

HIPAA FLOW CHART

Revised 09/09/03

When PHI is collected directly from participants (Interviews, Surveys, Questionnaires), HIPAA does not apply.

Activities that Access Medical Records (In or Out Patient) Retrospective or Prospective/or Data Bases/Tissue Banks Outside of Normal Business (Health Care Activities)

SUBMISSION OF PROTOCOL SUMMARY FORM & HIPAA SUMMARY FORM TO HIC IS REQUIRED

Data Set that has no PHI (Absence of 18 Specific Identifiers) Or Determined to be De-Identified by Independent Statistician

Data Set that includes only Three Specific Identifiers
 1. City, State, Zip code
 2. Elements of Dates
 3. Unique Codes/Numbers

Data Set includes Collecting PHI

HIPAA Authorization or Waiver of Authorization NOT REQUIRED

Protocol eligible to be approved as LIMITED DATA SET

Protocol eligible to be approved with AUTHORIZATION to access Med. Records

Protocol eligible to be approved with WAIVER OF AUTHORIZATION

HIC Approval Letter indicates that only de-identified PHI is being collected

USE ONLY By WSU & its Affiliate Institutions

USE by WSU & Affiliates and DISCLOSURE outside WSU & Affiliates

SUBMIT AUTHORIZATION TO HIC

SUBMIT REQUEST FOR WAIVER TO HIC

NO DATA USE AGREEMENT REQUIRED

DATA USE AGREEMENT REQUIRED & signed by WSU Official and outside organization

Approved by HIC With AUTHORIZATION to access Medical Records

HIC Approval Letter indicates that the IRB has approved WAIVER OF AUTHORIZATION

HIC Approval Letter indicates that use and/or Disclosure has been approved as a Limited Data Set

Grandfathering

Studies that are still open but are closed to accrual prior to 4/14/03 are exempt from HIPAA requirements. Studies open and accruing must get authorizations & consents signed for new subjects and authorizations of those enrolled prior to 4/14/03.