The Christ Hospital IRB
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(I.8.A)

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STANDARD OPERATING PROCEDURE

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

POLICY:

Federal regulations require that if research-related injury is possible in research that is more than minimal risk, the consent form must include an explanation of whatever voluntary compensation and treatment will be provided. It is the policy of The Christ Hospital Institutional Review Board to assure that research participants involved in greater than minimal risk research have knowledge of compensation and treatment availability for injury that may occur as a result of participation in research activities that fall under the jurisdiction of The Christ Hospital IRB.

I. Unless waived by the IRB, all participants must be provided with an explanation as to whether any compensation or an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of and where further information may be obtained.

II. For non-commercially funded research and some studies funded by Federal departments, NIH, or other Federal agencies for which no adverse event treatment funds are available from the sponsor for research injury compensation, immediate necessary care will be provided by The Christ Hospital and charged to the participant or his/her insurance company in the same manner any other medical care would be billed.

III. 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.

IV. For research conducted at The Christ Hospital, the informed consent document must contain specific TCH language (See the consent document template for language).

REFERENCE:

45 CFR 46.116(b)(6)
21 CFR 50.25(a)(6)

PROCEDURE

This procedure provides guidance for compensation or medical treatment if injury occurs while participating in research conducted under The Christ Hospital IRB jurisdiction.

Investigator Responsibilities:

I. The research consent form must include an explanation of whatever voluntary compensation and treatment will be provided.

a. 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. The approved language from the contract should be placed in the section of the informed consent document pertaining to research-related injury.

b. If a source of funds for payment of treatment costs is NOT available, the investigator should utilize the TCH Informed Consent template, which includes the following IRB-approved language regarding research-related injury, when composing the research consent form when the source of funds for payment of treatment costs is not available:

"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. (If you have a government insurer, your insurer will not be billed and you may be responsible for those costs. 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. If you are injured because of study participation, you will receive emergency medical care if needed and you will receive assistance in getting other medical care as needed. You or your insurance carrier will be billed for the cost of care, just as you would be billed for any other medical care. It is not The Christ Hospital's policy to pay compensation to research participants for injuries resulting from a study."

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, NIH, or other Federal agencies for which no adverse event treatment funds are available from the sponsors.

IRB Responsibilities:

I. 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.

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

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

i. Requests consultation from 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.

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

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

IV. New studies may be reviewed and approved 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 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.

IRB Staff Responsibilities:

I. The IRB Office assigns the reviewer checklists:
   a. The IRB Primary Reviewer is assigned the New Protocol Reviewer Checklist.
   b. Legal Counsel is assigned the Contract Legal Review Reviewer Checklist.
      i. The IRB staff will facilitate any communication between TCH legal counsel and the Investigator until research injury language has been proposed that is found to be acceptable by all parties involved.

II. 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, 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.

ADDENDUM
STANDARD OPERATING PROCEDURE 2.14
Compensation or Medical Treatment if Injury Occurs During Participation in Research Conducted at The Christ Hospital

1.0 PREVIOUS VERSIONS

Date Revised	Reason For Change	Revised By
6/8/15	Updated references	Becky
09/23/22	Added links to Mentor and regulations; added signature page; minor formatting updates; revised to state Legal Counsel may be consulted as needed.	Erica Jones
05/22/23	Added reviewer checklists; clarification of procedure; formatting changes.	Erica Jones

2.0 APPROVALS

IRB Chair, Steve Roberts, MD	Date of Approval