



**POLICY & PROCEDURE MANUAL**

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**PATIENT RECRUITMENT AND REFERRAL FOR RESEARCH IN THE JACKSON HEALTH SYSTEM EMERGENCY DEPARTMENT**

The IRB has always required approval of a research protocol before patient screening and recruitment could begin. However, the Health Insurance Portability and Accountability Act (HIPAA) has changed the ways in which a treating physician or treatment personnel may refer patients to a researcher for screening and recruitment. The Privacy Regulations under HIPAA regulate how identifiable health information created or received by a covered entity (such as Jackson Memorial Hospital) may be used or disclosed in connection with research. Under HIPAA, the use of this protected health information or "PHI" in research generally is not permitted without an authorization from the subject or an IRB waiver of authorization. Therefore, HIPAA requires either that an authorization from the subject or a full or partial IRB waiver of HIPAA authorization for recruitment be obtained.

If recruitment of protocol participants is being done in the Jackson Health System ED, the Principal Investigator should have previously accomplished two necessary components. First, the Principal Investigator should have satisfied the requirements of the Jackson Health System Clinical Trials Office. The phone number for this office is (305) 585-7226. Second, the Principal Investigator should have IRB approval of the protocol, including the method by which the Principal Investigator intends to recruit JHS patients for the protocol. Upon entering the JHS ED, a Principal Investigator should immediately contact the JHS Director of Research in the ED to ensure that proper recruitment methods are followed.

**Recruitment by the Clinician or the Treatment Staff (i.e., The ED Staff) by Patient Authorization:**

- A physician who has a treatment relationship with the patient (an "ER physician") and who is also the researcher may approach a patient about participation in any IRB approved trials in which the physician participates as a researcher. The physician's treatment personnel (those who have a "reason to know" identifiable health information by virtue of the treatment relationship i.e. consultants or admitted patients team physicians) also may approach the patient about this



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research. Before using the PHI for any reason related to research, the physician must have the patient sign an authorization for the release of his/her PHI. Because this method involves a dual role; the patient's physician is also the recruiting researcher, the physician is strongly advised to guard against ethical concerns, such as the appearance of coercion or undue influence.

- A treating clinician, who is not the researcher, or the clinician's treatment personnel, may approach a patient about participation in another researcher's IRB approved study. If the patient agrees to a referral to the researcher, the treating clinician must first request that the patient sign an authorization for the release of PHI, to be placed in the patient's medical record, before giving any PHI to the researcher.
- An ED physician who is not the researcher may discuss possible patient eligibility for an IRB approved study with the research personnel in a de-identified manner (i.e., with all specified subject identifiers removed). If the research personnel believe the de-identified patient would be eligible for the trial, the ED physician must first request that the patient sign an authorization for the release of PHI, to be placed in the patient's medical record, before giving any PHI to the researcher.

**Recruitment by Referral:**

- An ED physician who is not the researcher may verbally give the patient a researcher's name and contact information regarding an IRB approved study. In this case, the onus is on the patient to contact the researcher.
- The researcher may provide colleagues with an IRB-approved introduction letter describing the study. This letter would explain the purpose and procedures of the study and inform individuals how to contact the research team. Researchers are prohibited from having

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access to participant/patient names, addresses, or phone numbers; interested individuals would have to initiate contact.

- The researcher may send an IRB-approved letter to colleagues asking for referrals of eligible individuals/patients interested in the study. The research team may provide the referring colleague an IRB-approved information sheet about the study to give to the individuals/patients. If interested, the individual/patient contacts the Lead Researcher, or, with documented permission from the patient (a patient authorization for the release of PHI, to be placed in the patient's medical record), the Lead Researcher may be allowed to contact patients about enrollment.

**Recruitment by Waiver of Authorization:**

The IRB may grant the request of a researcher for a full or partial waiver of the patient's authorization for recruitment purposes if the IRB determines that the treating physician's direct approach to the patient or obtaining the patient's prior authorization is impracticable.

For a researcher and staff to review records or obtain lists of other physicians' patients, medical records, test results or other clinical information when the researcher/staff is not involved in the treatment of the patients, the researcher/staff must include a description of the plan for recruitment in the IRB protocol submission; describe the method of contacting the individuals; and demonstrate the concurrence of the primary treating physician. In addition, consistent with JMH and UM policies, the researcher/staff must agree that:

- the sole purpose for obtaining the patient information is to identify prospective research participants;
- the patient information sought to be reviewed is necessary to identify prospective participants; and



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- no patient-identifiable information will be copied or removed from the JMH premises.

The request for waiver of authorization may be granted in the following circumstances:

- Minimal risk studies (i.e., expedited level of review) in which subjects will not be contacted (e.g., many chart review studies). Researchers request a complete waiver of HIPAA authorization, if applicable. Justification for the waiver must be included in the IRB application.
- Chart review to identify prospective subjects who will then be contacted and asked to participate in the study. Justification for the waiver to review charts must explain why the study cannot be done without the waiver. A partial waiver may be granted to allow collection of only the minimum amount of information needed to make contact; informed consent is obtained before additional information is gathered.
  - It is recommended that patients identified through chart review be approached by someone already involved in their care (e.g., treating physician, administrative and research staff working with the physician).
  - In some circumstances it may be necessary for members of the research team who are not involved in the patient's care to make the approach, either in person or by phone or letter. The application should explain why the study cannot be done unless the researchers approach subjects directly. Direct approach by someone not involved in the patient's care is unusual but may be approved only under exceptional circumstances (e.g., emergency care research).
- A partial waiver of authorization may be requested to advertise about the study, screen potential subjects for the study, and to keep the screening database for use in screening for future studies

**SUPERSEDES:**

**CODE NO.**



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