The Christ Hospital IRB
Section: 02
Effective Date: 01/07
Revised/Reviewed Date: 2/23
AAHRPP Element: I.4.C, II.2.A, II.2.B**,** II.2.E, II.2.F

IRB REFERENCE MANUAL
SECTION 02
IRB REVIEW OF PROPOSED RESEARCH STUDIES

2.0 IRB REVIEW OF PROPOSED RESEARCH STUDIES

The Christ Hospital Institutional Review Board (TCH IRB) must review and approve all research activities involving human subjects that fall under the Institution's Human Research Protection Program prior to the implementation of such research activities. Notification to the IRB chair, or in his absence, designee, is required for emergency use of a non-approved investigational drug or a non-approved investigational device. (See Section 2.5)

There are four categories of IRB review of proposed research study: 1) Not Human Subjects Research review, 2) Exempt review, 3) Expedited review, 4) Full Board review. At The Christ Hospital, the IRB, not the researcher, determines the review level. Studies determined by the IRB to qualify for exempt or expedited review are reviewed by the IRB upon receipt. Studies determined by the IRB to qualify for full board review and which are received by the meeting deadline are placed on the agenda for review at the next scheduled IRB meeting. Studies received after the meeting deadline may be placed on the agenda for review at the next scheduled IRB meeting if it is determined there is adequate time for review. (See SOP 2.01 for more information on protocol submission.)

In order to receive full IRB approval, all investigators and key research personnel listed on the study application for a research project involving human research are required to complete the Collaborative Institutional Training Initiative (CITI) web-based education and certification program.

2.1 Designation that a Project is (1) Not Research or (2) is Research but Does Not Involve Human Subjects

Certain studies submitted for exempt review may not meet The Christ Hospital's definition of human subject research because the activity meets neither the DHHS definition of human subjects research [i.e., does not meet the DHHS definition of "research" as specified under 45 CFR 46.102(l) involving "human subjects" as specified under 45 CFR 46.102(e)] nor the FDA definition of human subjects research [i.e., does not meet the FDA definition of "research" as specified under 21 CFR 56.102(c) involving "human subjects" as specified under 21 CFR 56.102(e)]. For example, Quality Assurance projects may not meet the DHHS definition of "research" if they are not designed to develop or contribute to generalizable

knowledge (45 CFR 46.102(l)) and do not meet the FDA definition of research if they do not involve the administration of drugs or devices (21 CFR 56.102(c)). Studies that are research, but do not involve human subjects (according to the regulations) might include those in which (a) the investigator conducting research neither interacts nor intervenes with an individual to obtain data (including specimens) about that person, or (b) does not obtain identifiable private information. This determination is made by TCH IRB Chair or his/her designee. (Complete Form: Application for "No Humans" Designation)

2.2 **Exempt Review**

Research activities in which the only involvement of human subjects will be in one or more of the categories listed below are exempt from the HHS Federal Policy regulations (45 CFR 46.104(d)(1-8) including the requirement to obtain informed consent. However, the exemption criteria at 45 CFR 46.104(d) do not apply to research that is subject to FDA oversight except for research activities involving taste and food quality evaluation as provided for in 45 CFR 46.104(d)(6). (See RM Section 1.13). The Christ Hospital requires IRB review of human research activities appearing to meet these exempt criteria to ensure regulatory compliance. Research protocols qualifying for exempt review are reviewed administratively by the IRB Chair or his/her designee. Following an initial IRB determination of exempt status, exempt research activities are not subject to annual renewal requirements.

Category 1

Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact (1) students' opportunity to learn required educational content or (2) the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

Category 2

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

a. The information obtained is recorded by the investigator in such a manner that the identity of the human participants cannot be readily ascertained, either directly or through identifiers linked to the participants;
b. Any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation;
c. The information obtained is recorded by the investigator in such a

manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

Category 3
Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

a. The information obtained is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained, directly or through identifiers linked to the subjects;
b. Any disclosure of the human participants' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation;
c. The information obtained is recorded by the investigator in such a manner that the identity of the human participants can readily be ascertained, directly or through identifiers linked to the participants, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

For the purposes of this provision, benign behavioral interventions are brief, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purpose of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Category 4
Secondary research for which consent is not required; secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria are met:

a. The identifiable private information or identifiable biospecimens are publicly available;
b. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained directly or through identifiers linked to the participants, the investigator does not contact the participants, and the investigator will not re-identify participants;
c. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care options" or "research" as those terms are defined at 45 CFR 164.501 or for "Uses and disclosures for public health activities" as described under 45 CFR 164.512(b);
d. The research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501; NOTE: If all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

Category 5
Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

Category 6
Taste and food quality evaluation and consumer acceptance studies (45 CFR 46.104(d)(6)).

Category7
Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

Category 8
Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if criteria in 45 CFR 46.104(d)(8) are met.

NOTE: The Christ Hospital has made an Institutional decision that broad consent will not be permitted at this time. As a result, the TCH IRB will not consider applications under exempt category 7 or 8 which requires broad consent.

2.2.1 **Exempt Review Submission Requirements**
If an investigator is uncertain if his/her research meets the requirements for exempt research, he/she may contact the IRB Office at IRB_Office@thechristhospital.com to determine if the study is eligible for exempt status. If an investigator believes that his/her research study meets the federal regulations, as well as institutional and ethical criteria for an exemption from IRB review, they must submit the IRB Exempt Application along with any applicable questionnaires and screening or recruitment instruments, etc. to the IRB for review and approval.

2.3 **Expedited Review**
Research activities involving no more than minimal risk and in which the only involvement of human subjects will be in one or more categories listed below (carried out through standard methods) may be reviewed by the IRB through an expedited (i.e., administrative review) procedure. This means that these types of reviews are not conducted by the convened TCH IRB, but rather administratively. As defined by federal regulations, minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Under the expedited review procedure, the initial review of the research is carried out by TCH IRB chair or his/her designee. In conducting the review, these individuals may exercise all the authorities of the IRB except that they may not disapprove the research. A research activity may be disapproved only subsequent to the full board review. The Christ Hospital IRB will report each protocol approved by expedited review at its next regularly scheduled meeting.

NOTE:
a. The expedited review procedure may not be used where identification of the subjects or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation or may be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
b. The expedited review procedure may not be used for classified research involving human subjects.

c. Standard requirements for informed consent or its waiver, alteration or exception apply to the research protocol qualifying for expedited review.

Research activities eligible for expedited review are limited by federal policy and FDA regulations to the following: 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included in this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

Categories in this list apply regardless of age of subjects except as noted. The IRB recognizes that the standard requirements for informed consent or its waiver, alteration or exception apply regardless of the type of review, expedited or convened, utilized by the IRB. Categories 1 through 7 below pertain to both initial and continuing review. NOTE: Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."

Category1
Clinical studies of drugs and medical devices only when either condition below is met:

a. Research on drugs for which an investigational new drug application (21 CFR 312) is not required. NOTE: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.
b. Research on medical devices for which (1) an investigational device exemption application (21 CFR 812) is not required; or (2) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Category 2
Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Category 3
Prospective collection of biological specimens for research purposes by noninvasive means. Examples include:

a. Hair and nail clippings in a non-disfiguring manner
b. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction
c. Permanent teeth if routine patient care indicates a need for extraction
d. Excreta and external secretions (including sweat)
e. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue
f. Placenta removed at delivery
g. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor
h. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques
i. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
j. Sputum collected after saline mist nebulization

Category 4
Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications). Examples include:

a. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy
b. Weighing or testing sensory acuity
c. Magnetic resonance imaging
d. Electrocardiography, electroencephalography, thermography detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography
e. Moderate exercise, muscular strength testing, body composition assessment and flexibility testing where appropriate given the age, weight, and health of the individual

Category 5
Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). NOTE: Some research in this category may be

exempt from the federal regulations or TCH Policy and procedure. This listing refers only to research that is not exempt.

Category 6
Collection of data from voice, video, digital, or image recordings made for research purposes.

Category 7
Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

2.3.1 **Expedited Review Submission Requirements**

For expedited research in which TCH IRB will provide oversight, the following documents must be completed and/or uploaded in Mentor IRB, as applicable to the research:

a. Application (Mentor Smart form), which may include the following (as applicable):
    - Request for Full or Partial Waiver of HIPAA Authorization
    - Waiver of Informed Consent Request
    - Waiver of Documentation of Informed Consent Request
b. Informed Consent Documents, such as:
    - Informed Consent using the TCH template
    - The HHS-approved sample consent document (when available)
c. Protocol/Clinical Investigation Plan (CIP), such as:
    - Sponsor-approved protocol
    - Complete HHS-approved protocol (when available)
d. Electronic Signature Affidavit for all investigators and other key research personnel
e. Financial Conflict of Interest (FCOI) Affidavit (Mentor Smart form) or Disclosure of Financial Interest form (on a case-by-case basis) for all investigators and other key research personnel
f. Recruitment/Advertising Materials
g. Any relevant grant applications
h. Data Collection Materials
i. Investigator Qualifications
    - Certificates of completion for the required CITI courses for all investigators and other key research personnel including training in Human Subjects Research (HSR) and Good Clinical Practice (GCP), or approved alternative; transcripts of required CITI training must reflect completion within the most recent three years.
    - Most recent CV for all investigators and other key research personnel

- Medical or Nursing License for all investigators and other key research personnel, as applicable

2.3.2 Expedited Review Turnaround Time

Research protocols qualifying for expedited review will be reviewed by the IRB chair or designee for exempt/expedited review in order of date received by the IRB Office. Depending upon the volume of submissions received, expedited review turnaround time varies.

2.4 Full Board Review

Research activities which do not qualify for exempt review (see 2.2) or expedited review (see 2.3) under the stated categories must be reviewed and approved by a the full board at a regularly scheduled convened meeting. For complete requirements See Section 7.0 Research Protocol and Consent – Format and Requirements.

2.4.1 IRB Meeting Dates

All meetings of TCH IRB are held on the second Tuesday of each month at 7:30 a.m. The deadline for IRB submission is 21 days prior to the meeting date.

2.4.2 Full Board Review Submission Requirements

For greater than minimal risk research in which TCH IRB will provide oversight, the following documents must be completed and/or uploaded in Mentor IRB, as applicable to the research:

a. Application (Mentor Smart form), which may include the following (as applicable):
   - Request for Full or Partial Waiver of HIPAA Authorization
   - Waiver of Informed Consent Request
   - Waiver of Documentation of Informed Consent Request
   - Investigational Drug Information
   - Investigational Device Information

b. Informed Consent Documents, such as:
   - Informed Consent using the TCH template
   - The HHS-approved sample consent document (when available)

c. Protocol/Clinical Investigation Plan (CIP), such as:
   - Sponsor-approved protocol
   - Complete HHS-approved protocol (when available)

d. Electronic Signature Affidavit for all investigators and other key research personnel

e. Financial Conflict of Interest (FCOI) Affidavit (Mentor Smart form) or Disclosure of Financial Interest form (on a case-by-case basis) for all investigators and other key research personnel

f. FDA documentation for investigational products

g. Recruitment/Advertising Materials

h. Investigator's Brochure
i. Instructions for Use
j. Any relevant grant applications
k. Data Collection Materials
l. Investigator Qualifications
    - Certificates of completion for the required CITI courses for all investigators and other key research personnel including training in Human Subjects Research (HSR) and Good Clinical Practice (GCP), or approved alternative; transcripts of required CITI training must reflect completion within the most recent three years.
    - Most recent CV for all investigators and other key research personnel
    - Medical or Nursing License for all investigators and other key research personnel, as applicable

2.4.3 **Pre-Review of Research**

All research protocols shall undergo departmental review (and section review, if applicable). This includes a) industry initiated and sponsored clinical trials of drugs or devices that are subject to prior FDA acceptance of an IND or IDE application, b) research reviewed by an external scientific committee as a condition of research funding (e.g., NIH sponsored research) or for inclusion in cooperative group trials, and c) studies which meet one of the exempt criterion defined by the federal regulations (see RM Section 2.0). The purpose for this review is to assure that the department head is aware of the research being conducted in his/her department so that the department head can disseminate this information throughout the department and aid in recruitment. The department head should be aware of all scholarly research conducted by department members so that the department head can communicate this to any resident training program director for incorporation in their reports to their respective accrediting bodies. In addition, all research projects other than those indicated above will be reviewed by the department head and, if applicable, section chiefs or their designees or designated committee for approval and indication that the principal investigator has a) the appropriate training and experience, b) adequate resources, c) sufficient time allocation to conduct the research, d) determined that the research is pertinent to the needs and goals of the institution, department and community, and e) confirmed that the research has been found to be acceptable for IRB submission.

Substantial modification to the aims and/or design of a research protocol (with the exception of the categories of research defined above) may also need departmental review prior to submission of the modifications for IRB approval.

2.4.3.1 **Fiscal (Contract) Review**

The Chief Clinical Officer reviews contracts after IRB approval. This review includes an evaluation of the costs associated with the study and resources needed. The IRB fee typically covers the cost of initiating a research study.

2.4.3.2 **Christ Hospital Cancer Center Protocol Review Process**

The Cancer Research Administrative Team performs a timely and thorough review, and a respondent commentary (written or verbal when applicable) of potential projects and or relevant research. The Christ Hospital Cancer Collaborative Committee (CCC) members are also generally consulted regarding potential research projects. The review and commentary may be requested of the entire committee or select members as determined by the research director and may occur in a group setting or on an individual basis depending on the timing and specific situation.

The Christ Hospital Cancer Center Research Department also utilizes varying Christ Hospital support individuals in the study selection process, depending on the nature and depth of the project. These individuals include, but are not limited to, the research nursing staff (regarding clinical and regulatory implications), Cancer Center Director (regarding facility, financial and staffing feasibility), IRB Chairman (regarding complicated drugs, devices, and or techniques with regards to safety and accountability), The Christ Hospital Administration officers (regarding complicated fiscal, assurance and/or public relation concerns), Departmental Managers (regarding the feasibility of complicated medical or radiation oncology devices and or techniques), and Tumor Registry (for patient population feasibility).

2.4.3.3 **Research Protocols Involving Human Subject or Patient Exposure to Ionizing Radiation**

All new and investigational procedures involving potential radiation exposure will be reviewed by the Radiation Safety Officer and another Senior Physicist. The Radiation Safety Committee votes to approve the protocol given the recommendation of the RSO before initiation. (Ref. Radiation Safety Committee ATT 10.1a, 10.1b)

2.4.3.4 **Investigational Drug Service and Pharmacy Utilization**

Before IRB consideration of potential drug studies, protocols are reviewed for design and safety. Medication is reviewed for safety, side effects, and preparation/storage issues. Questions regarding any issues are addressed with the investigator at the

IRB meeting. The pharmacy's role in the study is determined during Site Initiation Visit Meetings and procedures are worked out for pharmacy/nursing handoffs. Questions may also be addressed with the sponsor at these meetings. The staff is educated on procedures and accountability prior to study initiation.
(Ref. The Christ Hospital Pharmacy Services Investigational Drug Study & Research Service)

2.5 **Early/Expanded Access of Non-Approved Investigational Drugs or Biological Devices**

See RM Section 13.0 Expanded Access to Investigational Medical Products

2.6 **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. The process typically (but not always) starts with a topic of importance to the community and has the aim of combining knowledge with action with the intention of instituting change to improve community well-being. Community residents may participate in the full spectrum of the research from concept, design, conduct, data analysis, interpretation, conclusions, and communication of results. Academic research and community partners join to develop models and approaches to building communication, trust and capacity, with the ultimate goal of increasing community participation in the research process. CBPR is an alternative research model integrating education and social action to improve communities and enhance the scientific knowledge base, and is most often associated with improving community health outcomes through transfer of evidence-based research from clinical settings to communities that can benefit most.

Community-based participatory research can present distinct challenges not addressed in traditional research paradigms including ethical and practical considerations particular to the design, review, and conduct of community-engaged research. CBPR requires that the researcher follow the best practices for respectful and productive relationships. The following principles are in addition to those required for all human research:

a. Certainty that the research topic addresses a community-defined need, question or problem
b. Recognizing the research as a partnership, i.e., engagement of research projects is to be led by a team of academic and community Co-Investigators collaborating as partners
c. Respect for the community partner's interest in the research
d. Openness to the guidance of community insights and experiences
e. Maintaining a balance in decision making between the researchers and community participants

f. Provision of continuous feedback to enhance the partnership and its outcomes
g. Dissemination of research findings to community stakeholders and participants.
h. Recognition that partnerships can dissolve and development of a plan for closure, as applicable

2.6.1 Community-Based Participatory Research Review Submission Requirements

In addition to the submission requirements for exempt, expedited or full board review as outlined above, principal investigators of CBPR studies shall submit enough information to assess whether the study adequately meets the criteria for approval of a CBPR research study, including:

a. Evidence that an equitable partnership between the investigator and the community partner exists
b. That investigators have defined the relevant community or communities
c. That investigators have identified the appropriate community or communities for the project
d. That the investigator has identified the appropriate research partner for the project
e. That community engagement is an integral part of the research
f. That letters of support (from the community) are clear and well-defined
g. That an appropriate division of funding (if applicable) exists
h. Adequate training opportunities for investigators and community members
i. That the research environment is adequate including that (1) the community benefits from the presence and implementation of the research, and (2) the research is conducted in an environment that enhances the likelihood of success
j. That the research strives for positive change in community outcomes
k. That the research fosters long-term relationships between the Institution and the Community for the benefit of both
l. Plan for Modifications: It is often necessary to make changes to the procedures or survey/data collection instruments as the research progresses or is implemented in the field. Researchers must anticipate and plan for this by including in the IRB application information that is sufficient to allow for a thorough review but general enough to allow flexibility.
m. Plan for Disclosure of Research Findings**:** To minimize the risk of group harms resulting from inappropriate disclosure of research findings, researchers should work with the community to inform its members about the research findings and plans to disclose the results, as well as possible implications of

disclosure. Thus, the possibility of harms resulting to the community as the research is published or presented may be reduced.

n. Benefits Are Available to Groups: Productive partnerships between researchers and community members should be encouraged to last beyond the life of the project with the research designed to provide benefits to the communities involved. Efforts should be made to increase the likelihood that research findings will be incorporated into ongoing community programs, therefore providing the greatest possible benefit to the community.
o. Community Involvement: A description of the aspects of the research in which community members will be involved, and how they will be involved. In community-based research, investigators often involve the community members in the research design or conceptualization, conduct or implementation of the study, and dissemination or distribution of study results. With some topics or research areas, it may also be necessary to involve the community members in the analysis and interpretation of data, and to seek their input into how the findings will be distributed to others, thus providing the community members the opportunity to include their views about the interpretation prior to final publication.

Informed Consent

In all research, informed consent forms should meet federal regulatory requirements of the U.S. Department of Health and Human Services (HHS) 45 CFR 46.116 and the US Food and Drug Administration (FDA) 21 CFR 50.20 to ensure that:

a. Participants understand the research study and voluntarily agree to participate
b. Consent explanations are in language understandable to the potential study participant or the individual's legally authorized representative
c. The consent does not include language through which the participant or their representative is made to waive the participant's legal rights or releases the investigator, the sponsor, the institution or its agents from liability for negligence
d. Appropriate documentation of consent takes place
e. All other requirements as outlined in RM 16, "Informed Consent" and SOP 2.02, "Informed Consent" are followed.

In community-based research, additional issues should be considered and, as appropriate, included in the consent document and process. The informed consent might specifically address the risk of harm and potential benefit of the research for the individuals and the community. For example, any

physical or psychosocial risks of harm to an individual's well-being or agency should be described, including risks of harm to individuals by virtue of their association with the group or community participating in the research involvement (Ross LF, Loup A, Nelson RM, et al. Empir Res Hum Res Ethics. 2010 Mar;5(1):5-17). Furthermore, in addition to describing a participant's right to withdraw from the research, the consent might also state, if true, that an individual's choice to withdraw will not affect their relationship or standing within the community.

Recruitment

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 (ref. SOP 1.14 Community Outreach on Human Subjects Research).

NOTE: Engaging the community early in the process, before a study actually begins, can promote trust in the research study and may help facilitate successful recruitment.

2.6.2 IRB Review of Community-Based Participatory Research

IRBs face unique challenges in reviewing research that involves collaborations between academic researchers and community member partners. Federal regulations governing the review and conduct of human subjects research are not explicitly designed to protect the rights and welfare of communities involved in research, nor are they written to protect against risks to the rights and welfare of individuals (with respect to their roles in the community) as a consequence of their research involvement (Ross LF, Loup A, Nelson RM, et al. Empir Res Hum Res Ethics. 2010 Mar;5(1):5-17). When preparing an initial application, investigators should include appropriate details allowing the IRB to apply the federal criteria for approval, yet when describing operational procedures, the descriptions should be general enough to allow flexibility. IRBs and researchers are encouraged to consider the following:

2.6.2.1 Community Consultation Regarding Risks

The traditional IRB review paradigm is to assess both risk of harm and potential benefit from the individual participant's perspective. However, in community-engaged research, the focus widens as including community members as part of the research team poses additional challenges to maintaining privacy and confidentiality during the recruitment process and during the study. For example, community members who serve as researchers or staff and who are recruiting or otherwise interacting with study participants may

know, or may be familiar with, the individuals they are recruiting. Additionally, researchers should work with the community members to identify any risks and potential issues (e.g., literacy, language barriers, local or cultural beliefs and attitudes) which the community researcher may not have considered.

To the extent feasible and allowable, researchers and IRBs should consider risk of harm for both individuals (e.g., social stigma or loss of status within the community) and the community (e.g., economic, political, educational, cultural, or adverse effects on the group's cohesiveness or function). Appropriate measures to minimize any foreseeable risks may be taken through consultation with the community members. Strategies to mitigate risk may include:

a. Ensuring privacy so that groups are not singled out as research participants
b. Working with a local, trusted partner who can help classify and discuss stereotypes of the community/population and advise on how best to approach these groups
c. Informing participants about the potential research results and the risk that these may reinforce negative stereotypes or harm the group
d. Referring participants to local support services
e. Ensuring that all risks and benefits to the community will be discussed in the consent process, as well as any future use of data, tissue, or samples

2.6.3 Collaborative IRB Review

Some groups, agencies or entities (e.g., tribes, retirement communities, and school districts) may have their own ethical review process for research. In such cases, researchers should apply to the local ethics review body for review and approval of their research. Institutional and/or investigator agreements may also be necessary.

2.6.4 Additional Considerations

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 research, invite consultants to assist in the review process. Ref. SOP 3.01 Scientific/Scholarly Review of Protocols - Minimizing Risks to Subjects

References

- CITI Training Module: Ethical and Practical Considerations in Community-Engaged Research
- University of Nevada, Reno