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 part to ensure the safety of subjects.

Access to protected health information (PHI) requires potential subjects to sign and date an authorization that includes rights of revocation before research personnel may view the medical record.

In some cases, a waiver of PHI may be granted by the IRB for access to PHI for pre-screening purposes only.

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 full or partial 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 full/partial 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.

• Research staff who are not employed by the treating physician may not review the medical record of a prospective subject without prior written authorization of the patient or a waiver by the IRB.