The Christ Hospital IRB
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IRB REFERENCE MANUAL
SECTION 05
RECRUITMENT OF RESEARCH SUBJECTS AND PATIENTS

5.0 RECRUITMENT OF RESEARCH SUBJECTS AND PATIENTS

The Christ Hospital IRB is responsible for reviewing study recruitment procedures and materials to ensure protection of the rights and welfare of human subjects and equitable subject selection into research. Any method of advertisement must be approved by the IRB before it is implemented. All advertisements must align with subject selection and informed consent regulations pursuant to 45 CFR 46.111 and CFR 46.116.

Investigators must submit recruitment materials, as they will be implemented, to the IRB for review along with the initial protocol submission or as an amendment for review through an expedited mechanism.

All advertisements must not be coercive, must not promise a possibility of benefit beyond what is outlined in the consent and the protocol, must portray accurate information, and must direct potential subjects to appropriate personnel for further information. This is particularly important when a study involves subjects who may be vulnerable to undue influence.

5.1 Recruitment Materials and IRB Approval

5.11 Types of Advertisements and Recruitment Materials Requiring IRB Approval:

a. Printed materials (i.e., newspaper, posters, flyers, pamphlets)
b. Direct recruitment scripts (e.g., telephone scripts)
c. Audio and video recruitment materials (scripts may be accepted)
d. National ad campaigns
e. Internet advertising (postings on federally maintained sites such as clinicaltrials.gov do not need prior IRB approval)

5.12 Types of items NOT requiring IRB approval:

a. Communication to be seen or heard by health professionals (e.g., letters from physician to physician)

b. News stories
c. Publicity intended for other offices

5.2 Content of Recruitment Materials

5.21 Recruitment materials SHOULD include:

a. Name and location of the institution and center/department conducting the research
b. Name of PI or department, if appropriate
c. The word "research"
d. Statement or condition under study and brief description of the purpose of the research
e. Brief list of the procedures involved
f. Brief summary of the eligibility criteria
g. Statement of approximate time commitment required, if appropriate
h. Brief description of the compensation/reimbursement
i. Contact for further information including telephone number

Recruitment materials should NOT include:

a. Any language that would contribute to therapeutic misconception (research subject's belief that enrolling in study will contribute to direct therapeutic benefit)
b. Claims about the efficacy, safety or superiority of an investigational agent
c. Claims about the security of confidential information
d. Enticing or inducing terms such as "free," "new," "exciting," "opportunity," "limited opportunity," or "you deserve to feel better"
e. Inducing phrases such as "limited enrollment," "call today" or "study ends soon"
f. Overemphasis on compensation; should not emphasize the payment or the amount to be paid by such means as larger or bold type. If the payments will be prorated, the ad should make this clear. For example, instead of stating "$300 compensation," the ad should state that subjects will receive $50 for each of six completed visits.
g. Links to sites/resources that are not IRB approved

5.3 Telephone Communications to Potential Subjects

Initiating telephone contact with the subject based on knowledge of confidential information (e.g., medical record information) regarding the subject and without prior introduction to the subject is prohibited by the IRB.

The investigator should NOT contact the patients of any particular clinic,

physician, or other caregiver unless the patient's physician or caregiver has previously notified the potential research subject (or the parent or Legally Authorized Representative of the potential research subject) and obtained his/her approval for such contact. This notification may be either verbal or in the form of a letter of introduction.

The investigator should NOT contact, based on knowledge of confidential information, the members of any community-, work-, school-, trade- or union-based program unless a program representative has previously notified the potential research subject (or the parent or Legally Authorized Representative of the potential research subject) and obtained his/her approval for such contact. This notification may be either verbal or in the form of a letter of introduction.

5.4 Internet Listings of Clinical Trials

IRB review and approval of listings of clinical trials on the internet would provide no additional safeguard and is not required when the system format limits the information provided to basic trial information such as the study title, purpose of the study, protocol summary, basic eligibility criteria, study site location(s), and how to contact the site for further information. Examples of clinical trial listing services that do not require prospective IRB approval include the U.S. National Library of Medicine's database, ClinicalTrials.gov, the National Cancer Institute's cancer clinical trial listing (PDQ), and the government-sponsored AIDS Clinical Trials Information Service (ACTIS). However, when the opportunity to add additional descriptive information is not precluded by the data base system, IRB review and approval may assure that the additional information does not promise or imply a certainty of cure or other benefit beyond what is contained in the protocol and the informed consent document.

5.5 Screening Tests and Interviews Prior to Subject Enrollment

Screening procedures (including interviews) that are performed solely for the purpose of determining eligibility for participation in a research protocol are subject to IRB oversight including the requirement for written informed consent. With respect to screening interviews/surveys, written informed consent must be obtained prior to conducting the interview/survey if (1) the interview/survey is being performed for research purposes, (2) the individual's responses to the interview/survey could place him/her at risk of civil or criminal liability or be potentially damaging to his/her employability or reputation, and (3) subject identifiers are recorded with the interview/survey responses.

5.6 Incentives for Participation in Research Studies

Subjects may be paid or otherwise rewarded for their time and inconvenience associated with participation in a research study. Remuneration of human research subjects is not, however, considered a

benefit; it is a recruitment incentive. Financial or other incentives are frequently used when the benefit of study participation is remote or non-existent.

a. The amount of payment, if any, should be reasonable based on the complexities and inconveniences of the study, and the subject population. The amount of payment should NOT be based on the risk of study participation.
b. The amount of payment or reward and the proposed method and timing of its disbursement must not be coercive or present undue influence over initial or continued participation in the study.
c. It is acceptable for students to be offered course credits for their participation in a research study. However, the student must be provided with alternate, equitable ways to earn the credits if they decide not to participate in the research study.

5.6.1 IRB Review and Approval of Incentives for Participation in Research Studies

Information concerning the remuneration of human research subjects, including the amount of payment or nature of the reward, and the schedule of its disbursement is subject to initial and continuing review by the IRB. This information should appear in the Compensation and Reimbursement section of the application in Mentor IRB, as well as any informed consent document(s). It should not be included as a benefit of study participation.

5.6.2 Payment Disbursement Guidelines

Any payment or reward should accrue as the study progresses and not be contingent upon the human research subject completing the entire study. Disbursement of a proportion of the total payment or reward contingent upon study completion is acceptable, provided that the amount of this incentive is not so large as to unduly induce subjects to remain in the study when they might otherwise withdraw voluntarily.

5.7 Community-Based Participatory Research

Community-based participatory research (CBPR) is a collaborative approach to research involving stakeholders outside of academic research organizations, equitably involving all partners in the research process and recognizing the unique strengths that each may bring. CBPR can be advantageous in that contact with community members may raise participation rates. Engaging with the community early in the process can also promote trust in the research study and may help facilitate successful recruitment.

However, CBPR also presents distinct challenges not addressed in traditional research paradigms. Community residents participating in the full spectrum of the research, including recruitment of potential research

subjects, raises issues of privacy and confidentiality requiring additional considerations. Such considerations include acknowledging, evaluating, minimizing any foreseeable risks to potential research subjects, especially when community members serving as researchers or staff may be recruiting or otherwise interacting with potential subjects they may know or may be familiar with.

Issues surrounding privacy and confidentiality may include:

- Community members participating in recruitment may be friends or neighbors of those approached in the recruiting process.
- Participants' willingness to reveal information, particularly if that information is sensitive or stigmatizing, may create the potential to inadvertently and unknowingly impact the quality of data collection.
- Study recruitment that occurs in community settings such as meeting halls and libraries may experience increased risk when such recruitment includes postings that proclaim the intent of the meeting and/or sensitive topics.

CBPR could also introduce selection bias (Ref. Viswanathan M, Ammerman A, et al. Community-based participatory research: assessing the evidence. Evid Rep Technol Assess (Summ). 2004 Aug;(99):1-8.)

Investigators working with a community-member research team should identify such risks as noted above, and other potential issues (e.g., literacy, language barriers, local or cultural beliefs and attitudes) which the community-member researcher may not have considered.

Institutional Review Board

The IRB provides guidance for investigators on identifying relevant community members for research studies. Guidance may also be provided via consultation with the IRB office/chairman, specific to the individual research study and resources available through The Christ Hospital Health Network (ref. SOP 1.14 Community Outreach on Human Subjects Research).

When evaluating the recruitment process in a CBPR study, the IRB (to the extent feasible and allowable) shall consider risk of harm for both individuals *and* the community. For additional information, see RM 02 IRB Review of Proposed Research Studies.

References

- Ross LF, Loup A, Nelson RM, et al. The challenges of collaboration for academic and community partners in a research partnership: points to consider. J Empir Res Hum Res Ethics. 2010 Mar;5(1):19-31

- CITI Training Module: Ethical and Practical Considerations in Community-Engaged Research