The Christ Hospital IRB **Number:** 1.25
Submitted By: Erica Jones, CIP **Effective Date:** 10/04/21
Reviewed By: S. Roberts, MD **Revised Date:**
Approved By: Steve Roberts, MD
(II.2.H)

STANDARD OPERATING PROCEDURE

Suspension or Termination of IRB-Approval of Research

POLICY:

A study may be suspended or terminated if there are serious concerns about the protection of the rights and welfare of human research participants or in an instance of continuing noncompliance. The procedures described in this document are based on the regulatory requirements outlined in 45 CFR 46.113 and 21 CFR 56.113 and apply when an IRB suspends or terminates a human research study.

TCH IRB has the authority to terminate or suspend its approval of a research protocol that is not being conducted in accordance with regulatory or IRB requirements or that is associated with serious harm to human research subjects. The IRB Chairman is authorized to suspend or terminate research on an urgent basis. Suspensions and terminations by someone other than the convened IRB are reported to and reviewed by the convened IRB.

DEFINITIONS:

Suspension- A suspension of IRB approval is directive of the convened IRB, or IRB designee either to stop temporarily some or all previously approved research activities, or to stop permanently some of all approved research activities. Suspended protocols remain open and require continuing review.

Termination- A termination of IRB approval is a directive of the convened IRB, or IRB designee to permanently halt the enrollment of new subjects, activities involving previously enrolled subjects, or other research activities.

PROCEDURE:

IRB Review

The IRB reviews all available information and determines and documents during a convened IRB meeting whether serious and/or continuing noncompliance occurred, whether or not to suspend or terminate the research, the reason for suspending/terminating the research, and the activities to stop (e.g., recruitment, enrollment, some or all interventions or interactions, follow-up, data analysis, or all research activities).

During review, the IRB will consider the following actions to protect the rights and welfare of subjects, including, but not limited to:

- Halting participant enrollment
- Halting study treatment and/or intervention
- Prohibition of use of data for analysis

- Notification of subjects of the suspension through appropriate communications (oral or written) approved by the IRB;
- Requiring withdrawal of current enrolled subjects;
- Changes to the protocol, consent form or other documents to correct any insufficiencies.

The suspension of a single aspect of the research (i.e. new participant enrollment) will not be considered a suspension of IRB approval unless it is associated with an unanticipated problem, serious noncompliance, and/or continuing noncompliance. The convened IRB may consider alternatives to termination as an approach to protect currently enrolled participants who may be at risk if the research is terminated.

IRB Communication

The IRB will notify the PI in writing of the determination. The communication will include the following as appropriate:

- Determination of serious and/or continuing non-compliance;
- Determination of suspension or termination;
- Reasons for the suspension or termination;
- Description of the research activities that are suspended or terminated;
- Corrective actions mandated by the IRB and actions needed to lift a suspension;
- Timelines for implementing the proposed actions and follow-up reporting to the IRB.

This information will be reported promptly to the investigator, appropriate institutional officials, Office of Human Research Protections (OHRP) and the Food and Drug Administration (FDA), as described in applicable regulations and this SOP. This information may also need to be reported the funding agency, as appropriate.

IRB Review of Response

The convened IRB will review the response to concerns from the PI, and may subsequently lift the suspension, require additional changes, or require termination of the study. If the concerns are not addressed, the IRB may terminate the research or take other action to protect the rights and welfare of subjects or others. Communications will include all pertinent information, as described in this SOP and will be reported promptly to the investigator, institutional officials, OHRP and FDA as proscribed in applicable regulations and this SOP.

IRB Reporting

Reporting to Office of Human Research Protections (OHRP)
To fulfill the regulatory requirements for reporting incidents, the IRB will include the following information in a report submitted to OHRP:

- Name of the institution conducting the research;
- Title of the research project and/or grant proposal that was suspended or terminated;
- Name of the principal investigator on the protocol;

- Number of the research project assigned by the IRB that was suspended or terminated and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
- A detailed description of the reason for the suspension or termination; and
- The actions the institution is taking or plans to take to address the suspension or termination (e.g., investigate alleged noncompliance, educate the investigator, educate all research staff, require monitoring of the investigator or the research project, etc.)

Reporting to Food and Drug Administration (FDA)

Reporting to the FDA will only occur for studies that are regulated by the FDA. 21 CFR 56.108(b)5 which requires that the IRB promptly report the following to appropriate institutional officials and the FDA:

- Any unanticipated problems involving risks to human subjects or others;
- Any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB; or
- Any suspension or termination of IRB approval.

When reporting suspensions or terminations of IRB approval to the FDA, the IRB will include the IND or IDE number, the full name of the research protocol, the name(s) of the investigators, and the reason(s) for the suspension or termination. These reports will be submitted in the appropriate format to the appropriate FDA contacts identified on the website.

REFERENCE:

45 CFR 46.103; 45 CFR 46.113; 21 CFR 56.113; 21 CFR 56.108

REVISION HISTORY:

Date Revised	Reason For Change	Revised By