

## HIPAA

HIPAA stands for the Health Insurance Portability and Accountability Act of 1996. The Privacy Rule establishes the conditions under which certain healthcare groups, healthcare clearinghouses, organizations, or businesses, called covered entities, handle the individually identifiable health information known as Protected Health Information (PHI). Principal Investigators should be aware of the Privacy Rule because it establishes the conditions under which covered entities can use or disclose PHI for research purposes. The specific regulations for HIPAA are found in: 45 CFR 160 and 164.

Many research organizations that handle PHI will not have to comply with the Privacy Rule because they are not covered entities. The Privacy Rule will not directly regulate researchers who are engaged in research within organizations that are not covered entities even though they may gather, generate, access, and share personal health information. For instance, entities that sponsor health research or create and/or maintain health information databases may not themselves be covered entities; however, the Privacy Rule may affect their relationships with covered entities. It is recommended that research sites consult their own legal counsel to determine if they would be a "covered entity". (See the decision tool, "Am I a Covered Entity?" on the HIPAA website at: <[www.hhs.gov/ocr/hipaa](http://www.hhs.gov/ocr/hipaa)>.)

Covered entities are permitted to use or disclose protected health information for research with individual authorization, or without individual authorization under limited circumstances set forth in the Privacy Rule.

### Authorization by Research Participant:

HIPAA specifies that a covered entity may neither use nor disclose PHI for research purposes unless the patient has provided, in advance, his or her written authorization for such use or disclosure. It may be combined with the informed consent document. California requires the individual authorization to be a separate document with its own signature lines. It is the responsibility of the PI to be aware of any state and local laws that raise the standard that HIPAA has set forth.

### Six Required Elements:

- A description of the PHI to be used
- The persons authorized to use or disclose information
- The persons authorized to receive information
- The purpose of the requested use or disclosure of information
- An expiration date which may be indicated as "end of study" or "none" for Authorization to place PHI in a research database (California requires an actual date)
- Signature of the subject and date

### Three Required Statements:

- A statement that the subject has the right to give written notice to withdraw their authorization at any time
- A statement that once the subject's PHI has been disclosed, it is possible that the receiver may redisclose the information
- A statement that informs the subject that they may choose to refuse to sign the authorization and this will not affect their medical treatment

### General Requirements:

- The authorization must be written in plain language (approximately 8<sup>th</sup> grade level)
- A copy of the authorization form must be given to the subject

Waiver or Partial Waiver of Authorization:

For research uses and disclosures of PHI, Sterling IRB may approve a waiver or partial waiver of authorization requirement. Partial waivers are likely to be sought to enable investigators to contact and recruit individuals as potential research subjects. The following criteria must be satisfied to grant a waiver or partial waiver of authorization:

- Minimal risk to privacy: There must be an adequate plan to protect patient identifiers, to destroy identifiers at the earliest opportunity (unless there is a health or research justification or it is required by law), and there are adequate written assurances against redisclosure
- Practicality: The research could not be practically conducted without the Partial Waiver/Waiver
- Access: The research could not be practically conducted without access to PHI