

The Christ Hospital IRB
Submitted By: Erica Jones, CIP
Reviewed By: Steve Roberts, MD
Approved By: Steve Roberts, MD
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STANDARD OPERATING PROCEDURE

Expectations for Research Sponsors & Contracts

POLICY:

The Christ Hospital requires a written site agreement/contract with sponsors or contract entities of proposed research with the following terms contained in such agreements. All contracts and funding agreements should include language that obligates The Christ Hospital to follow the protocol, applicable law, and its ethical standards. All agreement/contracts are reviewed by the Institutional Official, and approved by the Vice President and Chief Clinical Officer or designee. The hospital's Risk Management Department and/or outside legal counsel may be asked to review contracts if deemed necessary.

Written agreement with sponsors will address the following issues:

- Who takes responsibility to provide and pay for medical care for research participants with a research-related injury, when appropriate.
- Requirements for proper handling of study payments and a prohibition against acceptance of incentive payments by research investigators and staff.
- Insurance stipulations;
- When sponsors conduct research site monitoring visits or conduct monitoring activities remotely, the Organization has a written agreement with the Sponsor that the Sponsor promptly reports to the Organization findings that could affect the safety of participants or influence the conduct of the study.
- When the sponsor has the responsibility to conduct data and safety monitoring, the Organization has a written agreement with the Sponsor that addresses provisions for monitoring the data to ensure the safety of participants and for providing data and safety monitoring reports to the Organization.
- Plans for disseminating findings from the research and the roles that Researchers and Sponsors will play in the publication or disclosure of results
- When participant safety could be directly affected by the study results after the study has ended, the Organization has a written agreement with the Sponsor that the Researcher or Organization will be notified of the results in order to consider informing participants.
- Indemnification agreement

PROCEDURE:

Budget:

All costs determined for each study must be supported by the study budget. In accord with applicable law and regulation and institutional policies, all research related patient care costs must be supported by the study budget and not charged to the patient subjects and/or their

medical insurers. Routine care is that which is medically reasonable, necessary, and ordinarily furnished (absent any research study) appropriate to the medical condition of the patient. The study contract must also specify who will be the responsible party for the cost of routine patient care services that may not be covered by third party health insurance payors due to the patient's study participation, limits on insurance coverage and/or eligibility exclusions. IRB costs, whether internal or independent, must be paid by commercial sponsors.

Sponsor Monitoring/Reporting/Access to Study Data

Research sponsored by commercial or non-commercial sponsors must be governed by a protocol for all participating sites. The protocol and/or contract shall explain the monitoring role to be taken by the sponsor, if any.

If the sponsor has a regulatory obligation to monitor the conduct of the study, the contract or funding agreement should include general language that obligates the sponsor to promptly notify/report to The Christ Hospital and the PI at TCH the following:

- A. Any information discovered by the study monitor that could:
 - a. Affect the safety of subjects.
 - b. Affect the willingness of subjects to continue participation.
 - c. Influence the conduct of the study.
 - d. Alter the IRB's approval to continue the study.

- B. Interim findings and post-study results that could affect the human subjects protections associated with the study including information that may:
 - a. Affect the safety or medical care of current or former participants.
 - b. Affect the willingness of participants to continue in the research.

- C. Sponsor acknowledges that post-study results will be reported in accordance with FDA regulations.

The PI will develop a plan for disseminating such information to participants and to TCH IRB.

Contracts should also address the investigator's access to final study data and analysis for all sites and allow retention of a copy of the data generated at TCH to document the research. Contracts should also address communication of results from a research study to participants when those results directly affected their safety or medical care.

Sponsors may require confidentiality of sponsor-provided information and may request that the data generated by the study be treated as confidential information except for academic publication. The existence of the study agreement may not be confidential.

Consent Language:

As a general policy, contracts between TCH and commercial sponsors for human subjects' research will not specify language or terms that must be included in an informed consent document for a specific project. Contracts that propose to include specific language or terms that would vary from this policy and/or may affect statements contained in a protocol specific informed consent document must be agreed to by the IRB. The Institutional Official (IO) will

notify the IRB Chair of such terms, and the IRB Chair and IO will work together to ensure that the contract and informed consent document contain appropriate and consistent language.

The IRB is required to review and approve research in which the commercial sponsor holds the IND or IDE or is providing product for the study before a written contract with the sponsor has been signed. The contract will not be returned to the sponsor until IRB approval is received by the IO. The IO (who also sits on the IRB) will ensure the informed consent document is consistent with the terms of the executed contract.

The informed consent should also include the below statement, if the sponsor and principal investigator agree that the study fits the FDA's definition of "Applicable Clinical Trials". The FDA provided a definition in 42 U.S.C. § 282(j)(1)(A). This regulation is required on or after March 7, 2012.

"A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

HIPAA:

Clinical research agreements that involve providing protected health information (PHI) to a sponsor must include the sponsor's agreement to:

- Not use PHI to recruit for or advertise additional studies to subjects
- Not use PHI to perform marketing or market research
- Place the same restriction on any third party to whom sponsor discloses PHI.
- Not contact any study subjects, unless permitted by the informed consent form.
- Collect, use, store, and disclose PHI collected or produced in the study only for the purpose of the study and related studies (that is, other studies of the study drug, alone or in combination with other drugs or other studies that relate to the medical condition or disease area under investigation in the study), and for the purpose of complying with applicable law, provided that all such uses are disclosed in the IRB-approved informed consent form and authorized pursuant to a valid HIPAA authorization. If TCH's IRB-approved informed consent form so states, sponsor may use information that is not identifiable under any applicable U.S. laws for any research and development purpose.
- Implement and maintain such privacy and security safeguards as are necessary to ensure that PHI is adequately protected from unauthorized access
- Place the same restriction on any third party to whom sponsor discloses PHI.

In the event that this Agreement or any practices which could be or are employed in exercising rights under the Agreement are inconsistent with or do not satisfy the requirements of applicable law relating to the privacy of PHI, the parties shall take any action necessary to bring performance under this Agreement into compliance with such applicable law, including amending or modifying this Agreement.

Indemnification and Medical Care Costs: (Also see SOP 2.14, "Compensation or Medical Treatment if Injury Occurs During Participation in Research Conducted at The Christ Hospital")

All agreements/contracts and funding agreements should include language that describes who

takes responsibility to provide and pay for medical care for research related injury. The following terms must be contained in contracts negotiated by The Christ Hospital Administration when the research will involve an investigational drug, biologic or device or where the clinical or preclinical study data and/or IP may be utilized for such products in the future:

1. Studies in which a commercial sponsor holds the IND or IDE and also controls the protocol must provide indemnification coverage and defense of The Christ Hospital for performing the study, including its trustees, officers, investigators, employees and students, for all claims arising from the institution's conduct of the study that are not due to an institution's negligence or willful misconduct. If the indemnification terms specify types of claims to be covered, the contract must, at a minimum, cover claims arising from 1) study subject injury or illness caused by the product or protocol, 2) institutions' proper conduct of the protocol, and 3) sponsor's use of a study data and intellectual property assigned to the sponsor. 4) indemnification will contain survivorship addressing early termination or trial expiration.
2. Commercial sponsors holding INDs or IDEs are encouraged to fund medical care costs for any study related injury. Contracts may exclude medical care costs for illnesses primarily due to a participant's underlying medical condition, or known risks of routine patient care portions of the protocol.
3. Commercial entities providing product for investigational studies that are initiated by a non-commercial investigator (e.g., a collaborating non-commercial entity holding the IND or IDE and controlling the protocol) are required to provide indemnification for their responsibilities in the study (i.e., design, manufacture, and shipment of the product) and for the sponsor's use of the data and any intellectual property assigned to sponsor.
4. Investigator-initiated investigational studies do not require provision of medical care costs by the commercial entity providing the investigational product.
5. Non-commercial entities sponsoring and/or providing investigational products are not required to provide indemnification or medical care costs.
6. Commercial sponsors of non-investigational clinical studies and preclinical studies will be required to provide indemnification for their use of data and any assignment of intellectual property to them.

Publicity:

Press releases naming or referring to The Christ Hospital and/or staff require prior review and approval by The Christ hospital regarding the accuracy of the information being released, as outlined in The Christ Hospital Administrative Policy #4.30.110, "Release of Patient and Clinical Research Information to the News Media".

IRB Office

When necessary the IRB Office staff or Chair will review the agreement/contracts during a study audit.

REFERENCE:

45 CFR 46.103(b)(4-5)

21 CFR 56.108(a)(b)

SOP 2.14, "Compensation or Medical Treatment if Injury Occurs During Participation in Research Conducted at The Christ Hospital"

TCH Administrative Policy #4.30.110, "Release of Patient and Clinical Research Information to the News Media"