AAH RSPP GUIDANCE
RECRUITMENT OF RESEARCH SUBJECTS

PURPOSE
This document outlines which documents and activities need to be reviewed and approved by the IRB prior to use in the recruitment process.

Direct advertising for study subjects is considered to be the start of the informed consent and subject selection process, and therefore IRB oversight of these materials/activities is required. IRBs are expected to assure that the advertising/recruitment materials do not promise a certainty of cure beyond what is outlined in the consent and the protocol, and are not unduly coercive especially to vulnerable populations.

Definitions of Italicized words can be found in the AAH RSPP Glossary.

This guidance pertains to those research studies overseen by the AAH IRB. For studies that rely on external IRB oversight, you must follow that IRB’s policies and procedures as they pertain to subject recruitment.

GUIDANCE
What activities/materials might require IRB Review?
Any direct advertising for research subjects must be submitted to the IRB for review as part of the investigator’s initial submission to the Advocate Aurora Health (AAH) IRB or if added later, as a Change to the approved research (RSPP SOP #9). AAH IRB approval of direct advertisements/recruitment materials must occur prior to the publication, posting or issuance of such advertisement to the public.

What is direct advertising?
Per FDA guidance (Recruiting Study Subjects), direct advertising is that intended to be seen or heard by prospective subjects to solicit their participation in a study. Per the FDA, this is not an objectional practice. Examples of direct advertising includes, but is not necessarily limited to: newspaper, radio, TV, bulletin boards, posters, and flyers that are intended for prospective subjects.

The following are not examples of direct advertising: (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 study subjects), (2) news stories and (3) publicity intended for other audiences, such as financial page advertisements directed toward prospective investors.

IRB review and approval of listings of clinical trials on the internet provide no additional safeguard and is not required when the system format limits the information provided to basic trial information, such as: the title; purpose of the study; protocol summary; basic eligibility criteria; study site location(s); and how to contact the site for further information.
What information may the direct advertising contain?

Direct advertising may contain:

- general information about the study (ie. purpose, basic protocol summary, basic eligibility criteria);
- an appropriately worded listing of participation benefits, if any (e.g., a no-cost health examination);
- the time or other commitment required of the subjects;
- and the location where the research is to be conducted and by whom.

The direct advertising/recruitment materials should not include:

- A promise a certainty of cure beyond what is outlined in the consent and the protocol.
- claims that the drug, biologic or device is safe or effective for the purposes under investigation,
- claims that the test article is known to be equivalent or superior to any other drug, biologic or device.
- terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational.
- Promises of "free medical treatment" when the intent is only to say subjects will not be charged for taking part in the investigation
- Emphasis (e.g. in the form of larger font or bolding) of subject payment

What does the AAH IRB review require?

The AAH IRB will consider the information contained in the direct advertisement, and the mode of its communication, to determine whether the proposed recruitment procedure 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.

It is suggested that draft versions of recruitment materials (ads, posters, transcripts of taped broadcasts) be initially supplied to the AAH IRB for review, as the IRB may request changes. Final versions of all recruitment materials must be supplied to the AAH IRB for review and approval. Final versions of recruitment materials may not be used prior to securing IRB approval.

- In print advertisements, the AAH IRB will review the content of the material as well as evaluate the relative size of type used or other visual effects of the materials.
- In taped/broadcast materials, the AAH IRB will review the final transcript as well as the format to be broadcast to potential subjects (ie. the audio/video tape). If a visual medium, the IRB will also evaluate the visual effects of the materials.

The review of the final direct advertisements may be accomplished through expedited review.
Do I need to get approval from anyone else at AAH to post printed recruitment materials or use broadcast/taped recruitment materials?

If an investigator intends to use the name of an AAH Facility in the newspaper, television, radio or the internet for the solicitation of potential subjects for a research study being conducted at an AAH Facility, the AAH Public Relations Department may need to authorize this use. It is the responsibility of the research team to secure this authorization.

The posting of printed materials may also require the authorization of Administration of the facility where posting is intended. It is the responsibility of the research team to secure this authorization.

What about other forms of subject contact?

The AAH IRB will also need to review and approve these other methods of recruitment. These may also be included with the initial application to the IRB or submitted as a Change to the approved research (see RSPP SOP #9).

Use of a Receptionist

Often, the first contact prospective study subjects have is with a receptionist. The receptionist should follow a script approved by the IRB when approaching a patient about possible participation in a research study. If personal and sensitive information is being gathered by the receptionist about the prospective subject, the procedures to ensure that the confidentiality of the patient is being maintained must be provided in the application to the IRB.

Recruitment Letters

Recruitment letters to patients should 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.

- The IRB will consider how prospective subjects’ names are 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.

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.

Telephone Calls

The IRB will consider the nature of telephone calls (timing, duration, frequency) as well as the content when reviewing this method of subject recruitment. Information in the IRB application should address how a potential subject is identified, and whether HIPAA privacy standards are maintained. As part of the phone call, the potential subject should be informed of the same information as outlined above in “recruitment letters”. A transcript of the communication may be required to be submitted to the IRB.
Face to face contact with patients

The investigator should provide specifics to the IRB on this methodology in the submission application or Change form. Consideration of whether the patient has a treating relationship with the investigator will be given (see below about ‘cold-calling’). If the patient is part of the treating team of the investigator, contact may be made after IRB approval. If however, the patient does not have a treating relationship with the investigator, further action on the part of the research team may be required (see below).

What is ‘cold-calling’ as it applies to subject recruitment?

‘Cold calling’ is a method of contacting patients (whether in person, by phone or letter) for participation in a research study by an individual with no treating relationship to the patient. Out of concerns related to the Belmont Report principle of Respect for Persons and the HIPAA Privacy Act, the AAH RSPP does not generally condone the use of cold-calling of patients to be prospective subjects.

Therefore, any time that a researcher wishes to contact a patient for inclusion in a research study (whether in person, by phone or by letter) with whom they do not have a treating relationship, it is recommended that some action by the treating team occur first.

Also note that the IRB does not typically allow the release of names of potential participants to investigators without prior permission from the potential participants, unless a waiver of consent for this activity is approved by the IRB.

An example of recommended action may include a person from the patient’s treating team approaching the patient in the clinic or in-patient room and asking the patient for permission for the research team member to approach him/her to discuss the research study. Or the recruitment letter being sent from the treating physician mentioning possible participation in research study, and having the patient call the research team if interested.

The method of contact with the patient should be described in the submission/Change form, and will be considered by the IRB with the ethical and regulatory principles in mind. The method of contact/approach must be approved by the IRB prior to use.

No matter what method of approaching the patient is approved by the IRB, the patient’s decision on future contact with the research team must be respected.

APPLICABLE REGULATIONS, GUIDELINES AND STANDARDS

HHS regulations: 45 CFR §164.512(i)(1)(ii)

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


AAHRPP Accreditation Standards/Elements: II.3.C.