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	Title: Review of Recruitment Methods and Materials	Effective Date: 12/15/2008 Revision Date: 9/25/2018

I. PURPOSE

The purpose of this standard operating procedure is to document the mechanism for CHOP IRB review and approval of research study recruitment methods and materials of non-exempt human subjects research.

II. POLICY STATEMENT

The IRB is responsible for ensuring fair and equitable selection of subjects; this responsibility includes ensuring that the content of recruitment materials accurately reflect the study, and do not unduly induce potential subjects to participate. To fulfill this responsibility, the CHOP's IRB reviews participant recruitment methods, advertising materials and participation payment arrangements, and approves them when fair, honest and appropriate.

III. SCOPE

These policies and procedures apply to all researchers, research staff, IRB members and IRB staff.

IV. DEFINITIONS

eIRB: The electronic IRB management system.


Limits to the IRB's Authority: The IRB's authority includes materials created or distributed by the CHOP investigative team. The IRB will not review recruitment materials, websites, brochures, etc., that are directly distributed to prospective subjects by a non-CHOP sponsor or investigators.

Recruitment: The process by which an investigator conveys information to a prospective subject in order to allow the individual to determine whether or not they are interested in participating in the research.

Recruitment Materials: Websites, flyers, posters, newspaper advertisements, television scripts, radio advertisements, brochures, doctor-to-patient letters, e-mail templates, and any other material that participants will see or hear that may be used as part of the recruitment process. Recruitment materials do not include information conveyed as part of in-person or telephone recruitment conversation.

Recruitment Methods: Includes recruiting materials, advertised compensation, and other means and methods used to attract potential participants for research.

Final Version of Recruitment Materials: Recruitment materials that include all of the desired formatting and study-specific content, such that no additional edits are required prior to sharing with potential subjects. If IRB-approved final versions of recruitment materials include template contact information (e.g. "TBD" or other placeholders for

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investigator or potential subject names, numbers, email addresses, or mailing addresses), the investigator may populate these fields with study-specific contact information prior to use without additional IRB review and approval provided no additional changes to content or formatting are made.

V. PRINCIPLES


Recruitment methods, including advertisements, and participant payment arrangements affect the equitable selection of subjects and are therefore important components of the IRB's review and approval process. Advertisements, whether in print media, broadcast media, websites or other formats, often provide the prospective participant with their first exposure to study information. For this reason, recruitment materials are considered part of the process of informed consent.

Payment arrangements among sponsors, organizations, investigators and those referring research subjects may place subjects at risk of coercion or undue influence or cause inequitable selection. Paying finders' fees to healthcare professionals is a violation of the AMA Code of Ethics E-6.03, and is not permitted at this Institution.

A. Content of Recruitment Materials

Generally, the information included in recruitment materials should be limited to the information the prospective participants need to determine their eligibility and interest such as:

1. The name and address of the investigator, the research facility and/or the institution conducting the study;
2. The condition under study and/or the purpose of the research;
3. In summary form, the criteria that will be used to determine eligibility for the study;
4. A brief description of what is involved in study participation (i.e., number of visits, length of participation, general study procedures);
5. The location where the research will take place and the person or office to contact for further information; and
6. If reimbursement for expenses or payment for time and effort will be provided, these can be stated but the amount and terms should not be specifically stated unless the IRB determines such statements are appropriate and do not entice subjects. Nothing in this recruitment precludes the amount of compensation from being disclosed as part of in-person or telephone recruitment conversations.

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B. Recruitment materials must NOT include any of the following:

1. Any direct or implied claim that the purpose of the research is to treat the condition or that the test article, if any, is safe and effective, or equal or superior to an existing treatment; or
2. Any express or implied claim that the research will improve the participant's medical condition; or
3. A statement that promises "free medical treatment;" or
4. The term "new" unless modified (e.g., "new research medication" or "new investigational medication"); or
5. Use of terms such as "new treatment," "new medication," or "new drug" without explaining that the test article/test procedure is investigational; or
6. Exculpatory language; or
7. Emphasized payment/compensation amount (e.g. larger or bold type).

VI. PROCEDURES

A. Investigator Responsibilities


1. All recruitment materials, as defined above, must be submitted to the IRB for review and approval in accordance with **SOP 301**. These materials must meet the standards established in V.A. and V.B. (above) and must be submitted to the IRB at the time of initial submission of the protocol or at a subsequent time as a modification to the protocol.
 - (a) Recruiting materials developed or revised, with the exception of template contact information, after the initial IRB approval must be submitted to the IRB as a protocol amendment prior to use.
2. A change in any of the following during the course of the research is considered a protocol amendment and must be presented to the IRB for review and approval:
 - (a) Recruitment methods; or
 - (b) Revised or newly developed recruiting materials.
3. Investigators who get referrals from other physicians should use one of the following procedures to ensure that the prospective participant's permission to be contacted:
 - (a) The referring physician can obtain the individual's permission to be contacted; or

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- (b) The investigator may send a letter inviting the individual to participate and the prospective participant can then contact the investigator; or
- (c) The investigator can notify the prospective participant (e.g., by mail) that they will be contacted unless they opt-out and the individual can exercise the option to opt-out from further contact if they do not wish to take part.

B. IRB Review of Recruitment Material Content

1. The IRB will review:
 - (a) The information contained in the recruitment materials;
 - (b) The mode of its communication;
 - (c) The final copy of written recruitment materials;
 - (d) Screen shots of website recruitment materials;
 - (e) The final audio or video for broadcast recruitment materials.
2. If the material is included as part of the initial submission, the IRB will review the material as part of its review, using the principles described above.
3. If the material is submitted as a modification to the protocol, the Chair, CPHS or his/her designee will review the material using the principles described above to make sure the content is appropriate and does not pose any undue influence or coercion to potential research participants.
4. If the recruitment material needs to be formatted/recorded into the final version that potential participants will see/hear, the investigator will submit the IRB approved text and IRB approval letter to the entity responsible for creating the final format material (e.g., Research Communications).
5. The investigator will submit and the IRB will review the final version of all recruitment materials. The IRB will review the materials for grammar/syntax changes, for changes in emphasis due to layout or typographical design and will ensure that no material changes to previously approved content have been made.
6. Once the recruitment materials are approved, the IRB will communicate the approval to the investigator via eIRB. (Note: it might not be feasible for final versions of some materials, such as copies of websites, radio or television ads to reside within eIRB.)

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VII. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.111(a)(3)	21 CFR 50.20,
45 CFR 46.116	21 CFR 56.111(a)(3)
CHOP Research Institute: Use & Disclosure of Protected Health Information for Research	CHOP Policy A-3-14: Privacy of Patient Information

VIII. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301: Submission Requirements	
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IX. RESPONSIBILITIES

Title	Responsibility
IRB Reviewer	Responsible for reviewing the content of recruitment materials submitted for IRB review.
Principal Investigator	Responsible for submitting draft and final versions of all recruitment materials to the IRB for approval prior to use.

X. ATTACHMENTS

XII. REVISIONS:

- 7-25-06: Initial Approval Date:
- 11-20-07: Incorporated change in process with Research Communications as Appendix A and change in name of Research Communications (previously Stokes Studio).
- 12-15-08: Removed doctor-to-doctor letters from definition of recruitment materials.
- 6-10-10: Incorporated change in process with Research Communications and change in IRB process from paper to eIRB. Allow flexibility for IRB to determine whether statement of payment amount is appropriate.
- 9-18-12: Clarified the definition of Recruitment Materials to exclude in-person and telephone conversations.

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- 8-01-14: Clarified which recruitment materials are reviewed by the IRB and that compensation may be disclosed during in-person and telephone conversations when involving a written script.
- 9-25-2018: Revised to reflect that written recruitment scripts do not need to be submitted for IRB review and approval, combine sections, and to update definitions.

XI. APPROVAL:

 Director, Human Subjects Research

 Date

 Chair, Committees for the Protection of Human Subjects

 Date