
Yale University Institutional Review Boards

410 GD 2 Guidelines on Phone Screening for Recruitment into Human Research Projects

Overview

The guidance describes the requirements related to collecting health information over the phone for the purpose of determining eligibility for research participation prior to obtaining written consent and authorization.

Phone Screening and Health Insurance Portability and Accountability Act (HIPAA)

Many investigators use telephone screening as a method of recruitment and/or eligibility screening for their studies. When done properly, this can be a useful and effective tool. What's important for investigators to remember is that depending on the type of information collected and recorded during this initial conversation, HIPAA regulations may apply- even if the potential research participant is the one initiating the contact.

The reason that HIPAA may apply is that once an investigator collects and stores identifiable health information it effectively "enters" Yale and is therefore subject to HIPAA requirements as protected health information (PHI). PHI would include information that is typically collected during a phone screen or "pre-screen" such as, name, date of birth, address, medical conditions, etc. Therefore, investigators should design phone screening procedures to avoid, or minimize, the collection and retention of PHI when possible (for example, collecting age rather than birth date).

However, when it is necessary to collect PHI then the investigator must indicate this in the IRB protocol application and request a waiver of HIPAA Authorization to collect and store the information during such recruitment activities. The waiver is considered effective until the potential subject presents to the research office and signs a Research Authorization Form (RAF) or until the study ends. Note that HIPAA only recognizes written authorization, so verbal authorization from the potential subject to permit the investigator to retain the information as required for the purpose of the immediate single study also requires a waiver approved by the IRB prior to initiating the recruitment/screening plan in the conduct of research.

In cases of verbal authorization, the investigator should consider incorporating the following language into telephone scripts used to screen potential subjects: "We will keep the information we just talked about in our files until you come in to screen for the study. If you qualify and choose to be part of the study, this information will become part of your study file. If you don't come in or if you don't qualify for the study, we will keep this information until [*the duration can be modified but as a suggestion-* the study is over] and then we will destroy it. We are required by law to keep this information confidential and we will not use it for any purpose other than to see if you qualify for this study."

Investigators who wish to retain phone screening information to recruit individuals for future studies or to keep a record of ineligible subjects will also need a waiver. Additionally, a protocol to maintain a subject recruitment database may be necessary.

For more information on this topic please see the website <http://info.med.yale.edu/hic/> or call the HIC at 203-785-4688.

The official version of this information will only be maintained in an on-line web format. Any and all printed copies of this material are dated as of the print date. Please make certain to review the material on-line prior to placing reliance on a dated printed version.
