

Guidance for Requesting Use of Protected Health Information (PHI) for Recruitment

Whenever identifiable health information is accessed from a covered entity, such as Boston Medical Center, without signed authorization—whether it involves reviewing medical records or clinic schedules—a waiver of HIPAA (Health Insurance Portability and Accountability) authorization is necessary. Below is a template outlining how to complete the HIPAA section of the INSPIR application for this purpose. You must tailor this section according to the requirements of your study. Also, ensure that any use of Protected Health Information (PHI) for recruitment or pre-screening is clearly stated in the recruitment section of the INSPIR application. Should you require assistance with completing the HIPAA section for recruitment, please do not hesitate to contact us at medIRB@bu.edu.

HIPAA Compliance section:

Q1: Please indicate "YES" as you will be accessing PHI without signed authorization.

Q2: Select "YES" as you will require PHI solely for recruiting/pre-screening purposes.

Q3: Any patient presenting with XXXXX (as defined in the study eligibility criteria, which should match the subject population description provided earlier in the application).

Q4: Enter the estimated date range for records you need to access to identify eligible individuals in mm/dd/yyyy - mm/dd/yyyy (or specify "through the end of the recruitment period").

Q5: List all variables accessed to assess eligibility and approach the patient (e.g., MRN, name, diagnosis, upcoming appointment date, contact information, etc.). Be as specific as possible.

Q6: Most often this is study staff; however, if utilizing the Clinical Data Warehouse for Research (CDW-R), consider contacting them to ensure your INSPIR application aligns with the necessary variables in your CDW-R query.

Q7: Please indicate "YES." Common identifiers include MRN, name, and dates. Even if not abstracting, include identifiers if necessary to access the required data (e.g., MRN required to access a chart).

Q8: "Recruiting without prior knowledge of potential subject eligibility would consume excessive study staff time and may involve ineligible subjects." Or similar

Q9: "Approaching ineligible subjects could lead to confusion and waste their time; eligible and interested subjects will provide authorization during consent." Or similar

Q10: "All identifiable information will be handled, transmitted, stored, analyzed, or otherwise managed solely on HIPAA-compliant electronic systems meeting PHI protection standards for Boston Medical Center," or similar aligning with details provided in the confidentiality section.

Q11: "Identifiers will be promptly destroyed upon determination of eligibility for potential subjects." Or similar. Note: Study teams may retain identifiers through the recruitment period to prevent rescreening. If applicable, specify this and mention that the list of names/MRNs will be destroyed at the conclusion of the recruitment period.