

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