Institutional Review Board
Request for HIPAA Waiver of Authorization
and/or Waiver of Consent

Use this form if you are requesting to waive or alter <u>some or all</u> of the elements of consent and/or of HIPAA authorization requirements.

IRB Protocol Number Name of Principal Investigator

Title of Study

Please indicate and explain nature of request below (check all that apply):

☐ Partial Waiver for telephone phone screens.

☐ Partial Waiver for internet survey research.

☐ Full Waiver for the purpose of accessing an existing database or records (paper or electronic) to identify potential subject or to conduct above research.

Describe the identifiable information that you will be collecting or accessing under this waiver (**Be specific to allow the IRB to determine whether the information includes any of the 18 HIPAA identifiers or any other method of identifying the individuals):**

Please explain how your study, or the phase of the study for which the waiver is being sought, meets the following criteria:

1. The study, or phase of the study for which the waiver is being sought, presents no more than a minimal risk to the individual subjects, including risk to their confidentiality

2. Indicate how you plan to protect the identifiers from improper use and disclosure. Check all that apply:
   ☐Electronic safeguards where only study staff has access and the database meets all security requirements as outlined in OMH/OPWDD security requirements for investigators (e.g. password protection, data encryption, firewall, no outside transmission of data, restricted access etc).
   ☐Physical safeguards where only study staff has access to areas with study information and OMH/OPWDD recommendations for physical security are in place (locked cabinets, locked filing room, restricted access etc).
   ☐No identifiers, links or codes will be retained to permit data to be identified.
   ☐Other:

3. Describe your plan to destroy the identifiers at the earliest opportunity:
   ☐Identifiers will be destroyed if the patient does not meet criteria for admission to the study

☐Identifiers will be retained until potential subjects sign consent and authorization and complete the study. Destruction of all identifiers will be consistent with federal, state and Facility policies, and or other contractual agreements.
☐ N/A as I will not record identifiers or create links or codes to connect the data

4. Explain why the waiver or alteration will not adversely affect the rights and welfare of the subjects.

5. Explain why is it not practical to obtain consent and/or authorization from subjects?

6. Can the research practicably be conducted without access to, and use of, the individually identifiable information? If not, why?

7. Where applicable: Describe how subjects will be provided with additional pertinent information after participation.

By submitting this application you are certifying that the protected health information or other identifiable information will not be reused or disclosed except as required by law, for authorized oversight of the research, or for other research that has been reviewed and approved by the IRB with specific approval regarding access to this protected health information.

☐Agree ☐Do not agree

Please also complete the following to describe selection criteria for requests involving access to medical records:

Selection Criteria for records required (e.g. diagnosis, age, date of admission)

Dates of required records: from / / through / /

Anticipated sources of information (check all that apply)
☐ Paper medical records, Owner ☐ OMH EMR

☐ Other (describe)

Number of records needed: Number _____ ☐ ≥ 50 ☐ < 50

_____