IRB Appendix N- Waiver or Alteration of HIPAA Research Authorization

Rev. February 2019

Complete this form to request a waiver/alteration of HIPAA authorization to access, use, or disclose Protected Health Information (PHI) for the proposed research. The Privacy Rule permits waivers (or alterations) of authorization if the research meets certain conditions. Include only information that will be accessed with the waiver/alteration.

For more information, see 45 CFR Parts 160 and 164 or "Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule."

Principal Investigator:

Project Short Title:

1. Indicate the type of waiver/alteration requested:

- ☐ Partial Waiver (recruitment purposes only)
- ☐ Full Waiver (entire research study)
- ☐ Alteration (written documentation)

2. List the source(s) of the PHI (requested under the waiver/alteration) (e.g., eResults, physician's office records, clinical database, etc.). Be as specific as possible.

3. Provide information below about the PHI accessed in the research under the waiver/alteration (e.g., medical record number, health history, diagnosis, test results, etc.).Be as specific as possible.

a. Describe the PHI ***accessed*** for the research.

b. Describe information that will be ***recorded*** and ***provide a copy of the data collection form(s) to be used.***

4. Explain why access to and/or use of the PHI is essential to conduct the research.

5. Explain how the PHI described above represents the minimum necessary information to accomplish the objectives of the research.

6. Explain how the access, use, or disclosure of PHI presents no more than a minimal risk to the privacy of the individual.

7. Describe your plan to protect the identifiers (or links to identifiable data) associated with the PHI from improper use and disclosure, including where PHI will be stored, what security measures will be applied, and who will have access to the information. Describe the safeguards for electronic and/or hard copy records.

8. Will identifiers (or links to identifiable data) be destroyed?

☐ **Yes** - Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. Include **when** and **how** identifiers will be destroyed.

☐ **No -** Provide the legal, health, or research justification for retaining the identifiers. Legal justification should include a brief description/citation of the legal requirement.

☐ **N/A** - Will not record identifiers or create links or codes to connect the data.

9. Explain why a waiver or alteration (instead of written authorization) is needed to conduct the research.