
STANDARD OPERATING PROCEDURE

Suspension or Termination of IRB Approval of Research

1.0 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.

The Christ Hospital (TCH) Institutional Review Board (IRB) has the authority to suspend or terminate 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 chair 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.

2.0 DEFINITIONS

2.1 Suspension

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

2.2 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.

3.0 PROCEDURE

3.1 IRB Review

The IRB reviews all available information during a convened IRB meeting and determines and documents 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 its review, the IRB will consider the following actions to protect the rights and welfare of research participants, including but not limited to:

- 3.1.1 Halting participant enrollment;
- 3.1.2 Halting study treatment and/or intervention;
- 3.1.3 Prohibition of use of data for analysis;
- 3.1.4 Notifying subjects of the suspension through appropriate communications (oral or written) approved by the IRB;
- 3.1.5 Requiring withdrawal of current enrolled research participants;
- 3.1.6 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.

3.2 **IRB Communication**

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

- 3.2.1 Determination of serious and/or continuing non-compliance;
- 3.2.2 Determination of suspension or termination;
- 3.2.3 Reasons for the suspension or termination;
- 3.2.4 Description of the research activities that are suspended or terminated;
- 3.2.5 Corrective actions mandated by the IRB and actions needed to lift a suspension;
- 3.2.6 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 for 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 to the funding agency, as appropriate.

3.3 **IRB Review of Response**

The convened IRB will review the PI's response to the IRB's concerns 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 (within 30 days) to the investigator, institutional officials, OHRP, and FDA, as proscribed in applicable regulations and this SOP.

3.4 IRB Reporting

3.4.1 Reporting to Office for Human Research Protections

Reporting to OHRP will only occur for nonexempt human subjects research conducted or supported by the U.S. Department of Health and Human Services (HHS). The HHS Federal Policy for the Protection of Human Subjects (the Common Rule), which is codified for at [45 CFR Part 46 Subpart A](#), requires prompt reporting to OHRP of the following:

- 3.4.1.1 Any unanticipated problems involving risks to human subjects or others;
- 3.4.1.2 Any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB; and
- 3.4.1.3 Any suspension or termination of IRB approval per pre-2018 Requirements at [45 CFR 46.103\(a\) and \(b\)](#) and [45 CFR 46.113](#), and the 2018 Requirements at [45 CFR 46.108\(a\)\(4\)](#) and [45 CFR 46.113](#).

3.4.2 Reporting to Food and Drug Administration

Reporting to the FDA will occur only for studies that are regulated by the FDA. FDA regulation requires prompt reporting to appropriate institutional officials and the FDA of the following:

- 3.4.2.1 Any unanticipated problems involving risks to human subjects or others;
- 3.4.2.2 Any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB; or
- 3.4.2.3 Any suspension or termination of IRB approval.
(Ref. [21 CFR 56.108\(b\)](#))

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 investigator(s), and the reason(s) for the suspension or termination. These reports will be promptly submitted (within 30 days) in the appropriate format to the appropriate FDA contacts identified on the FDA website [Mandatory IRB Reporting: FDA Contacts](#).

4.0 REFERENCES

- 4.1 Code of Federal Regulations
 - 4.1.1 U.S. Department of Health and Human Services (HHS)
 - 4.1.1.1 [45 CFR Part 46 Subpart A](#)
 - 4.1.1.2 [45 CFR 46.103\(a\) and \(b\)](#)
 - 4.1.1.3 [45 CFR 46.113](#)
 - 4.1.1.4 [45 CFR 46.108\(a\)\(4\)](#)
 - 4.1.1.5 Office for Human Research Protections (OHRP) Guidance: [Reporting Incidents to OHRP \(2022\)](#)
 - 4.1.2 U.S. Food and Drug Administration (FDA)
 - 4.1.2.1 [21 CFR 56.113](#)
 - 4.1.2.2 [21 CFR 56.108\(b\)](#)
 - 4.1.2.3 [Mandatory IRB Reporting: FDA Contacts](#)
- 4.2 AAHRPP Domains and Elements
 - 4.2.1 [II.2.G.](#)
 - 4.2.2 [II.2.H.](#)