Assurance for Use of Protected Health Information (PHI) as Preparatory to Research and/or on Decedents
Pursuant to 45 CFR 164.512 (i)(1)(ii, and iii)

CHECK THE CATEGORY THAT APPLIES TO THIS PROJECT.

Preparatory to Research (45 CFR 164.512 (i)(1)(ii))

Preliminary Protocol Title:

Principle Investigator:

The researcher will provide assurance that:

A. The use or disclosure is sought solely to review phi as necessary to prepare a research protocol or for similar purposes preparatory to research;
B. No phi will be removed from the covered entity (Health Center) in the course of the review
C. The phi for which use or access is sought is necessary for the research purpose.

Decedent Information (45 CFR 164.512 (i)(1)(iii))

IRB # (to be assigned by IRB) :

Protocol Title:

Principle Investigator:

The researcher will provide assurance that:

A. The use or disclosure is sought solely for research on the phi of decedents;
B. The phi for which use or disclosure is sought is necessary for the research purposes;

The researcher is aware that documentation of the death of such individual may be requested.

In this area provide a brief narration addressing the points listed above. Include the specific elements of PHI that will be used in this project. (Point and click within the cell. It will expand to accommodate text.)

Response:

Signature of Researcher   Date

IRB Approval:

The researcher has provided sufficient assurance to the IRB that the protected health information sought will be used in accordance with regulations.

Signature of IRB Chair or Authorized Designee   Date