

Principal Investigator Acknowledgement of Responsibilities

TidalHealth Research Review Committee

Principal Investigator:

Protocol Title:

I, the above named investigator have reviewed, understand and hereby accept the responsibility to comply with the standards and requirements stipulated in the following : (a) the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research; (b) the U.S. Department of Health and Human Services regulations for the protection of human subjects at 45 CFR 46; (c) the relevant institutional and IRB policies and procedures for the protection of human subjects; (d) HIPAA to protect the rights and welfare of human subjects involved in research conducted under this agreement.

- 1) I will abide by all determinations of TidalHealth's RRC and the IRB of record, and will accept the final authority and decisions of the RRC and IRB, including but not limited to directives to suspend or terminate participation in designated research activities.
- 2) I will conduct research in accordance with the protocol submitted to and approved by the RRC and the IRB of record.
- 3) I will protect the confidentiality of all personally identifiable information collected and will train research staff and collaborators on policies and procedures for ensuring confidentiality.
- 4) I acknowledge and agree to cooperate in the RRC's and IRB's responsibilities for initial and continuing review, record keeping, reporting, and certification. Submissions include, but are not limited to:
 - a. TidalHealth Research Application and supporting documents
 - b. Principal Investigator Acknowledgement of Responsibilities
 - c. Certificate of IRB Approval (JHCRN and Waiver of Jurisdiction studies only)
 - d. Protocol Update Form (available online at CTSU) – Annual submission
 - e. Study Closure Form (available online at CTSU)
 - IRB required documentation is at the direction of the IRB of record.

This Agreement does not preclude the Investigator from taking part in research not covered by the Agreement

I understand my responsibilities and agree to comply with the points outlined in this document.

Principal Investigator's Signature: _____ Date: _____

Printed Name: