

HIPAA: Activities Preparatory to Research Provisions

The HIPAA preparatory to research provision permits covered entities, i.e., physicians / investigator sites, to use or disclose protected health information (PHI, i.e., individually identifiable health information that has “touched” a covered entity) for purposes preparatory to research, such as the generation of hypotheses for testing and the screening of potential subjects for inclusion in research studies. Without this provision, the Department of Health and Human Services - Office of Civil Rights was concerned that the HIPAA rules could produce unintended results such as delaying research and prohibiting a physician / investigator from being able to review his / her own clinical records for research purposes without first seeking an Authorization from each patient whose record is reviewed. This provision also permits a covered entity (often, the patient’s physician) to allow an outside researcher to engage in activities preparatory to research, including the review of clinical records and the full range of PHI. For activities involved in preparing for research, covered entities (physicians and investigator sites) may internally use or disclose PHI to an outside “researcher” without an individual’s Authorization, a waiver or an alteration of Authorization by an IRB or internal privacy board, or a data use agreement.

A “researcher” may be an employee or member of the covered entity’s workforce or an outside “researcher” such as personnel of the sponsor or CRO (e.g., study monitors). If the researcher is an employee or a member of the covered entity’s workforce, the internal researcher may use PHI to contact prospective research subjects. If the researcher is NOT a member of the covered entity’s workforce, i.e., an outside “researcher”, the researcher may not contact prospective research subjects *without* an individual’s Authorization or a waiver from an IRB.

In practice, the covered entity / physician has three methods of seeking an Authorization from an individual patient after PHI has been reviewed preparatory to research by an outside researcher: (1) the covered entity seeks a waiver of Authorization from an IRB so that the outside researcher can contact the individual; (2) the covered entity / physician contacts the individual to seek an Authorization under which the outside researcher will be allowed to use the individual’s PHI in order to contact that person; or (3) having screened and identified the individual as appropriate for the study, the outside researcher requests the covered entity / physician to contact the individual and explain the study and enroll the individual.

The covered entity must obtain from a researcher representations that

(1) the use or disclosure is requested solely to review PHI as necessary to prepare a research protocol, to identify prospective research participants, or for similar purposes preparatory to research;

(2) the PHI will not be removed from the covered entity (investigator site) in the course of review, but information de-identified under HIPAA’s standards may be removed.

- **Regarded as de-identified under HIPAA:** age, gender, three digit zip code, diagnosis
- **Not regarded as de-identified under HIPAA:** direct identifiers, dates of birth, dates of service, initials, specific demographics

(3) the PHI for which use or access is requested is necessary for the research. The covered entity may permit the researcher to make these representations in written or oral form.

If the investigator site is subject to HHS Protection of Human Subjects Regulations, i.e., The Common Rule, which would cover most academic medical centers, any preparatory research activities involving human subjects research, which are not otherwise exempt, must be reviewed and approved by an IRB and must satisfy the informed consent requirements of HHS regulations.

Also, under this HIPAA provision, the covered entity must do an “accounting for disclosures”, which means that the covered entity must retain a log of identifiable health information that an outside “researcher” looked at. To assist the covered entity, the outside “researcher” may provide a log to the site for its records, but it is still the site’s (i.e., covered entity’s) responsibility under HIPAA. For a description of what is required for Accounting for Disclosures – see below.

HIPAA Accounting for Disclosures - Requirements:

- **Generally**
 - Description of PHI
 - date
 - recipient
 - recipient address, if known
 - purpose
- **Multiple disclosures to same person for same purpose**
 - Description of PHI
 - date of first disclosure
 - recipient
 - recipient address if known
 - purpose
 - frequency, periodicity or number of disclosures
 - date of last disclosure.
- **For disclosures of PHI of 50 or more individuals for a particular research purpose**
 - Name of protocol,
 - description of protocol or research activity
 - PHI disclosed,
 - date or period of time during which disclosure occurred or may have occurred and last date of disclosure,
 - name, address, and phone no. of sponsor and recipient (and a requirement to assist in contacting the sponsor / researcher)
 - statement that the PHI may or may not have been disclosed for a particular protocol or research activity.