Procedure Name: **Subject Recruitment and Referral Procedures**
Effective Date: **March 26, 2010**
Revision: **01**
Initiating Department: **Office of Clinical Trials**
Procedure Number: **OCT-009**
Application: **Subject Recruitment and Referral**

OBJECTIVE:

The objective of this procedure is to define the process by which subjects may be recruited for or referred to research studies.

REFERENCES:

OPHS-IRB Manual, Section 11.3	Referral Fees
OCT SOP #CR-007	HIPPA Compliance

SCOPE:

This procedure applies to all Clinical Research Investigators, Research Coordinators, and other Key Personnel associated with the research team.

BACKGROUND:

At UNTHSC, the Institutional Review Board (IRB) has always required approval of the research protocol before patient screening and recruitment could begin. However, the Health Insurance Portability and Accountability Act (HIPAA) has changed the ways 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 UNTHealth, the Patient Care Center, and UNTHSC in general) 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. HIPAA regulations, then, determine whether or not an authorization from a potential subject must be obtained prior to recruiting that subject to participate in a research project. In some cases, though, an IRB waiver or partial waiver will suffice to allow recruitment of potential subjects.

GENERAL RECRUITMENT PRINCIPLES:

- Efforts to identify and recruit potential human research subjects should always respect personal rights to privacy and confidentiality.

- Everything possible should be done to avoid coercion of subjects in the recruitment for research study participation.

- Whenever possible, the research study should be designed to fully encompass racial, ethnic, and gender diversity.

PROCEDURE:

When the Researcher Is a Clinician Seeking to Recruit His or Her Own Patient

The research study may be presented or introduced to the potential subject by the patient's clinician or a staff member of the patient's clinician. This is a common approach when the clinician is also the researcher[1] of the IRB-approved study. Thus, a physician who has a treatment relationship with the patient and who is also the researcher may approach a patient about participation in any IRB-approved study in which the clinician participates as a researcher. The clinician's treatment personnel (those who have a "reason to know" the patient's identifiable health information by virtue of the treatment relationship) may also approach the patient about this research. This could be a staff nurse, research coordinator, study nurse, or research assistant with prior appropriate access to patient health information. However, the clinician or other treatment personnel must note the communication in the patient's medical record.

When the Researcher Is a Clinician Seeking to Recruit Someone Else's Patient

- A clinician who is <u>not</u> the researcher may send a letter to their patient about how to join an IRB-approved study so long as the content of the letter is approved by the IRB. Often such a letter from the physician directly mailed to his or her patient is quite useful, providing some general background information and directing the patient, if interested, how to contact the research project personnel. It is important to note that unless the IRB approves a waiver of authorization for study recruitment purposes, the letter may NOT be co-signed by the researcher and the researcher may not have a copy of letters sent to patients that contain any patient identifiers.

- A clinician who is <u>not</u> the researcher may give the patient another researcher's name and contact information, and the patient may contact the researcher if interested.

When the Researcher Is <u>Not</u> a Clinician, but Would Like Access to Patients

- The best approach is for the non-clinician to establish a working relationship with appropriate clinicians and have them contact the patient for the researcher.

- Another approach is to directly advertise for patients using only IRB-approved ads, flyers, handouts, email notices, etc. Please note that direct advertising can be used by clinicians as well as non-clinicians, but in all cases must follow IRB policies, procedures, and guidelines.

[1] "Researcher" is broadly defined to include Principle Investigator, Co-Investigator, or other key personnel associated with the research team.

- In most cases, though, recruiting patients with direct face-to-face information and invitations to participate is preferred, since it allows for immediate clarification and patient-clinician interactions.

Patient Shows Interest in Research – Contacts Researcher
In all the examples described above, once the potential research subject indicates an interest in study participation, she or he should be instructed to contact research investigators directly using information provided by the clinician, handout, flyer, etc. The researcher must avoid initial telephone contact with a potential subject, but calling a patient back based on a request left by the patient for the researcher to do so is permitted.

Telephone Recruiting
Direct researcher-to-patient telephone contacts where the researcher initiates the contact must be avoided, since privacy issues cannot be assured. If someone initiates a call to a stranger, how would the caller know the person on the other end is in fact the person whose health information being discussed?

Additionally, telephone scripts and interactions vary considerably even under the best of circumstances. Finally, telephone contacts and the context of the interaction cannot be accurately documented.

HIPAA and Privacy
The individual who initially introduced the study to the potential subject should document this permission in the potential subject's records. HIPAA privacy regulations state that a health care provider may not share individually identifiable health information with research investigators without the written authorization of the patient. Hence, whenever there is the possibility that the potential subject's health information and identity will be shared with members of the research team, a valid HIPAA authorization may be required from the potential subject. There are exceptions, however. For example, when a UNTHSC clinician refers a potential subject to a UNTHSC researcher, a written HIPAA authorization is not required. However, the referring UNTHSC clinician must document in the clinical record the potential subject's permission for his or her contact information to be shared with the UNTHSC researcher.

For studies involving children, a letter introducing the study following the guidelines and procedures described above should be sent to the child's parents, and parental permission obtained prior to enrolling the child in the research study. Except by explicit prior IRB approval in extremely rare situations defined by law, at no time can a clinician or investigator recruit a child into a research study without prior parental permission.

REVISION HISTORY

Rev	DCO	Description of Change	Approved by
1	10-109	Replacement of "policy" with "procedure"; addition of references and change history	MVWB