Review of Data Preparatory to Research

Definition:

Protected Health Information (PHI) - Protected health information includes all individually identifiable health information, including demographic data, medical histories, test results, insurance information, and other information used to identify a patient or provide healthcare services or healthcare coverage. 'Protected' means the information is protected under the HIPAA Privacy Rule.

Using PHI to determine if a study is feasible

Because it may be necessary for a researcher to obtain access to and review PHI in order to prepare a research protocol, HIPAA rules allow such review upon compliance with specified criteria. This provision might be used, for example, to design a research study or to assess the feasibility of conducting a study, or to identify potential participants for a study.

According to HHS guidance on the Privacy Rule:

The preparatory to research provision permits covered entities to use or disclose protected health information for purposes preparatory to research, such as to aid study recruitment. However, the provision at 45 CFR 164.512(i)(1)(ii) does not permit the researcher to remove protected health information from the covered entity's site. As such, a researcher who is an employee or a member of the covered entity's workforce could use protected health information to contact prospective research subjects. The preparatory research provision would allow such a researcher to identify prospective research participants for purposes of seeking their Authorization to use or disclose protected health information for a research study.

The Review Preparatory to Research may be used by an investigator in order to review PHI of potential research subjects, but may not contact the potential subjects to ask them to participate in a research study until IRB approval of the research study is granted. HIPAA allows investigators to retain lists of prospective subjects obtained during Review Preparatory to Research, provided that the data does not leave the covered entity.

Submission to use PHI for research preparation

If an investigator wishes to review protected health information (PHI) to determine the feasibility of a research study, the IRB should be notified using a "Review Preparatory to Research" form (45CFR164.512(i)(1)(ii)). As a covered entity under HIPAA, Woman's IRB must obtain from the researcher representations that:

> (A) Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;
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> (B) No protected health information is to be removed from the covered entity by the researcher in the course of the review; and

(C) The protected health information for which use or access is sought is necessary for the research purposes.

FAQ

1). Can I review my own office records to plan for a new study without IRB approval?

You cannot use, access, or record PHI on human subjects without one of the following three things:

- Using a HIPAA Authorization; or
- Obtaining an IRB Waiver of Authorization; or
- Submitting a Representation of Activities Preparatory to Research form to the IRB

If the review of records does not involve use of PHI then it can proceed without IRB approval or submission of a Work Preparatory to Research certification.

For example, if a database administrator runs a report to count up the number of potential subjects with a specific medical condition between the ages of 1 and 5 years, that search would not involve use of PHI by the investigator. The report would simply provide a summary of the number of potential subjects. If PHI is viewed, recorded or used in any way, the investigator must submit a Representation of Activities Preparatory to Research form before doing the work.

2). I am submitting a Representation of Activities Preparatory to Research form so that I can review my records to identify how many potential subjects are in my clinic. What information, if anything, can I retain when I'm done?

You must limit the data collected to the **minimum necessary** to meet the objectives of the preparation activities (e.g., establish feasibility, plan the study, identify potentially eligible subjects, etc.). You may not collect study data but you may retain names and contact information to be used, after the study is approved by the IRB, for recruitment purposes.

3). Do I need to submit the Representation of Activities Preparatory to Research form as part of my IRB submission for my protocol?

Work preparatory to research is submitted when the investigator is planning research or is uncertain if it is feasible. There is no need for this form when an actual protocol will be submitted to the IRB.