

Children's

Hospital & Regional Medical Center
Office of the Vice President for Research

OPERATING PROCEDURES/POLICIES

Committee:	<u>Institutional Review Board</u>
Policy Number:	<u>IRB-24</u>
Effective Date:	<u>June 20, 2005</u>

POLICY TITLE:

RECRUITING POTENTIAL RESEARCH PARTICIPANTS

POLICY:

The IRB shall review the methods used to recruit subjects as potential participants for research studies. The methods approved by the IRB shall be guided by the principle of respect for persons and acknowledgement of individuals and families rights to privacy and confidentiality.

DEFINITION:

For the purpose of this policy, advertising shall be defined as any medium intended to recruit subjects as potential candidates for research studies, including but not limited to flyers, brochures, information sheets, recruitment letters, newsletters, newspapers, web sites, radio and television.

PROCEDURE:

- 24.1 When researchers intend to do research studies where they will interact with research participants, the researcher must provide the IRB sufficient information on their proposed methods for recruiting research participants. The IRB requests information on how participants are to be recruited and any materials used for recruiting. Researchers are requested to provide information on when and by whom the recruitment will be done.
- 24.2 When the researchers are not known to the research participants, the recruitment methods must take steps to protect the privacy and confidentiality of participants. When researchers propose to directly contact individual participants in person, by telephone or by letter or email, the approach to recruit must be done by an individual known to the participant or their legally authorized representatives or by an individual who would have

access to the participant and their representatives by virtue of providing routine care and services. For example:

- A. When participants who are patients are sent letters to recruit them for a research study, the letter must be signed by the participants' doctors or by the Director of the clinic or service that provided the care to the patient.
- B. When participants are patients who will be recruited at the time of a routine visit to the hospital, clinic, doctor or provider's office, the person approaching must have access to the patient by virtue of providing care or services, e.g., clinic nurse, clinic receptionist.
- C. When participants are patients who are recruited directly by a telephone call, the person making the call must be known to the patient or their legal representative.

24.3 In most cases, the IRB does not approve direct telephone calls (item 24.2.C. above) as the first method to recruit participants. The IRB recommends that the first methods for recruitment utilize in person approaches, recruitment letters, or advertising. The IRB does allow follow-up telephone calls as a second method of recruitment after participants have been initially approached to take part in the research either in person or by letter.

24.4 When Children's patients' protected health information (PHI) are needed to identify and recruit potential research participants, only persons who are considered part of Children's work force (the covered entity) shall have access to PHI for recruitment purposes. . [45 CFR 164.512(i)(1)(ii)] These persons must sign Children's Oath of Confidentiality – Recruitment. (Appendix 15.C.) The PHI collected shall be limited to information necessary a) to ensure prospective participants meet the basic selection criteria and b) to contact the participant, e.g., to send a recruitment (approach) letter. If prospective participants decline to take part or do not respond to the recruitment attempts, the PHI collected shall be destroyed or converted to information without any direct or indirect identifiers as defined in the federal privacy rule (HIPAA).

24.5 As in the requirements for obtaining consent, the *timing* of direct recruitment approaches to prospective participants and/or their legal representatives must take into consideration circumstances that can increase the vulnerability of participants. Examples of situations where timing considerations for direct approaches need to be considered include approaches to newly diagnosed patients, patients diagnosed with a terminal illness, patients in emergency or critical care situations, family members of a recently deceased patient; patients scheduled for day surgery.

24.6 As in the requirements for obtaining consent, the IRB shall require researchers to develop recruitment methods that take steps to minimize or

avoid participants feeling pressure, undue influence, or coercion to take part in the research. The IRB will consider the individual(s) who is recruiting participants and that individual's relationship to the prospective participant and/or their legal representative.

24.7 The IRB shall require that advertisements, at minimum, inform potential participants of the following:

- A. The participant is being asked to take part in **research**;
- B. The basic purpose of the research study;
- C. The basic eligibility criteria for research participants;
- D. A brief description of the project, e.g., whether it involves a blood draw, use of an investigational drug, or an interview;
- E. The length of expected participation for individual participants;
- F. Compensation, payment or inducement participants will receive.
- G. Contact information to obtain more information about the research project such as the name and telephone number of the research study coordinator or the name and contact information for the Principal Investigator. In some cases the research coordinator or PI may wish not to be named in the advertisement. In such cases, a title, e.g., research coordinator, will suffice.
- H. The Department/Division of the Principal Investigator and the PI's institutional affiliation, e.g., Children's Hospital and Regional Medical Center; University of Washington. The Children's logo should be used on all recruitment advertisements, and must adhere to the hospital graphic identity standards (typestyle and graphics). Questions about using the Children's logo should be referred to Children's Communications Department.

24.8 The IRB shall look for misleading information that sends the wrong message to participants or that places undue emphasis on monetary rewards for participation.

24.9 Within Children's Hospital, fliers may be posted in designated areas only. IRB-approved advertisements may also be placed in the Family Resource Center. Investigators may request that a recruitment advertisement be placed in specific clinics. Requests must be submitted to the IRB first, along with a description of the arrangements to be made by the investigator for distribution and removal of the advertisements from the clinic areas. Fliers should **not** be placed in elevators, hallways or other public areas within the hospital.

24.10 When potential participants are recruited via a letter to the participant or their legal representative, e.g., parent(s) of the child, the recruitment letter in addition to the elements described above, should:

- A. Be signed by a person who has access to the participant's/parent's name and address and confidential information about the potential participant's diagnosis or care. This could be the child's doctor or the director of the clinic where the child received care. In no circumstances should researchers unknown to participants/parents send approach letters directly to the participant/parent.
 - B. The letter should be written on CHRMC letterhead if the patient is to be approached by a representative of the hospital. If another agency will make the approach, then it may be appropriate that letterhead from that organization be used instead.
 - C. Instructions for the participant/parent on what will happen if they do not respond to the letter, e.g., receive a follow-up telephone call in two weeks. In many cases, the IRB will require researchers to provide a return envelope with a form that families can indicate yes they are interested in hearing more about the research and best way and time to contact them and their contact information or no they are not interested and to request no further contact. Return postcards should not be used as they do not allow participants to provide information to researchers in a manner that will guarantee their privacy.
- 24.11 Recruitment methods to address high non-response rates or low accrual rates in approved studies must adhere to the IRB's requirements that recruitment methods minimize the potential that participants will feel pressure, undue influence or coercion to take part in the research (as stated in 24.6 above). When researchers notify the IRB that they are not meeting accrual goals for the research with the approved recruitment procedures and materials the IRB will request researchers to develop specific plans on how they will address the low accrual rate. In reviewing these plans the IRB shall balance the researchers' goal to accrue participants with the potential research participants' right to privacy and right to consider research participation free of undue pressure, influence or coercion to take part. The particulars of the research including the vulnerability of the research participants or their legal representatives shall be considered by the IRB in reviewing and approving recruitment methods to address low accrual rates.
- 24.12 Among the recruitment methods the IRB will consider to address low accrual rates are:
- A. A second recruitment letter to be sent to non-responders. This recruitment letter must provide a response form with a stamped envelope that allows the potential participant to indicate whether they are interested or whether they do not want to be contacted further.
 - B. Follow-up telephone calls to potential participants or their legal representative in an effort to elicit a response on whether the participant is interested in taking part in the research. In general, the IRB allows no more than 2 telephone calls (a voice message on the

