Is Your Research Covered By HIPAA’s Privacy Rule?

Are you collecting PHI?

Yes

From Research Subject

From Medical Records at BUMC or outside entity

Your access to PHI is governed by HIPAA

Your use & disclosure of PHI are HIPAA covered functions

HIPAA Exempt

No

HIPAA does not apply

Is PI a member of covered workforce?

Yes

HIPAA

De-identified

Limited Data Set

Identified

HIPAA Authorization

Waiver of Authorization

Preparatory to Research

Decedent Research

No

HIPAA Exempt
If the data have none of the 18 HIPAA identifiers, then complete **Deidentified Data** form

If the data have only limited identifiers (dates, zip codes and city, and any other unique identifying number, characteristic, or code that is not expressly precluded), then complete **Limited Data Set** form

If any data are from deceased people, then complete **Decedent** form

If I need data with HIPAA identifiers, what form do I complete?

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**HIPAA**

Will your study need to review medical records to write the protocol or for recruitment?

- Yes: **Preparatory to Research**

Does your study have written informed consent?

- Yes: **HIPAA Authorization**
  - Was study submitted after 1/9/06?
    - After 1/9/06: **HIPAA Authorization language in ICF**
    - Before 1/9/06: **Separate HIPAA Authorization form**
  - Before 1/9/06: **Waiver of Authorization**

- No: **The protocol**
  1. requests Waiver of Informed Consent (J4)
  2. requests Waiver of Documentation of Consent (J3), or
  3. is Exempt (B1)