

## RECRUITMENT OF RESEARCH SUBJECTS

Clinical Research Policy/Procedure	
Approved: December 2007	Next Review: December 2010

### Purpose

To protect the rights of prospective research subjects who are solicited to participate in research study. To ensure that research recruitment activities are not misleading and minimize the possibility of coercion and undue influence.

### Responsible Persons

Principal Investigator and Research Coordination Staff.

### Definitions

**Clinical Trial Listings** are registries of clinical research studies that are actively recruiting research subjects. Clinical trial listings are typically limited to basic study information (e.g., title, purpose of study, protocol summary, basic eligibility criteria, study site location(s), and site contact information). Examples of clinical trial listing services include ClinicalTrials.gov and the National Cancer Institute's clinical trials listing. Swedish Medical Center (SMC) also provides a clinical trials listing via the Swedish Research Center (SRC) website. For the purpose of this Policy/Procedure, clinical trials listings are not considered recruitment materials.

**Recruitment Materials** are advertisements and/or promotional materials that are intended to be seen or heard by prospective subjects to solicit their participation in a research study. Examples of direct advertisements include: newspaper ads, radio announcements, television commercials, public service announcements, internet advertisements, billboards, bulletin boards, posters, newsletters, flyers, letters, and other communications intended, in whole or in part, for prospective subjects. Not included are: (1) communications intended to be seen or heard by health professionals, such as "dear doctor" letters and doctor-to-doctor letters (even when soliciting for research subjects), (2) news stories without direct intent and solicitation for enrollment, and (3) publicity intended for other audiences, such as financial page advertisements directed toward prospective investors.

## Policy

Research recruitment activities, i.e., activities intended to solicit individuals to participate in a research study, are considered the start of the informed consent and research subject selection process. As such, the Principal Investigator is responsible for ensuring IRB review and approval of the methods and materials that (s)he proposes to use to recruit research subjects.

Investigators and SRC Research Coordination Staff may not offer, induce or accept finder's fees, recruitment incentives, enrollment bonuses, or any similar remuneration or payment arrangement in association with the recruitment of research subjects. Reimbursement for justifiable and actual documented time spent on enrollment activity is acceptable.

*Recruitment materials* must be approved by an IRB prior to use. Recruitment materials may not include any claims, either explicitly or implicitly, that the test article under investigation is safe or effective, or that the test article is known to be equivalent or superior to any other drug, biologic or device.

*Clinical trial listings*, on the other hand, do not require prospective IRB review and approval so long as the listing is limited to basic study information. However, if a Principal Investigator intends to recruit research subjects from the Medicare population, (s)he must ensure that the research study is registered with the ClinicalTrials.gov registry.

## Procedure

### RECRUITMENT MATERIALS; CLINICAL TRIALS LISTINGS

1. All proposed recruitment materials must be reviewed and approved by an IRB prior to use. Recruitment materials may not be used until the Principal Investigator receives written approval from the IRB. IRB-approved recruitment materials are marked with an IRB approval stamp. Only exact copies of IRB-approved recruitment materials may be reproduced for publication or dissemination.
  - Print recruitment materials must be submitted to the IRB in final format (i.e., as intended for publication including format, font, size, bolding, graphics, and other visual effects).
  - Audio or video recruitment materials should be submitted first with a written script and when found acceptable to the IRB, can be used to produce the final audio/video tape. The final tape must be reviewed and approved by the IRB prior to broadcast.
  - ➔ **NOTE:** All recruitment materials utilizing the Swedish logo must be reviewed by the SMC Corporate Communications department (Marketing) prior to submittal to the IRB. The SMC marketing department is also available to assist with the preparation, designing, and dissemination of recruitment materials and is encouraged for all print, internet, or audio-visual mediums.
2. Recruitment materials should be submitted with the IRB application at the time of initial review of the research protocol. Recruitment materials may, however, be submitted to the IRB at a later date.
3. The IRB has the authority to approve, require modifications in, or disapprove all research activities, including recruitment activities. Among other criteria, the IRB reviews proposed recruitment materials to assure that they are not misleading, overly reassuring, unduly coercive, and do not promise a certainty of cure beyond what is outlined in the research study protocol and informed consent form. If the IRB proposes modifications to recruitment materials during its review, such modifications (or other modifications acceptable to the IRB) must be implemented before the recruitment materials can be used. The IRB must re-review and approve the modified recruitment materials before the materials can be used.

4. A Principal Investigator may advertise a research study via the SRC clinical trial listing provided that the research study has been approved by the IRB. Utilize a *SMC Research Study Web Posting Form* to publicize the research study on the Swedish clinical trial listing. Before submitting the form, obtain Sponsor approval for the posting so as not to be in potential conflict with confidentiality requirements in an existing clinical trial agreement.  
  
➔ **NOTE:** If the Principal Investigator intends to recruit research subjects from the Medicare population, the Principal Investigator should ensure that the research study is registered with the ClinicalTrials.gov registry. See Clinical Research Policy/Procedure: REVENUE COORDINATION FOR RESEARCH SUBJECTS.

#### **ADDITIONAL SMC REQUIREMENTS**

5. **Recruiting Process.** SRC Research Coordination Staff may solicit the participation of prospective research subjects into IRB-approved research studies on file with the SMC institutional review office (IRO). The SRC staff member is responsible for ensuring that the study is IRB-approved and on file with the SMC IRO.  
  
➔ **NOTE:** Prospective research subjects may be referred to IRB-approved studies conducted by non-SMC investigators; however, the prospective subject must be first be approached by a SRC Research Coordination staff member and provided the opportunity to decline the referral. The prospective subject may also specify the extent of identifiable information that may be provided with the referral.
6. **SMC employees.** SMC employees may not be specifically targeted or solicited to participate in a research study through the use of organizational media that is designed for the sole purpose of employee communication.
7. **Research subject interviews.** Use of research subjects in interviews is permitted with prior approval of the Manager of the relevant SRC department or SRC Director, and the Corporate Communications department. If photographs of a research subject will be taken, consent of the research subject must be obtained via a specific consent form for photography which can be obtained from Corporate Communications.

#### **REPORTABLE EVENTS**

8. Use of any recruitment material without prior IRB approval must be promptly reported to the reviewing IRB and the Swedish Institutional Review Office. See Clinical Research Policy/Procedure: UNPLANNED PROTOCOL DEVIATIONS.
9. Unapproved release of any patient or research subject identifiable or protected health information must be immediately reported to the Research Education & Compliance Officer and the reviewing IRB.

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#### **Forms**

- ◆ SMC Research Study Web Posting Form

## **Supplemental Information**

- Clinical Research Policy/Procedure: IDENTIFYING POTENTIAL RESEARCH SUBJECTS
- Clinical Research Policy/Procedure: REVENUE COORDINATION FOR RESEARCH SUBJECTS.

## **Expert Consultants**

Research Education & Compliance Officer  
Manager, Institutional Review Office

## **Author**

Peter Kim, JD CIP, Research Education & Compliance Officer

## **Regulatory Requirement**

21 CFR 50.20  
45 CFR 46.116

## **References**

“Recruiting Study Subjects,” Information Sheet Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors, U.S. Food and Drug Administration (1998).

## **Addendum**

1. SMC Research Study Web Posting Form

pk:Recruitment of Research Subjects – v. 2.0.doc (12/07/07)

<b>RECRUITMENT OF RESEARCH SUBJECTS</b>
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**ADDENDUM 1**

**SMC Research Study Web Posting Form**

## SMC Research Study Web Posting Form

[www.swedish.org](http://www.swedish.org)

New study posting    
  Update to current posting    
  Deletion of study posting

### FORM KEY

<b>Active Date:</b>	Date posting needs to be activated (or posted) on website (will not be seen on web).
<b>Expire Date:</b>	Date study posting should be deleted from website (will not be seen on web).
<b>*IRB Number:</b>	Required field. Must always be included for new postings, updates, or deletions (will not be seen on web).
<b>Campus:</b>	Option to list First Hill, Providence, or Ballard
<b>Type of Study:</b>	Department study falls under i.e., Cardiovascular, Sleep, etc.
<b>Trial Type:</b>	Subcategory of type of study i.e., subcategory for Cardiovascular study is Carotid Artery.
<b>*Title:</b>	Required field. Always include. <b>IMPORTANT NOTE:</b> <u>Commercially sponsored studies MUST have a <i>modified</i> study title to post on the web. 255 character spaces available for this field.</u>
<b>Description:</b>	Purpose of the study. Please keep as brief as possible. 600 character spaces.
<b>Eligibility Criteria:</b>	Inclusion/Exclusion - must be short list and in terms general public can understand.
<b>Status:</b>	Open, temporarily closed, or closed to accrual.
<b>Start Date:</b>	Date study begins at SMC.
<b>P.I.:</b>	Please include investigator's credentials after name i.e., M.D., Ph.D., etc.
<b>Contact Name:</b>	Name of coordinator or person from department public can contact about studies.
<b>Phone:</b>	Number of contact person listed above. Always in the form of (area code) 1 space, then a – between phone number.
<b>Alternate Phone:</b>	If alternate number not available for department use the general research number (206) 215-3100.
<b>Email:</b>	Address of contact person named above. ALWAYS list emails in lower case letters.
<b>Alternate Email:</b>	If no alternate email available use research email, <a href="mailto:research.center@swedish.org">research.center@swedish.org</a>

NOTE: For new study postings, please complete as many fields as possible. If there is no information for a field, the field title will not show up on the web. The IRB number and study title are always needed.

Active Date	
Expire Date	
*IRB Number	
Campus	First Hill
Type of Study	
Trial Type	
*Title	
Description	
Eligibility Criteria	
Status	Open
Start Date	
Principal Investigator	
Contact Name	
Contact Phone	( ) -
Alternate Phone	( ) -
Email	
Alternate Email	