THE OHIO STATE UNIVERSITY
COLLEGE OF MEDICINE

Research Recruitment Tip Sheet for Investigators

The purpose of this document is to provide guidance on the recruitment of potential subjects for research purposes and ensure compliance with applicable university and medical center policies (see below).

Investigators and research staff should be aware of the Privacy Rule because it establishes the conditions under which covered entities can use or disclose protected health information (PHI) for many purposes, including research. As an Investigator it is important to ensure the use of appropriate research recruitment methods as inappropriate methods can delay an IRB approval or an Honest Broker (HB) data request.

Use of PHI for Research Subject Recruitment

1. Informed Consent for Research Provided: Investigators are permitted to access PHI in approved OSUWMC/The James sources of potential subjects who have already provided consent to be contacted for research recruitment pursuant to an existing IRB approved or exempt study.

2. Existing Patient Care Relationship: If the investigator is a medical staff member and has an existing patient care relationship with a potential subject, the investigators and members of the clinical treatment team may access PHI for identifying and contacting potential subjects if the IRB approved study is related to the patient's care (i.e., diagnosis or condition).

3. No Existing Patient Care Relationship: If an investigator does not have an existing patient care relationship with a potential subject, or if the patient care relationship is unrelated to the focus of the research study, the investigator or research staff members are permitted to access the PHI of potential subjects for recruitment purposes by:

    a. Obtaining a Partial Waiver for recruitment purposes from the Privacy Board or IRB; or

    b. Through an IRB-approved recruitment protocol that describes how research staff will access the PHI of potential subjects for screening and recruitment purposes.

Note: The research team must not "cold call" potential subjects; investigators must coordinate with a treating clinician before contacting the potential subject. Recruitment scripts (e.g., phone, email, and letter scripts) must contain a link between treating clinician and investigator.

Recruitment Methods

All recruitment methods (including recruitment scripts) for an individual study must be approved by the IRB. Research requests for data will be reviewed and approved by the Honest Broker Committee. The Committee will provide data pursuant to what was approved by the IRB, including mailing address, phone, email address, and MyChart.

Recruitment methods must consider the privacy of potential subjects. For example, when leaving voicemails with a potential subject it is important to limit the information to the ***minimum amount necessary*** to convey the intended purpose of a study to the potential subject. Leaving a detailed message may disclose information to individuals the potential subject did not want to know.

If the investigator does not have a prior relationship with the potential subject, establishing a link between the clinician and investigator is critical. Without that link, it may leave the potential subject wondering how the investigator obtained their medical information and lead to a privacy complaint.

Examples of Creating a Link between Clinician and Investigator

Non-Compliant: "Hello, my name is (researcher name) and I am part of a study team at OSUWMC/COM. You are a possible eligible patient for a research study."

Compliant: "Hello, my name is (researcher name) and I am a colleague of your provider at OSUWMC. Providers in your clinic were notified about the following research study…"

Non-Compliant: "Hello, (patient name), I am (researcher name), a part of a research study team working at OSUWMC/COM. The reason I am calling today is that you have been identified as a possible eligible patient for a research study for people with…"

Compliant: "Hello, (patient name), I am (researcher name), a part of a research study team working at OSUWMC/COM. The reason I am calling today is that your doctor, (patient's provider) has identified you as a patient who might be eligible for a research study on people with…"

Non-Compliant: "Dear (patient name), I would like to invite you to participate in a research study that will develop a program which provides…"

Compliant: "Dear (patient name), (patient's provider or provider group) and I would like to invite you to participate in a research study that will develop a program which provides…"

Policies

The Ohio State University Office of Research, Office of Responsible Research Practices, Human Research Protection Program Policy #17: Recruiting Methods, Recruitment Materials, and Participant Compensation

- https://orrp.osu.edu/files/2022/01/17-Recruiting-Methods.pdf

The Ohio State University Wexner Medical Center, Medical Center Research HIPAA

- https://osumc.policytech.com/dotNet/documents/?docid=93832&anonymous=true

The Ohio State University Wexner Medical Center, Patient Information and HIPAA Requirements 09-03

- https://osumc.policytech.com/dotNet/documents/?docid=97367&anonymous=true

Resources

HIPAA and Human Subjects Research, Office of Responsible Research Practices

- https://orrp.osu.edu/irb/investigator-guidance/hipaa/

Honest Broker Data Requests

- https://medicine.osu.edu/research/research-information-technology/services-and-products/honest-broker-for-clinical-data-requests
- https://ccts.osu.edu/content/research-data-request-form

Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule, National Institutes of Health Publication Number 03-5388

- https://privacyruleandresearch.nih.gov/pdf/HIPAA_Privacy_Rule_Booklet.pdf

University HIPAA Policy What It Means for Your Research, Presentation Slides, June 2021

- https://orrp.osu.edu/files/2021/07/University-HIPAA-Policy-What-It-Means-for-Your-Research-FINAL.pdf