



## STANDARD OPERATING PROCEDURE ADDENDUM

### Recruitment of Research Participants

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## I. **General Guidelines:**

- Efforts to identify and recruit potential participants for research studies should always respect personal rights to privacy and confidentiality.
- All recruitment procedures must accurately reflect information in the consent form and protocol in order to avoid coercion or undue influence.
- The selection of research subjects must be equitable, and should encompass racial, ethnic and gender diversity whenever possible.
- Recruitment of participants is viewed as the beginning of the informed consent process and is, therefore, subject to the regulations that govern informed consent.

## II. **Identification of Potential Participants from Medical Records, Databases or Other Non-public Records**

Potential participants can be identified through review of medical records, databases, or other non-public records under the following conditions:

- The investigator is a physician or health care provider who is directly engaged in the patient's clinical care and has clinical access to these records (All physicians or health care providers within a HMC clinical unit; e.g., Pulmonary/Critical Care, Dermatology, or Neurosurgery; are considered to be directly engaged in the clinical care of all patients treated within the division.); or
- The investigator is a physician or health care provider who is not directly engaged in the patient's clinical care and has an IRB-approved Request for Review Preparatory to Research in accord with federal regulations.

IRB review will include confirmation that the investigator is allowed access to such records and that the investigator accepts the responsibility for confidentiality and protection of privacy of this information.

## III. **Contacting Potential Participants**

### A. **Initial Contact by Investigator**

Acceptable methods of contacting/recruiting potential participants if the investigator is a physician or health care provider directly engaged in the potential participant's clinical care:

- Person-to-person contact
  - At routine clinic visits
  - Inpatient situations
- Letters or e-mails to potential participants
- Phone calls to potential participants

The initial contact, regardless of method, must come from a person who can be expected to be reasonably familiar to the potential research participant, such as a physician or health care provider directly engaged in the patient's clinical care or an acceptable representative or a physician or healthcare provider from the clinical unit in which the patient has been seen, or a referring physician. The IRB will not approve any recruitment strategies that involve initial contact (based on

knowledge of confidential information, e.g., medical record information) by investigators who are not expected to be familiar to the potential participants.

1. Person-to-Person Contact

It is helpful to present the research in advance so that individuals have time to think about and discuss the research with family. Investigators should also select a location that is private, especially for research involving sensitive issues. The person doing the recruiting should be known to the potential participant or be an acceptable representative (as described above) and should be qualified and knowledgeable about the research.

2. Letters and Phone Scripts

a. IRB Review

The IRB must review and approve letters to potential participants and phone scripts when contacting individuals by telephone.

b. Content of Letters and Phone Scripts

Letters and phone scripts should inform the potential participant of the following:

- Why they are being contacted about participation in a research study, e.g., medical diagnosis or history, or age criteria;
- How their names were obtained, e.g., seen in a particular clinic or had a specific type of surgery in the past;
- That participation will not affect current or future care; and
- Plans to recontact individuals again by phone or mail, and outline the conditions under which recontact will happen, if applicable.

Letters and phone scripts should also include:

- Use of the word “research”;
- Name and address (department) of the investigator;
- Summary of the purpose of the research with a brief listing of major eligibility criteria;
- Factual description of the benefits to the participant from participation in the study, if applicable;
- Compensation if provided; and
- The location of the research and contact information.

c. Second Mailing/Return Cards

If the investigator plans to send a second mailing or to call individuals who did not respond to the initial mailing, he/she should indicate so in the recruitment letter and outline the conditions under which this will happen. One option would be to include return cards and a postage-paid envelope with the recruitment letter to allow individuals to indicate their desire to participate in the research or not. In this way, the investigator would know whom they may contact for further discussion. The IRB recommends that investigators contact only those individuals who return the card and indicate that they are interested in receiving more information about the research. Investigators need to justify contacting individuals who do not return the card.

d. Sensitive or Personal Topics

If the research involves sensitive or personal topics, it is recommended that the letter be vague in an effort to protect the privacy of the recipient. For instance, the investigator may decide not to disclose many details of the research in case someone other than the intended recipient sees the letter.

## **B. Direct Advertisements for Research Participant Recruitment**

### **1. IRB Review**

Federal regulations treat advertising as the beginning of the informed consent process.

**Therefore, all advertising and recruitment materials, that are intended to be seen or heard by prospective participants to solicit their participation in a study, must be submitted to the IRB for review and approval prior to their use or publication.** In its

review of recruitment materials the IRB will consider the sites where the materials will be placed. These materials include, but are not limited to, newspaper or magazine ads, television or radio ads, videotapes, e-mail, web sites, posters, brochures, direct mailers, public announcements, theater ads, flyers and internal postings, letters to potential participants, and letters to treating physicians and healthcare professional for recruitment purposes.

- Letters to referring physicians and healthcare providers only need to be reviewed by the IRB if potential participants may view this information. The requirement for IRB review does not apply to communications intended to be seen or heard by healthcare professionals only.
- In order to determine if a web site listing of a research study needs IRB review and approval, refer to section C below. .

Recruitment materials should be submitted as a part of the original protocol application, but may be submitted after a research study receives IRB approval. Any changes to the content, presentation or method of communication of approved recruitment material must be reviewed and approved prior to use. When submitting a new advertisement or changes to an approved advertisement **after** the research study has received IRB approval, forward the recruitment materials to the IRB by submitting a Modification/Amendment.

The IRB must review the final advertisement content. When advertisements are in writing, the IRB must review the final copy of printed advertisements. When advertisements are to be taped for broadcast, the IRB must review the final audio/video tape. It is strongly advised that the IRB review and approve the wording of the advertisement prior to taping to preclude re-taping because of wording not meeting institutional and regulatory requirements.

The IRB will review the information contained in the advertisement and the mode of its communication, to determine that the procedure for recruiting participants is not coercive and does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.

## 2. Required Elements for Direct Advertisements

Any advertisement directed at the recruitment of potential research participants should be limited to the information the prospective participants need to determine their eligibility and interest. The required elements for advertisements are:

- Use of the word “research”
- Name and address (department) of the investigator
- Summary of the purpose of the research with a brief listing of major eligibility criteria
- Factual description of the benefits to the participant from participation in the study
- The location of the research and contact information
- The following mandatory statement at the bottom of the ad: “This research study has been approved by the Institutional Review Board, under federal regulations, at Penn State Milton S. Hershey Medical Center.”

## 3. Additional Guidelines for Direct Advertisements

- Any information listed on the advertisement must be commensurate with the scientific protocol and consent forms. No additional information may be included in the advertisement.
- When applicable, advertisements must state if the research includes the use of an investigational (non FDA-approved) drug or device.
  - Advertising should not use terms such as “new treatment,” “new medication” or “new drug” in reference to an unapproved drug or device; investigators must state “investigational” or “experimental”.
  - A phrase such as “receive new treatment” implies that all study participants will be receiving newly improved products of proven worth.
- No claims should be made, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device. Such representation would not only be misleading but would also be a violation of the FDA’s regulations concerning the promotion of investigational drugs and investigational devices.
- Advertisements should not promise “free medical treatment,” when the intent is only to say participants will not be charged for taking part in the investigation.
- Advertisements may state that participants will be paid, but should not state the payment or amount to be paid. Simply say that participants will be paid for their time and travel or that participants will be compensated.
- Advertise for “volunteers” or “participants”; do not advertise for “patients”.
- No exculpatory language may be included in advertisements

## **C. Advertising on Internet Web Sites**

### 1. IRB Review

Web sites provide a significant opportunity not only to recruit human subjects, but also to foster informed consent by increasing the amount of information that is available to an individual interested in a clinical trial. IRB review requirements are based on whether the web advertisement is a simple listing or more descriptive listing, defined below.

a. Simple listings

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

- Title
- Purpose of the study
- Protocol summary
- Basic eligibility criteria
- Study site location(s)
- Information on how to contact study sites for further information

b. Descriptive listings

When additional descriptive information is provided by the web site, IRB review and approval is needed to assure that the additional information does not promise or imply a certainty of cure or other benefit beyond what is contained in the protocol and the informed consent document.

All web site advertisements requiring IRB review should be submitted with the web link clearly noted, so the IRB/HSPO can check the posted version.

Investigators should ensure that the contact phone line is answered by someone who is knowledgeable about the requirements and procedures of the protocol.

2. Posting Trial Results on Web Sites. Trial results may be posted once the trial is terminated at the Hershey Medical Center. No patient identifying information may be included. Trial results information does not need IRB approval.

#### **IV. Phone Screening Procedures**

##### **A. IRB Review**

In research studies where potential participants call the investigator to find out more about the research after interest is stimulated by an advertisement, letter or web site listing, an initial telephone interview/phone screening procedure is sometimes used to determine basic eligibility. For the IRB to review and approve the use of phone screening for the research, the investigator needs to provide the following:

- Phone screening procedure, which includes what will be done with the information collected during the phone screening for individuals who decide to participate and those who decline to participate; and
- Phone screening script for obtaining verbal consent and authorization, if applicable; and
- Phone screening questions, if applicable.

The IRB will review the screening procedures to ensure that the process adequately protects the rights and welfare of the prospective subjects, and that any personal or sensitive information is appropriately handled.

## **B. Waiver of Written Consent/Alteration of Authorization for use of PHI**

Telephone screening must comply with both federal regulations governing research and with the new federal medical Privacy Rule. Under federal research regulations, the collection of identifiable private information about individuals over the phone for research screening requires informed consent or an IRB waiver. If the information is identifiable health information, the Privacy Rule requires authorization or a waiver/alteration of authorization for the investigator to use this information for research screening purposes.

Since telephone screening typically occurs before researcher can obtain written informed consent and authorization, the researcher will need to apply for waiver under both federal research regulations and the Privacy Rule:

- Waiver of the requirement to obtain written documentation of informed consent for telephone screening; and
- Alteration of HIPAA authorization for telephone screening.

For waiver of written documentation of informed consent:

- The researcher must demonstrate that the screening poses no more than minimal risk of harm to the subjects and that questions asked are similar to those for which informed consent is normally not required outside of the research context.
- The researcher must still obtain verbal informed consent prior to the research screening.
- The phone script that will be used to obtain verbal consent must be reviewed and approved by the IRB. The script should address all applicable elements of informed consent required under federal regulations, including a description of the measures that will be followed for protecting the confidentiality of this information for individuals that qualify. In addition, the phone script should describe how the information from individuals who do not qualify will be handled.

For alteration of HIPAA authorization, the IRB must be able to justify that:

- The screening and the proposed use of the participants' PHI presents no more than minimal risk to the privacy of the individuals.
- The research could not be practicably carried out without this alteration.
- The research could not practicably be conducted without access to and use of the protected health information.
- There is a plan to protect the identifiers from improper use and disclosure.
- There is a plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research or there is a justification for retaining the identifiers.

## **C. Other Requirements**

The researcher must also describe what will be done with the information collected on individuals who do not qualify for the research or who decide they are not interested in participating. It is strongly recommended that the phone scripts be designed so that identifying information is only collected from individuals who meet the basic eligibility criteria and continue to be interested in

participation. If the investigator plans to store the contact information and any medical history data collected during the phone interviews for future recruitment purposes, the phone script must describe this plan, including a description of how the information will be stored and who will have access to the information. The investigator must obtain verbal consent/authorization to store the information for future recruitment purposes.

#### **D. When Written Informed Consent is Required for Screening Surveys**

For some screening interviews/surveys, written informed consent must be obtained prior to conducting the interview/survey if all of the following criteria are met:

- The interview/survey is being performed for research purposes; and
- The individual's responses to the interview/survey could place him/her at risk of civil or criminal liability or be potentially damaging to his/her employability or reputation; and
- Identifiers are recorded with the interview/survey responses.

#### **V. Screening Tests and Interviews**

While investigators may discuss availability of research studies and the possibility of entry into a study with a prospective participant without first obtaining consent, informed consent must be obtained prior to initiation of any clinical procedures that are performed solely for the purpose of determining eligibility for research (screening procedure), including withdrawal from medication (wash-out). Medically accepted procedures that would be performed as part of the practice of medicine and which would be done whether or not study entry was contemplated, may be performed without first obtaining informed consent for the research and the results subsequently used for determining eligibility.

#### **VI. Recruitment Incentives and Compensation for Research Participants**

##### **A. IRB Policies**

Federal regulations emphasize that investigators must seek legally effective informed consent under circumstances that minimize the possibility of coercion or undue influence (45 CFR 46.116 and 21 CFR 50.20). Thus, the IRB must consider the compensation offered to research participants when evaluating the appropriateness of the informed consent process and the informed consent document for any given protocol.

Payment to research participants for participation in studies is not considered a benefit. Rather, it should be considered compensation for time and inconvenience or a recruitment incentive. The IRB reviews both the amount of compensation and the schedule of payment to assure that neither are coercive nor present undue influence for initial or continued participation in the study.

##### **Amount of compensation:**

- The amount and type of compensation should be based on:
  - The complexity of the research as it relates to the inconvenience to the participant;
  - The type and number of procedures to be performed;
  - The time involved;
  - The anticipated discomfort or inconvenience of the study; and

- The subject population
- The amount of compensation should not be based on the risk of study participation
- Compensation for participation in a trial offered by a sponsor may not include a coupon good for discount on the purchase price of the product once it has been approved and marketed.
- Compensation may include additional amounts to cover travel and incidental costs or these may be reimbursed separately.

**Timing of compensation payments:**

- Any credit for payment should accrue as the study progresses and not be contingent upon the participant completing the entire study. The participants should be compensated in proportion to their time and inconvenience as a result of participation in the research study.
- Unless it creates undue inconvenience or a coercive practice, payment to participants who withdraw from the study may be made at the time they would have completed the study (or completed a phase of the study) had they not withdrawn. For example, in a study lasting only a few days, an IRB may find it permissible to allow a single payment date at the end of the study, even to participants who had withdrawn before that date.

**Completion bonus:**

- While receiving the compensation payment should not be contingent upon completion of the entire study, payment of a small proportion as an incentive for completion of the study is acceptable, provided that such incentive is not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.

**Disclosure of compensation:**

- All information concerning compensation, including the amount and schedule of payment(s), should be described in the informed consent document.

**Advertisement of compensation:**

- Advertisements may state that participants will be compensated or reimbursed for expenses, but should not emphasize the payment or the amount to be paid.

**Alterations in compensation payment:**

- Any alterations in research participant compensation must be reported to the IRB prior to implementation, as an amendment or modification request.

**PSU procedures for paying participants:**

- Investigators will follow the payment procedures and record keeping requirements as outlined in PSU Procedure CR2078 “Payments to Research Participants” when providing compensation to research participants.

**B. IRB Guidelines for Compensating Research Participants**

An individual’s decision to participate in a research study is generally based on altruism and/or potential personal benefit from experimental therapies, and not financial gain. Reasonable monetary compensation for this time commitment is appropriate but compensation for research participation is not required.

- The IRB Executive Committee developed the following guidelines for compensating research participants for their participation in a study. These guidelines provide examples for calculating payment amounts based on different models.
    - Investigators may choose the amount for a category or to offer no compensation. It is recognized that greater compensation amounts may be offered for complex studies, or where a long duration of participation and/or multiple participant procedures and responsibilities are involved.
    - The investigator will need to provide the IRB with a justification and an explanation of why the amount does not present undue influence.
- Flat rate: Participants may be compensated a flat rate per visit. This flat rate might be based on an amount calculated by combining an hourly amount and travel/incidental expenses.
- Hourly: Hourly compensation may be provided for the subjects involved in the study. For example, a modest hourly rate may be appropriate for participation in a simple study. A higher hourly rate may be warranted for a study that involves a lot of time or requires responsibilities at home in order to compensate for the additional disruption and inconvenience.

This should include:

- Time in the hospital or clinic that is solely for the study;
- Travel time;
- Time spent recovering from a procedure or an anesthetic agent used for a procedure; or
- Time required at home for record keeping, specimen collection and other activities; and
- Time that the participant is unable to perform his/her routine activities of daily living due to study related issues should be included in this time.

*(The IRB may ask for an itemized list in order to justify the hourly estimate.)*

- Travel reimbursement: Travel expenses include costs such as transportation (state mileage rate, tolls), parking, meals, incidentals, and accommodations.
  - Subjects should be reimbursed by an equitable method of calculation. For example:
    - Subjects might be reimbursed based on actual mileage and travel expenses, or
    - Flat travel reimbursement might be provided to all subjects who travel a specified number of miles or less, with additional reimbursement for the miles over a specified number, and overnight accommodations reimbursed for the subjects who travel longer distance.
- Bonuses: A bonus may be given for completion of a long term study or for studies that involve low risk but are inconvenient or involve uncomfortable procedures. For example, a bonus of \$50 might be appropriate for a study involving several visits to reward a subject's follow through; or a multi-year study might warrant a greater bonus. The investigator may need to provide a justification.

- Pediatric subject involvement: Additional protections may need to be included when offering compensation for pediatric subjects' (a vulnerable population) participation in research.
  - If compensation is to be provided, the compensation should be given to the subject in a form, manner, and amount appropriate for the age and developmental status of the pediatric subject.
  - Alternative payment options should be considered, to minimize the possibility of undue influence. For example, consider compensation of parents/guardians for travel and meals alone, or with separate compensation to subjects in the form of savings bonds or gift certificates.
  - If both adult and pediatric subjects are enrolled on a study, the compensation should be the same for both age groups.

The IRB will decide if the compensation as described in the informed consent document is appropriate based on the study description and may require adjustment.

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