13) The Agreement does not preclude the Investigator from taking part in research not covered under the Agreement.

(14) The Investigator acknowledges that her/his primary responsibility is to safeguard 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.

Signatures:

Investigator:_____ **Date:** _____

Department Official:_____ **Date:** _____