MISSISSIPPI STATE DEPARTMENT OF HEALTH

Request for Waiver of Authorization

To use protected health information (PHI) in a study protocol, you must have one of the following:

- **Authorization** from the research participant which meets HIPAA requirements.
- **Waiver** of the HIPAA authorization requirement from the IRB. A waiver is a request to forgo the authorization requirement based on the fact that the disclosure of PHI involves minimal risk to the participant and the research cannot practically be done without access to/use of PHI.
- **Data Use Agreement** A limited data set under a data use agreement. A limited data set is a subset of information (PHI) that only contains the following identifiers linked to the participant: city, state, zip code, date of birth, death or service. A data use agreement must be in place.

The MSDH Notice of Privacy Practices informs the public that some uses and disclosures of PHI do not require individual consent or authorization when the activity is used for public health activities and oversight. If the principal investigator believes the study fulfills the waiver requirement above, he/she may submit a request for waiver of HIPAA authorization. Please complete the form and return by email to Meg Pearson, IRB Chair, at Meg.Pearson@msdh.ms.gov or by mail at P.O. Box 1700, Jackson, MS 39215-1700.

1. Check the method of access you propose for your study:

☐ Authorization

☐ Waiver (Complete section 5: Request for Waiver of Authorization)

☐ Limited Data Set

2. Provide a description of the (PHI) to be used or disclosed for your research and a brief summary of the collection, use and sharing.

3a. Indicate the source(s) of the protected health information:

- ☐ Physician/clinic records
- ☐ Lab, pathology and/or radiology results
- ☐ Biological samples
- ☐ Interviews/Questionnaires
- ☐ Hospital/medical records (in or out patient)
- ☐ Data previously collected for research purposes
- ☐ Billing records
- ☐ Other (explain below):

3b. Indicate how you will receive or collect the protected health information:

- ◯ With a code that can be linked to the identity of the participant.
- ◯ With limited identifiers: ZIP codes, geocodes, dates of birth, or other dates only. (The study qualifies as a Limited Data Set and requires a Data Use Agreement.)
- ◯ With unrestricted identifiers.*

* Requires Consent and Authorization from the participant or a Waiver of Consent and Waiver of Authorization from the IRB.

4a. Who may <u>receive</u> PHI during the course of the research?

- ☐ Statistician
- ☐ Colleagues/Collaborators
- ☐ Off-site Research Laboratory(s)
- ☐ Study Data Coordinating Center
- ☐ Consultants
- ☐ Data, Tissue, Specimen Registry(s)/Bank(s)
- ☐ Sponsor/Funding Agency
- ☐ Publication(s)
- ☐ Study Personnel
- ☐ Other (explain below):

4b. How will PHI be shared?

- ◯ Without identifiers.
- ◯ With a linked code. (May require Authorization)
- ◯ With identifiers. (Requires Authorization)
- ◯ As a Limited Data Set. (Requires a Data Use Agreement)
- ◯ N/A PHI will not be shared.

Complete section 5 <u>ONLY</u> if you are requesting a waiver of HIPAA authorization.

5a. Explain how the use and disclosure of the information presents no more than minimal risk to the privacy of the individual.

5b. Describe the plan to protect the identifiers from improper use and disclosure (i.e., where will the identifiers will be stored and who will have access).

5c. Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. If there is a health or research justification for retaining identifiers or, if retention is required by law, please provide this information as well.

5d. Explain why the research could not be practicably conducted without the alteration or waiver.

5e. Explain why the research could not be conducted without access to and use of the PHI.

5f. The Privacy Rule requires that when a waiver is granted only the minimum necessary health information be used/disclosed. Provide justification that the PHI being requested is the minimum necessary information reasonably necessary to accomplish the objectives of the proposed research.