**The Christ Hospital IRB**
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**STANDARD OPERATING PROCEDURE**

# Recruitment of Subjects in Research

## 1.0 POLICY

### 1.1 Equitable Selection

Approval of research at initial review, continuing review, and review of proposed modifications to research performed by The Christ Hospital (TCH) Institutional Review board (IRB) will determine that the selection of subjects is equitable including consideration of:

1.1.1 The purpose(s) of the research,
1.1.2 The setting in which the research will be conducted, and
1.1.3 Whether potential subjects are vulnerable to coercion or undue influence.

The IRB will apply additional safeguards in accordance with federal regulations and institutional policies for pregnant women, infants and fetuses (ref. SOP 3.17, "Additional Safeguards for Pregnant Women and Fetuses and Neonates in Research), for children (ref. SOP 3.22, "Additional Protections for Children Involved as Subjects in Research"), and for decisionally impaired adults (ref. SOP 3.18, "Additional Safeguards for Individuals Without Decision-making Capacity").

NOTE: The Christ Hospital does not do research on prisoners. Should a research participant become a prisoner while actively participating in research, refer to SOP 3.19, "Additional Safeguards for Vulnerable Populations Other Than Decisionally Impaired, or Pregnant Women, Fetuses or Neonates', and SOP 3.23, "Unexpected Incarceration of a Research Participant".

The investigator will consider equitable selection of subjects in the research design and provide information on the targeted research population to the IRB for making its determinations. Such information will include population characteristics (e.g., age, sex, race, ethnicity), the anticipated number of subjects to be enrolled, inclusion/exclusion criteria, and additional information as requested by the IRB.

The IRB will evaluate recruitment processes, enrollment procedures, and participation arrangements for clinical studies as each relates to equitable selection of subjects and the potential for undue influence and/or coercion. All recruitment

materials (e.g., newspaper ads, posters, flyers) must be reviewed and approved by the IRB prior to distribution to prospective research subjects. As part of sound study design, investigators should assess recruitment and enrollment practices for fairness and equitable selection, and provide information to the IRB for the board's evaluation and determinations.

## 1.2 Advertising

Advertising to be seen or heard by prospective participants to solicit enrollment into a study must receive IRB review and approval prior to dissemination. Advertisements that are easily comparable to an approved informed consent document may undergo review and approval using the expedited review procedure. The IRB or IRB chair will review the advertising content and the mode of communication to determine that the procedures are not coercive.

### 1.2.1 Printed Advertising

The IRB or IRB chair will review the final copy of printed advertisements to assess the relative size and type used, and other visual effects.

### 1.2.2 Audio/Visual Advertising

For audio and video advertisements, the IRB or IRB chair will review the final taped version. However, the IRB or IRB chair may approve the script of the advertisement prior to taping in order to avoid the need to re-tape because of inappropriate wording.

### 1.2.3 Inclusions

Advertisements to recruit subjects should be limited to information prospective enrollees need to determine their eligibility and interest. When appropriately stated, the advertisements **should include:**

1.2.3.1 Name and location of the institution and the center/department conducting the research;
1.2.3.2 Name of the principal investigator or department, if appropriate;
1.2.3.3 The word "research";
1.2.3.4 Statement about or the condition being researched and/or the purpose of the research;
1.2.3.5 Brief list of the procedures involved;
1.2.3.6 Brief list of participation benefits, if any;
1.2.3.7 Brief summary of the eligibility criteria;
1.2.3.8 Statement of approximate time commitment required, if appropriate;
1.2.3.9 Brief description of the compensation/reimbursement; and
1.2.3.10 Contact for further information including telephone number.

### 1.2.4 Exclusions

IRB review of advertisements should ensure that advertisements **do not include:**

1.2.4.1 Language that could contribute to therapeutic misconception (i.e., a research subject's belief that enrolling in the study will contribute to direct therapeutic benefit);
1.2.4.2 Language which states or implies a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol;
1.2.4.3 Exculpatory language;
1.2.4.4 Claims about the efficacy, safety, or superiority of the investigational agent;
1.2.4.5 The security of confidential information;
1.2.4.6 Enticing or inducing terms such as "free", "new", "exciting", "opportunity", "limited opportunity", or "you deserve to feel better";
1.2.4.7 Inducing phrases such as "limited enrollment", "call today", or "study ends soon";
1.2.4.8 Links to sites/resources that are not IRB approved for FDA-regulated research:
1.2.4.8.1 Claims, either explicit or implicit, about the drug, biologic, or device under investigation which are inconsistent with FDA labeling;
1.2.4.8.2 Compensation, offered by a study sponsor, for participation in a trial involving a coupon good for a discount on the purchase price of the product once it has been approved for marketing;
1.2.4.9 Overemphasis on the compensation, or emphasis on the payment, including the amount to be paid, by such means as larger or bold type. If the payments are to be prorated, the ad should make this clear. For example, instead of stating "$300 compensation", the ad should state that participants "will receive $50 for each of six completed visits".

## 1.3 Internet Listings

### 1.3.1 IRB Review/Approval of Internet Listings

IRB review and approval of listings of clinical trials on the internet would provide no additional safeguard, and review/approval is not required when the system format limits the information provided to basic trial information, such as:

1.3.1.1 Study title
1.3.1.2 Purpose of the study
1.3.1.3 Protocol summary
1.3.1.4 Basic eligibility criteria
1.3.1.5 Study site location(s)
1.3.1.6 Site contact for further information

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.

1.3.2 **Clinical Trial Listing Services**

Examples of clinical trial listing services that do not require prospective IRB approval include:

1.3.2.1 ClinicalTrials.gov

1.3.2.2 National Cancer Institute Cancer Clinical Trial Listing (PDQ)

1.4 **Screening Tests/Interviews**

Screening procedures including interviews that are performed solely for the purpose of determining whether individuals are eligible 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:

1.4.1 The interview/survey is being performed for research purposes,

1.4.2 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

1.4.3 Subject identifiers are recorded with the interview/survey responses.

1.5 **Incentives/Payments**

Financial or other incentives are frequently used when the benefit of study participation is remote or non-existent. Participants in human subjects research may be paid or otherwise rewarded for their time and the inconvenience associated with participation in a research study.

**Note:** Remuneration provided to human research subjects is to be utilized as a recruitment incentive, not a benefit of study participation**.**

1.5.1 **Important Considerations**

When monetary or another reward incentive is offered as part of participating in a research study, considerations should include:

1.5.1.1 The amount of payment, if any, should be reasonable based on the complexities and inconveniences of the study and the subject population.

1.5.1.2 The amount of payment should NOT be based on the risk of study participation.

1.5.1.3 The amount of payment or reward, and the proposed method and timing of its disbursement, must not be coercive or present undue influence for initial or continued participation in the study.

1.5.1.4 Offering course credits as rewards to students for participation in a research study is acceptable; however, the student must be provided with alternate, equitable means of earning these credits if they decide not to participate in the research study.

1.5.1.5 Any payment or reward should accrue as the study progresses and not be contingent upon the participant in human research 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 participants to remain in the study when they might otherwise withdraw voluntarily.

1.5.2 **Restrictions**

1.5.2.1 Finder's Fees

1.5.2.1.1 Payments to professionals in exchange for referrals of potential subjects ("finder's fees") are prohibited.

1.5.2.1.2 Payments to subjects in exchange for referrals of potential subjects ("finder's fees") are prohibited, unless they are judged not to increase the possibility of coercion or undue influence on subjects by using unreasonable compensation or unreasonable conditions for distribution of compensation.

1.5.2.2 Bonus Payments

Payments designed to accelerate recruitment that are tied to the rate or timing of enrollment ("bonus payments") are prohibited, unless they are judged not to interfere with providing prospective subjects with sufficient opportunity to consider whether to participate and do not increase the possibility of coercion or undue influence on investigators or subjects.

1.5.3 **IRB Review**

Information concerning the remuneration provided to participants in the research is subject to initial and continuing review by the IRB. This information should appear in the Costs and Payments section of the research protocol and informed consent document(s).

## 3.0 RESPONSIBILTIES & PROCEDURE

### 3.1 Investigator Responsibilities

3.1.1 **Initial Review/Study Application**

3.1.1.1 Includes information on the target population:

3.1.1.1.1 Number of subjects to be enrolled;

3.1.1.1.2 Participants' age range;

3.1.1.1.3 Participants' health status; and

3.1.1.1.4 Any requirements for specific gender, race or ethnicity of inclusions.

3.1.1.2 Describes the process to be used to recruit subjects including:

3.1.1.2.1 Location and setting (e.g., doctor's offices, businesses, other institutions)

3.1.1.2.2 Methods and materials (e.g., flyers, letters, videos, etc.)

3.1.1.2.3 Any compensation for participants, type, amount and payment schedule.

3.1.1.2.4 How participants are screened for eligibility (e.g., databases, employees, medical records review, etc.)

3.1.1.2.5 How participants are enrolled.

3.1.1.2.6 Inclusion/exclusion criteria.

3.1.1.2.7 Whether vulnerable populations are targeted and any need for added protections.

3.1.1.2.8 The consenting process, including:

3.1.1.2.8.1 How consent will be obtained and by whom;

3.1.1.2.8.2 Time period between informing and soliciting a decision, if applicable; and

3.1.1.2.8.3 Any project-specific information sheets.

3.1.2 **Continuing Review/Continuation Report**

3.1.2.1 Number of subjects enrolled.

3.1.2.2 Information on any problems encountered in obtaining informed consent.

3.1.2.3 Information on withdrawals and reasons for withdrawal.

3.1.2.4 Information on any complaints related to the research

3.1.3 **Amendments/Modifications**

Submits modifications to the recruitment/selection procedures described in the protocol for review and approval prior to initiation of implementing the change(s) including, but not limited to, advertising, eligibility requirements, or increasing enrollment.

3.2 **IRB Staff Responsibilities**

At the time of initial review, continuing review, and for any modifications, the IRB staff shall review the protocol and consent documents, or review of modifications, to ensure that the following have been included, as appropriate:

3.2.1 Description of participant recruitment including any recruitment materials, screening, and enrollment procedures;

3.2.2 Description of the selection criteria of participants and explanation for inclusion or omission of participants;
3.2.3 Use of any additional safeguards to prevent undue influence or coercion in the selection/enrollment process, as applicable;
3.2.4 Proposed changes in the inclusion/exclusion criteria;
3.2.5 Any compensation to participants and the schedule for disbursement;
3.2.6 Any incentives to the investigator or research personnel for enrollment of participants; and
3.2.7 Any payments by investigators to others for enrollment

IRB staff shall also examine all advertisements and other recruitment materials for appropriate content.

3.3 **IRB Responsibilities**

At the time of initial review, continuing review, and for any modifications, the IRB, or IRB chair or designee for expedited review, shall review the proposed research and approve only if IRB determines that:

3.3.1 The selection of subjects is equitable based on the purposes of the research, the setting in which the research will be conducted, and the adequacy of additional safeguards to protect vulnerable populations from undue influence or coercion;
3.3.2 All recruitment materials contain appropriate wording;
3.3.3 Recruitment processes, including advertisements, minimize the possibility of any undue influence or coercion; and
3.3.4 The time between informing the participant and soliciting a decision to participate is sufficient.

For expedited review, the IRB chair (or designee) shall refer any research or modification that the reviewer cannot approve to the next convened IRB meeting for review by the convened IRB.

## 4.0 REFERENCES

4.1 **IRB Standard Operating Procedures**

4.1.1 SOP 3.17 - Additional Safeguards for Pregnant Women and Fetuses and Neonates in Research
4.1.2 SOP 3.18 - Additional Safeguards for Individuals Without Decision-making Capacity
4.1.3 SOP 3.19 - Additional Safeguards for Vulnerable Populations Other Than Decisionally Impaired, or Pregnant Women, Fetuses or Neonates

4.2 **Code of Federal Regulations**

U.S. Food and Drug Administration (FDA)
4.2.1 21 CFR 56.107(a) – IRB Membership

4.2.2 21 CFR 56.111(a)(3) – Criteria for IRB approval of research; selection of subjects
4.2.3 21 CFR 56.111(b) - Criteria for IRB approval of research; vulnerable populations
4.2.4 21 CFR 50.20 - General requirements for informed consent
4.2.5 21 CFR 50.25 – Elements of informed consent
4.2.6 FDA Information Sheet - Recruiting Study Subjects
Guidance for Institutional Review Boards and Clinical Investigators

4.3 **AAHRPP Domains and Elements**

4.3.1 II.3.C - The IRB or EC has and follows written policies and procedures to evaluate the equitable selection of participants.
4.3.2 III.1.E - Researchers and Research Staff recruit participants in a fair and equitable manner.