

## 5.0 RESEARCH SUBJECT AND PATIENT RECRUITMENT

### 5.1 General Recruitment Policies

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

### 5.2 Contact of Potential Human Research Subjects

#### 5.2.1. "Cold-Calling"

The IRB prohibits "cold-calling" of potential research subjects. "Cold-calling" is the practice of investigators or research staff, unknown to the potential research subject, initiating contact with the potential subject based on their prior knowledge of private information. To avoid a cold-calling scenario, the research study should be introduced to the potential research subject by an individual who, by virtue of his/her position, would normally have access to the potential subject's confidential information (e.g., the personal physician of the potential subject or a member of this physician's clinical staff). If the potential research subject indicates an interest in study participation, s/he should be instructed to either (a) contact the investigators directly or (b) permit the individual who initiated this contact to share with the research team the person's interest in study participation so that the researchers can subsequently contact the potential subject and provide more information about the study.

The individual who initially introduced the study to the potential subject should document this permission in his/her records. As per the HIPAA privacy regulations, 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 UPMC clinician refers a potential subject to a UPMC researcher a written HIPAA authorization is not required. The referring UPMC clinician must document in the clinical record the potential subject's permission for his/her contact information to be shared with the UPMC researcher. More discussion of this, with model HIPAA authorizations for sharing health information is available in the [IRB HIPAA Guidance Web page](#).

#### 5.2.2 Acceptable Methods of Contacting/Recruiting Potential Research Subjects

Acceptable methods of contacting and/or recruiting potential research subjects include:

- Random digit dialing and the Cole's (reverse) Directory.
- A mailing from the potential research subject's physician or clinic (or program) representative (or the investigator, but only after appropriate introduction by the physician or his/her staff), the investigator) that describes the purpose of the study and requests that the subject return a postcard (or makes a telephone call) indicating his/her agreement to participate.

A less preferable option is to request the person send back a postcard (or call a designated phone number) only if s/he does not wish to participate. If no response is made within a specified time period, the subject may then be contacted by the investigator or a member of the research team. A drawback to this approach is that individuals so contacted may feel harassed by the researchers if, for example, they never receive the letter, can't read the letter, or are confused by the instructions.

- For studies involving children, a letter introducing the study should be sent to the child's parents and parental permission obtained prior to enrolling the child in the research study.
- Public advertisements or notices posted in public places.

### **5.3 Advertisements for Research Subject Recruitment**

#### **5.3.1 IRB Review of Advertisements for Human Research Subject Recruitment**

Direct advertising that is intended to be seen or heard by prospective subjects to solicit their participation in a study must be submitted for IRB review and approval before use.

Direct advertising for research subjects includes, but is not limited to: newspaper, radio, television and Internet ads; audio/video tapes; notices; and flyers. Not included are: 1) communications intended to be seen or heard by health professionals (e.g., "dear doctor" letters and doctor-to-doctor letters (even when soliciting for study subjects), 2) news stories (so long as readers are not invited to consider participating in the research and specific contact information is included within the story), and 3) publicity intended for other audiences (e.g., financial page ads directed towards prospective investors).

IRB review and approval of listings of clinical trials on the internet, is NOT required when the system format limits the information provided to basic trial information, such as:

- study title;
- purpose of the study;
- protocol summary;
- basic eligibility criteria;
- study site locations; and
- how to contact the site for further information.

Examples of clinical trial listing services that do not need IRB review and approval include the National Institutes of Health (NIH) ClinicalTrial.gov website, the NIH National Cancer Institute's cancer clinical trials listing (Physician Data Query [PDQ]), and the government-sponsored AIDS Clinical Trials Information Service (ACTIS).

When information posted on a clinical trial website goes beyond directory listings, as noted above, such information is considered part of the informed consent process and therefore requires IRB review and approval. Examples of information which would exceed such basic listing information include descriptions of clinical trial risks and potential benefits, or solicitation of identifiable information (e.g., name and contact information).

### 5.3.2 Advertisement Guidelines

Any advertisement directed at the recruitment of potential human research subjects should be limited to the information that the subject needs to determine his or her eligibility and interest. Per Food and Drug Administration guidelines (FDA Information Sheets for IRBs and Clinical Investigators, 1998 Update), advertisement statements should be limited to the following information and should not include exculpatory language:

1. Advertisements cannot state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the protocol and consent document.
2. Advertisements cannot claim, either explicitly or implicitly, that the drug, biologic, device or other type of intervention is safe or effective for the purposes under investigation.
3. Advertisements cannot claim, either explicitly or implicitly, that the test article or other research intervention is known to be superior or equivalent to any other drug, biologic, device or intervention..
4. Advertisements for recruitment into a research study involving an investigational drug, biologic, or device should not use terms such as "new treatment", "new medication", or "new drug" without explaining that the test article is investigational.
5. Advertisements cannot promise "free medical treatment" when the intent is only to state that subjects will not be charged for taking part in the investigation.
6. Advertisements may state that subjects will be paid, but should not emphasize the payment or the amount to be paid by such means as larger or bold type. Advertisements aimed at recruitment of children cannot contain the dollar amount of the compensation.
7. Advertisements cannot include exculpatory language through which the participant or their legally authorized representative waive legal rights or releases the investigator, the sponsor or institution from liability for negligence.
8. The advertisement should generally be limited to the information that potential subjects need to determine their eligibility and interest in the research. When

appropriately worded, the following items may be included in advertisements, but are not required:

- a. The name and address of the clinical investigator and/or research facility.
- b. The condition under study and/or the purpose of the research.
- c. In summary form, the criteria that will be used to determine eligibility for study participation.
- d. A brief list of participation benefits, if any.
- e. The time or other commitment required of the subjects.
- f. The location of the research and the person or office to contact for further information.

#### 5.4 Screening Tests and Interviews Prior to Subject Enrollment

Screening procedures,(including interviews) that are performed solely for the purpose of determining if individuals' eligibility for participation in the research are subject to IRB oversight including the requirement for written informed consent. When screening interviews or surveys are used, written informed consent must be obtained prior to conducting the interview if 1) the interview is being performed for research purposes; 2) the individual's responses to the questions could place him/her at risk of civil or criminal liability or be potentially damaging to his/her employability or reputation; and 3) subject identifiers are recorded with responses. Note: if this screening interview meets the 'minimal risk' criteria (see Chapter 2), the investigator may be able to request a waiver of written consent (see Chapter 8).

Medically proven and accepted procedures that are performed for prospective research subject's medical management and which would have been done whether or not study entry was contemplated (e.g., procedures consistent with the diagnosis or treatment of the person's disease or medical condition) may be performed and the results subsequently used for determining research study eligibility without requiring that the person sign a research consent form.

#### 5.5 Incentives for Participation in Research Studies

Subjects may be paid or otherwise rewarded (e.g., gift card) for participating in a research study. Note, however, that remuneration is a recruitment incentive; it is not a benefit of study participation. Incentives are frequently used when the benefit of study participation is otherwise remote or non-existent.

- The amount of payment, if any, should be reasonable, based on the complexities and inconveniences of the study. The amount of payment should NOT be based on the risk of study participation.
- The magnitude of the incentive and the proposed method and timing of its disbursement must not be coercive or present undue influence for initial or continued participation in the study.

- It is acceptable for students to be offered course credits for their participation in a research study. However, the student must be provided with alternate, equitable ways to earn these credits if they decide not to participate in the research study.

### 5.5.1 IRB Review and Approval of Incentives for Participation in Research Studies

Information concerning the remuneration of human research subjects, including its amount or nature and the schedule of its disbursement, is subject to initial and continuing review by the IRB. This information should appear in the Costs and Payments section of the research protocol and informed consent document(s). **It should not be included as a benefit of study participation.**

### 5.5.2 Payment Disbursement Guidelines

Any payment or reward should accrue as the study progresses and not be contingent upon the human research subject completing the entire study. Disbursement of a proportion of the total payment or reward contingent upon study completion is acceptable, provided that the amount of this incentive is not so large as to unduly induce subjects to remain in the study when they might otherwise withdraw voluntarily.

## 5.6 Finder's Fees and Bonus Payments

It is not permissible for investigators to pay or receive finder's fees for referral of research subjects. Physicians who refer a potential subject for participation in a research study are permitted to be paid, at a reasonable amount, for any services (e.g., obtaining a medical history, performing screening examinations, conducting medical record reviews, etc.) that they perform in support of the research study.

It is not permissible to pay or receive bonuses with respect to subject recruitment goals or completion of a study.