

HIPAA FLOW CHART

Revised 11/26/2019

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)

COMPLETE THE IRB SUBMISSION & HIPAA FORM

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

HIPAA Authorization or Waiver of Authorization NOT REQUIRED

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

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

Protocol eligible to be approved as LIMITED DATA SET

USE ONLY
By WSU & its Affiliate Institutions

NO DATA USE AGREEMENT REQUIRED

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

USE by WSU & Affiliates and DISCLOSURE outside WSU & Affiliates

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

Data Set includes Collecting PHI

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

SUBMIT AUTHORIZATION TO THE IRB

Approved by IRB With AUTHORIZATION to access Medical Records

Protocol eligible to be approved with WAIVER OF AUTHORIZATION

SUBMIT REQUEST FOR WAIVER TO THE IRB

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