The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

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

1.0 PURPOSE

This procedure establishes the process of providing guidance on compensation or medical treatment following research-related injury which may occur when an individual participates in research conducted under the jurisdiction of The Christ Hospital (TCH) Institutional Review Board (IRB).

2.0 POLICY

Federal regulations require that if research-related injury is a possibility in a research study that has been determined to be more than minimal risk, the consent form must include an explanation of the voluntary compensation and treatment which will be provided to the individual participating in the study. It is the policy that The Christ Hospital IRB will assure that research participants involved in greater than minimal risk research have knowledge of the compensation and treatment available for injury that may occur as a result of participation in research activities that fall under the jurisdiction of The Christ Hospital IRB.

2.1 Unless waived by the IRB, all participants must be provided:

- 2.1.1 Explanations as to whether any compensation or medical treatment are available if injury occurs,
- 2.1.2 If so, a description of the available compensation and treatment, and
- 2.1.3 Where further information may be obtained.

2.2 For non-commercially funded research and some studies funded by federal departments, the NIH, or other federal agencies for which no compensation nor treatment funds are available from the sponsor for research-related adverse events, immediate necessary care will be provided by The Christ Hospital. Costs for such care will be charged to the participant and/or his/her insurance company in the same manner as any other (non-research related) medical care would be billed.

2.3 For commercially sponsored studies, compensation or payment of immediate necessary care for injury related to participation in research activities shall be provided according to the contractual agreement between the sponsor and The Christ Hospital.

2.4 For research conducted at The Christ Hospital, the informed consent document must contain specific TCH language. Refer to the TCH IRB consent document templates for specific language.

3.0 PROCEDURE

3.1 Investigator Responsibilities

3.1.1 The research study's consent form must include an explanation of any provision of voluntary compensation and treatment available to study participants, in the event of a research-related injury.

3.1.2 For commercially sponsored studies, the approved language from the contractual agreement between the study sponsor and The Christ Hospital regarding compensation or payment of immediate necessary care for research-related injury should be placed in the section of the informed consent document pertaining to research-related injury.

3.1.3 If a funding source for payment of treatment is NOT available, the investigator should utilize the TCH Informed Consent template to compose the consent form including the template's IRB-approved language regarding research-related injury:

> "In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

This language will apply to all greater than minimal risk protocols that are non-commercially funded research, for all studies with no benefit to human participants (normal volunteers) and some studies funded by federal departments, the NIH, or other Federal agencies for which no adverse event treatment funds are available from the sponsors.

3.2 IRB Responsibilities

The IRB chair and/or the convened IRB will review and approve the proposed compensation and injury language as a part of the new study submission.

3.2.1 IRB Determination

The IRB will render its determination for approval of compensation or medical treatment for medical injury as follows:

3.2.1.1 The IRB will verify that the appropriate template language for injury is contained in the informed consent document.

3.2.1.2 The IRB will consult with TCH Legal Counsel for requests to remove and/or revise TCH IRB templated research injury language, as needed, for non-commercially funded research, for all studies with no benefit to human participants (normal volunteers) and some studies funded by federal departments, NIH, or other Federal agencies for which no adverse event treatment funds are available from the sponsors.

3.2.1.3 The IRB will review the injury language to assure readability and understandability in relation to the proposed target study population.

3.2.2 Contractual Language & IRB-Approved Template Language

Contracts that propose to include specific language or terms that would vary from the language contained in the IRB consent template must be agreed to by the IRB. The IRB chair and Legal Counsel will work together to ensure that the contract and informed consent document contain appropriate and consistent language.

3.2.3 Review, Approval, and Initiation of Research

New studies may be reviewed and receive conditional approval prior to the contract being completed and signed by all parties. However, the research may not begin until the contract has been signed and distributed as appropriate. Contracts are developed and implemented between the sponsor, investigator and hospital administration. TCH Legal Counsel serves as the liaison between the institution and the IRB to assure documents adhere to contractual agreements. Upon submission of a new research proposal, Legal Counsel is assigned as an ancillary reviewer in the IRB management system to ensure all AAHRPP-required elements are addressed in the agreement, as applicable, prior to receiving final IRB approval.

3.3 IRB Staff Responsibilities

3.3.1 The IRB Office assigns the Reviewer Checklists:

3.3.1.1 The IRB Primary Reviewer is assigned the New Protocol Reviewer Checklist.

3.3.1.2 Legal Counsel is assigned the Contract Review Reviewer Checklist.

The IRB office staff will facilitate any communication between TCH Legal Counsel and the investigator (or designee) until the proposed research injury language has been found to be acceptable by all parties involved.

For non-commercially funded research, for all studies with no benefit to human participants (normal volunteers) and some studies funded by federal departments,

the NIH, or other federal agencies for which no adverse event treatment funds are available from the sponsors, requests to remove and/or revise TCH IRB templated research injury language may be forwarded to The Christ Hospital Legal Counsel (Risk Management Department) via email by the IRB Office for legal consultation as needed.

4.0 REFERENCES

4.1 IRB Standard Operating Procedures

4.2 IRB Reference Manuals

4.3 Code of Federal Regulations

4.3.1 U.S. Department of Health and Human Services (HHS)
45 CFR 46.116(b)(6)

4.3.2 U.S. Food and Drug Administration (FDA)
21 CFR 50.25(a)(6)

4.4 AAHRPP Domains and Elements
I.8.A