The Christ Hospital IRB
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Number: 1.14
Effective Date: 11/08
Revised/Reviewed Date: 1/23

STANDARD OPERATING PROCEDURE

Community Outreach on Human Subjects Research

POLICY:

The Christ Hospital has the responsibility to provide information and promote understanding of human subjects research for participants, prospective participants and the community. The Christ Hospital Institutional Review Board (TCH IRB) will develop materials and engage in outreach activities to accomplish this goal.

PROCEDURE

IRB Staff/Chair

The Christ Hospital IRB promotes understanding of human subjects research by participants, prospective participants, and the community through:

- **Office for Human Research Protections Educational Materials:** The IRB provides a link to the current OHRP brochure, "Becoming a Research Volunteer" on TCH IRB webpage and SharePoint for distribution to research departments and investigators.
- **TCH Marketing and Public Relations Materials:** The IRB reviews pamphlets and brochures from the hospital's Marketing and Public Relations Department to approve use for distribution by researchers.
- **Investigator and Study Sponsor Materials:** The IRB reviews recruitment materials provided by the investigator and/or study sponsor for approval prior to distribution to potential research participants. Such materials include advertising to be seen/heard by prospective research subjects to solicit enrollment into a study (e.g., newspaper and audiovisual ads, posters, and flyers). Ref. SOP 2.10 Recruitment of Subjects in Research; SOP 2.06 News Releases or Recruitment Materials Regarding Research
- **Information for Investigators:** The IRB provides guidance for investigators on identifying relevant community members for research studies (ref. RM 05 Recruitment of Research Subjects and Patients). 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.
- **Receipt of Complaints:** The IRB maintains mechanisms to receive complaints from participants or others in a confidential manner. Ref. SOP 3.08 Complaints and Inquiries for Research Participants, Investigators, Research Staff, and the Community
- **TCH Website:** The IRB ensures that TCH IRB webpages contain current information.
- **Microsoft SharePoint:** The IRB maintains and keeps current TCH IRB SharePoint web pages including Participant Resources. SharePoint allows sharing of content and knowledge to aid investigators, research subjects, prospective subjects, and the community in finding relevant information.

- **The Lindner Center at TCH:** The Lindner Center for Research and Education reports on any community outreach projects recorded by The Lindner Center at quarterly HRPP meetings. However, The Lindner Center is not currently directly involved in community-based research.

IRB Committee Members

- Are available to volunteer for speaking engagements for community groups
- Review and comment on educational information prepared by IRB staff
- Engage in educational opportunities focused on community based participatory research through professional meetings/conferences (national, regional, and local), as available, and The Collaborative Institutional Training Initiative (CITI Program) training (e.g., HSR Core: Ethical and Practical Considerations in Community-Engaged Research).

Frequency of IRB Review of Information

The Christ Hospital IRB shall review for approval all materials and mechanisms to be used in educating and recruiting prospective research subjects. Research study materials are evaluated during initial review of research applications, during annual continuing review, and with any new amendments as applicable to the study (ref. RM 05 Recruitment of Research Subjects and Patients). Review of webpages and online resources is ongoing (at minimum, annual review).

Investigators

- Assure that each consent form contains a contact number for research subjects to use regarding questions, concerns or complaints about his/her rights as a research participant
- Provide information, if requested, for outreach education to community groups
- Follow guidelines as outlined in SOP 2.06, "News Releases or Recruitment Materials Regarding Research" when using publications or media to recruit subjects for a research study (i.e., radio ads, TV ads, newspaper ads, etc.).

Mechanisms for Supporting Investigators

- **Publication of Research Projects:** The Christ Hospital Health Network recognizes the public's interest in being informed of major news items, and maintains administrative policy for when an investigator deems it appropriate to publicize a human research project. Policy includes directives confirming project details obtained through the IRB and its chairperson, and guidance to investigators on adhering to HIPAA regulations including that no information will be released until a research participant has been given the opportunity to decide whether he or she chooses to restrict any of his or her information (45 CFR 164.510(a)(1)(i)). Ref. TCH Administrative Policy 4.30.110 Release of PHI to the News Media; IRB SOP 2.06 News Releases or Recruitment Materials Regarding Research
- **Education and Training:** TCH IRB requires training of all investigators in Human Subjects Research (HSR) and Good Clinical Practice (GCP), or approved alternative. Such training is certified through The Collaborative Institutional Training Initiative (CITI Program). Within the required HSR Core training is a module specific to community-based research: Ethical and Practical Considerations in Community-Engaged Research.
- **Support in the Application Process:** TCH IRB electronic application submissions system, Mentor IRB, includes a section to be completed by the investigator regarding Community Based Research. The IRB also provides checklists to investigators to ensure accurate completion of application materials including any community based participatory research, as applicable to the study.

- **Evaluation of Demographic Characteristics of Subjects Enrolled in Research**
  The Christ Hospital IRB supports investigators in the equitable selection of research subjects by evaluating enrollment procedures, recruitment processes and participation arrangements for clinical studies. TCH IRB will determine that the selection of subjects is equitable during initial review of the study, continuing review, and review of proposed modifications to research. The investigator shall consider equitable selection of subjects in the research design and provide information on the targeted research population for the IRB to make its determinations. Such information will include population characteristics (i.e., age, sex, race, ethnicity), anticipated number of subjects to be enrolled, inclusion/exclusion criteria, and additional information as requested by the IRB. Additionally, new research studies also undergo departmental review to confirm that the research is pertinent to the needs and goals of the institution, department and community. Ref. SOP 2.10 Recruitment of Subjects in Research; SOP 3.01 Scientific/Scholarly Review of Protocols - Minimizing Risks to Subjects

IRB Review of Research That Involves Community Members In the Research Process
The Christ Hospital IRB is comprised of members with multidisciplinary expertise and backgrounds including a non-affiliated community member(s), as required by federal policy and FDA regulations: (1) the IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes; 2) regarding regular reviews of research involving a vulnerable category of subjects, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with those subjects; and (3) the IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. Ref. SOP 3.20 Periodic Review and Assessment of IRB Members, Chair, and Staff; 21 CFR 56.107

When reviewing studies involving community based research, the IRB may, in the absence of a member with expertise in such studies, invite consultants to assist in the review process. Ref. SOP 3.01 Scientific/Scholarly Review of Protocols - Minimizing Risks to Subjects

For additional information, see RM 02 IRB Review Of Proposed Research Studies.