

SOP: RR 406 Version No.: 05 Effective Date: 12/3/10	RECRUITING OF AND ADVERTISING FOR SUBJECTS	Supersedes Document Dated: 7/1/08
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Steering Committee approved 9/19/11

1. POLICY

The informed consent process begins when a potential human research subject first learns of a study, which is usually accomplished through-recruitment efforts. The IRB is required to review all documents and activities related to recruitment that bear on the rights and welfare of human subjects. Accordingly, direct advertisements (defined below) that solicit participation in, advertise for, or educate the public about research activities also require prospective IRB review and approval. Such IRB review should include the review of the materials the investigator proposes to use and the recruitment process used to recruit subjects. Such review and approval of direct advertisements by the IRB must occur prior to release of such direct advertisements to the public. Any payment or other financial incentive offered to prospective research subjects to take part in the research study must also be reviewed and approved by the IRB.

Specific Policies

The following are key definitions used in this policy. Other terms used in this policy but not defined herein shall have the meanings set forth in the Glossary.

1.1. Definitions

1.1.1. “Direct advertising or recruitment materials” refers to any form of solicitation for prospective research subjects including, but not limited to, fliers, posters, brochures, screening tools (i.e. scripts or questionnaires), recruitment letters, postcards, clinical trial web sites, or communications intended to be seen or heard by health care professionals such as “dear doctor” letters and doctor-to-doctor letters (unless not soliciting for study subjects), or oral communications by an investigator or his staff. Not included in this definition are news stories (unless the potential subject has the opportunity to call for more information) and publicity intended for other audiences, such as financial page advertisements directed towards prospective investors.

1.1.2. “Clinical trial web sites” means any clinical trial web site managed by Aurora Health Care or one of its affiliated entities that lists clinical trials being conducted at one or more of Aurora’s Facilities, or that is sponsored by Aurora. An internet advertisement is not automatically a clinical trial web site. Aurora IRB does not assume oversight of a “public” clinical trial web site (e.g., CenterWatch, NCI).

1.1.3. “Recruitment letter” means any letter, postcard, or other personal communication sent to potential subjects that solicits research participation.

1.1.4. “Word of mouth” means soliciting research participation via network groups, seminars, lectures or other oral presentations.

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1.2. IRB Review and Approval of Direct Advertisements

1.2.1. IRB Review

Any direct advertising related to research studies must be submitted to the IRB for review as part of the investigator's initial submission to the Aurora IRB (see Policy FO 301). Aurora IRB approval of direct advertisements must occur prior to the publication, posting or issuance of such advertisement to the public.

The IRB will review the information contained in the direct advertisement, and the mode of its communication, to determine that the procedure for recruiting subjects is not unduly 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.

The IRB should review the final copy of printed advertisements to evaluate relative size of type used or other visual effects. When advertisements are to be taped for broadcast, the IRB will review the final transcript, and should review the final audio/video tape. The IRB requires review and approval of the wording of the direct advertisement prior to taping to preclude the need to retape because of inappropriate wording. The review of the final taped message prepared from IRB-approved text may be accomplished through expedited review procedures (see Policy RR 401).

Recruitment materials shall not disclose the fact that a research study is to be conducted at any Aurora Facility until the IRB has reviewed and approved the conduct of the particular research study and the content of the recruitment material. The IRB will consider whether the recruitment material is appropriate and whether the content complies with Sections 1.3.1 and 1.3.2 below.

Such recruitment material may specify that the research study is being conducted at a specific facility (hospital, clinic, etc.), but if it is an Aurora Facility, the Aurora Public Relations Department should be contacted in accordance with Section 1.4 below. However, the fact that the research study has been approved by the IRB may not be mentioned in the recruitment material.

1.2.2. Direct Advertisements Submitted after Aurora IRB Approval of a Study

When the investigator decides, after the approval of a research study by the IRB, to use direct advertising to solicit subjects on the research study, the proposed advertising and recruitment plan shall be considered by the Aurora IRB as an amendment to the ongoing research study in accordance with Policy RR 403. When appropriate under federal regulations, such direct advertisements may be reviewed pursuant to the expedited approval procedures described in Policy RR

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401. The IRB shall utilize the guidelines set forth below (in section 1.3) in conducting such expedited reviews. In all cases, the investigator is required to provide the IRB with a copy of the final version of the direct advertisement which will be dated and maintained by the RSPP office.

1.3. Guidelines for the Content of Recruitment Materials Prepared by Investigators

1.3.1. Limitations on Content

Recruitment materials to solicit subjects may be used so long as the information contained in the advertisement is not coercive, does not include exculpatory language, and does not imply a certainty of favorable outcome.

No claims should be made, either explicitly or implicitly, that the Investigational Drug or Investigational Device is safe or effective for the purposes under investigation, or that the investigational drug or the investigational device is known to be equivalent or superior to any other drug, biologic or device. Such representation would not only be misleading to subjects, but would also be a violation of applicable federal regulations concerning the promotion and commercialization of Investigational Drugs and Investigational Devices. Recruitment materials for solicitation into Investigational Drug or Investigational Device research studies should not use terms such as “new treatment” or “new drug” without explaining that the drug or device is investigational. A phrase such as “receive new treatments” leads subjects to believe they will be receiving newly improved products of proven worth.

Recruitment materials should not promise “free medical treatment,” when the intent is only to say subjects will not be charged for taking part in the research study. Materials may not emphasize the payment or the amount to be paid by such means as larger or bold type. They may not allow compensation for participation in a trial offered by a sponsor to include a coupon good for a discount on the purchase price of a product once it has been approved for marketing.

1.3.2. Permissible Content

Generally, any recruitment materials should be limited to the information the prospective subjects need to determine their eligibility and interest. When appropriately worded, the following items may be included in advertisements.

- A. The name and address of the investigator and the Aurora Facility or other site where the research study will be conducted;
- B. A statement that it is a “research” study;

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C. The condition that is being investigated under the research study and the purpose of the research study;

D. The inclusion/exclusion criteria that will be used to determine eligibility for the research study in summary form;

E. A brief list of participation benefits, if any (e.g., a no-cost health examination);

F. The time or other commitment required of the subjects (number of visits, total duration including follow-up visits, etc.);

G. Whether or not compensation/reimbursement will be provided to subjects; and

H. The contact person for further information.

The Aurora IRB does not require inclusion of all of the items listed above in recruitment materials. Other information will be considered on a case-by-case basis.

1.4. **Coordination with Aurora Public Relations Department**

If a physician or investigator intends to use the name of a Facility in the newspaper, television, radio or the internet for the solicitation of potential subjects for a research study being conducted at a Facility, the investigator (or study representative) must contact the Aurora Public Relations Department and provide the department representative with a copy of the proposed transcript. The final transcript must be submitted to the Aurora IRB for review and approval. Any final audio/videotape, as may be applicable, must be forwarded to the RSPP office for review of consistency with the approved transcript in advance of use of such direct advertisement.

1.5. **Clinical Trial Web Sites**

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:

- Title
- Purpose of the study
- Protocol summary
- Basic eligibility criteria
- Study site location(s)

Additional descriptive information requires Aurora IRB approval. Posted information must not promise or imply a certainty of cure or other benefit.

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1.6. Recruitment Letters

1.6.1. Recruitment letters to patients must include a statement indicating how the research subjects were identified and whether the subject's participation will affect future care and whether results of the research will be released to the subject.

1.6.2. Recruitment letters to solicit students under the age of 18 should be directed to the parents and comply with federal regulations governing the privacy of educational records.

1.6.3. The IRB should consider how prospective subjects' names will be identified by the investigator, and if the investigator has obtained the names from a hospital, clinic, or other physician and whether such recruitment method complies with HIPAA privacy standards (see Policy HI 1201).

1.7. Telephone Calls

The IRB should consider the nature of telephone calls (timing, duration, frequency, and content) used to recruit potential subjects and should also assess how a potential subject is identified.

1.8. Word of Mouth

If an investigator intends to recruit potential subjects by any oral communication he/she should submit a transcript of such oral communication to the Aurora IRB before communicating the solicitation. The investigator's intent to recruit subjects in this manner should be mentioned in the written protocol/application submitted to the Aurora IRB.

1.9. Recruitment of Patients from a Facility

1.9.1. If the prospective subject is the patient of the physician or investigator only, the physician or investigator may directly recruit such patient.

1.9.2. If the prospective subject's name is identified when the investigator or research staff reviews PHI maintained by a Facility, such review of PHI must comply with Policy SC 502 and Policy HI 1201, section 1.7.2. In addition, only Aurora personnel who have a treating relationship with the potential subject may contact the patient to recruit such individual into the research study. In other words, investigators who do not have a treating relationship with the potential subject may not directly contact the patient for recruitment purposes.

1.10. Payment or Compensation

Any payment or other financial incentive offered to prospective research subjects for their part in the research study must be disclosed to the IRB at the time of initial submission (via Form

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FO 301-A) or during the course of the study (via Form RR 403-C). The IRB shall review the amount of payment and the proposed method and the timing of disbursement to ensure that neither are coercive or present undue influence.

Credit for payment should occur as the study progresses and should not be dependent on completion of the entire study. Any amount paid to subjects as a bonus for completion has to be reasonable, and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn.

Information regarding payment must be included in the informed consent document (see the Aurora Consent Document template (IC 710-A) Cost section). **Payment to research subjects for participation in studies is not considered a benefit; its purpose is a recruitment incentive.**

2. SCOPE

These policies and procedures apply to Direct Advertisements and recruitment processes used to recruit research subjects.

3. APPLICABLE REGULATIONS, GUIDELINES AND STANDARDS

20 U.S.C. §1232g (b) and 34 CFR §99.31 (2002)

21 CFR §56.107(a), 111, 312.7(a), 812.7(d)

Food and Drug Administration Information Sheets Guidance for Institutional Review Boards and Clinical Investigators, 1998

Office of Inspector General – Recruiting Human Subjects: Pressures in Industry-Sponsored Trials 2001

Recruiting Human Subjects: Sample Guidelines for Practices 10EI-01-97-00196, 2000

45 CFR §164.512(i)(1)(ii)

AAHRPP Element II.3.C.

4. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301

SOP 401

SOP 402

SOP 403

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SOP 502

SOP 701

SOP 1201