

Pre-Screening of Study Subjects

Guidance

The Principal Investigator is responsible for ensuring subjects that participate in research meet the inclusion and exclusion criteria. Pre-screening of study subjects is crucial to ensure the safety of subjects. To prescreen for eligibility, Investigators frequently need access to identifiable private information to do so.

To access identifiable private information found in a medical record, the access requires either:

- The potential subject will sign and date an authorization, or
- A waiver of authorization granted by the IRB to access records or stored identifiable biospecimens.

To request a waiver of authorization to screen for eligibility only, submit the request as part of the IRB materials using the 'Appendix for Alterations/Waivers of Consent or PHI' found on the Human Subjects Protection Program website.

Requirements

- Treating physicians who are also listed as researchers on an IRB-approved study may review the medical records of their own patients for inclusion/exclusion criteria for the study without an IRB-approved full or partial waiver.
- Treating physicians who are not involved in the research study, but are affiliated with the Principal Investigator's Department, may give their permission to the Principal Investigator and/or a delegated research member to access their patients' PHI provided there is an IRB-approved waiver of PHI Authorization in place.
- Treating physicians who are not involved in research may directly inform patients about studies and ask if they would like to speak to study staff. If a patient decides to participate and signs a PHI Authorization or an IRB approved waiver of PHI Authorization is in place, the research staff may access the medical record.
- If a subject indicates to a treating physician that s/he would like to learn about a research study, study personnel may contact the patient to present the details.