HIPAA WAIVER

DOCUMENTATION OF IRB APPROVAL:

WAIVER OF THE HIPAA AUTHORIZATION TO ACCESS AND USE PROTECTED HEALTH INFORMATION/PATIENT MEDICAL RECORD INFORMATION

(This documentation form is not for Exempt with HIPAA waiver)

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IRB Number: **Principal Investigator:**

(The PI of this study must (a) be a UPMC staff member and/or have UPMC-privileges, and (b) provide related care (i.e., related to the information desired), or is in the position to provide related care (including treatment and/or diagnostic services), to the types of patients whose medical records will be studied in this investigation.)

The IRB approved a request for a waiver of the requirement to obtain HIPAA authorization to access and use protected health information/patient medical record information.

In granting approval of this waiver request, the IRB Chair/Vice Chair determined, based on an evaluation of the research procedures and the waiver justification submitted by the principal investigator, that all the following criteria were met.

☐ The investigator(s) has(have) provided assurances that he/she has access to the respective medical record information by virtue of his/her (their) job responsibilities in providing direct health care to the respective patients.

HIPAA Waiver Criteria:

1. The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

   ☐ an adequate plan to protect the identifiers from improper use and disclosure;

   ☐ an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

   ☐ an adequate written assurance that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted (i.e., under the HIPAA regulations).

2. ☐ The research (research activity) could not practicably be conducted without the waiver or alteration.

3. ☐ The research (research activity) could not practicably be conducted without access to and use of the protected health information.