The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

Misconduct in Research

1.0 PURPOSE

This procedure establishes the process for managing allegations of research misconduct and conducting related proceedings.

2.0 DEFINITIONS (ref. 42 CFR Part 93 Subpart B)

2.1 Allegation: An accusation of falsification, fabrication, or plagiarism received through any means of communication and brought directly to the attention of an institutional official that prompts the procedures described in this policy.

2.2 Assessment: The initial review to determine if each allegation fits within the definition of research misconduct and if each allegation is credible and specific so that potential evidence of research misconduct may be identified.

2.3 Complainant: Person who in good faith makes an allegation of research misconduct.

2.4 Fabrication: Making up data or results and recording or reporting them.

2.5 Falsification: Manipulation of research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

2.6 Good Faith Allegation: Allegations of research misconduct that a complainant or witness believes is true and that a reasonable person in the same position would likewise believe to be true based on the information known at the time.

2.7 Home Institution: The institution with jurisdiction over a specific allegation because it is the institution where the research misconduct took place and which retains and/or is responsible for the retention of the original research records.

2.8 Inquiry: Preliminary information-gathering and fact-finding to determine that sufficient evidence exists that research misconduct may have occurred to warrant investigation.

2.9 Institutional Deciding Official (IDO): The institutional official responsible for final determinations on allegations of research misconduct and any institutional actions. The same individual cannot serve as the Institutional Deciding Official and the Research Integrity Officer.

2.10 Institutional Record: The institutional record consists of three core components:

2.10.1 Records compiled or generated during the proceeding and relied upon by the institution,
2.10.2 A single index listing all research records and evidence considered, and
2.10.3 A general description of records that were sequestered but not relied upon.

2.11 Intentionally: To act with the aim of carrying out the act.

2.12 Investigation: The formal review of all evidence to determine if research misconduct occurred and by whom, and to recommend appropriate corrective actions and/or sanctions.

2.13 Knowingly: To act with awareness of the act.

2.14 Plagiarism: The appropriation of another person's ideas, processes, results, or words, without giving appropriate credit. Plagiarism:

2.14.1 Includes the unattributed verbatim or nearly verbatim copying of sentences and paragraphs from another's work that materially misleads the reader regarding the contributions of the author. It does not include the limited use of identical or nearly identical phrases that describe a commonly used methodology;

2.14.2 Does not include self-plagiarism or authorship or credit disputes, including disputes among former collaborators who participated jointly in the development or conduct of a research project. Self-plagiarism and authorship disputes do not meet the definition of research misconduct.

2.15 Preponderance of the evidence: Proof by evidence that, compared with evidence opposing it, leads to the conclusion that the fact at issue is more likely true than not.

2.16 Recklessly: The act of proposing, performing, or reviewing research, or reporting research results, with indifference to a known risk of fabrication, falsification, or plagiarism.

2.17 Research: A systematic experiment, study, evaluation, demonstration, or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) by establishing, discovering, developing, elucidating, or confirming information or underlying mechanisms related to biological causes, functions, or effects; diseases; treatments; or related matters to be studied.

2.18 Research Integrity Officer (RIO): The institutional official responsible for administering the institution's written policies and procedures for addressing allegations of research misconduct in compliance with this policy.

2.19 Research Misconduct: The fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

2.20 Respondent: The individual against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

3.0 POLICY

The Christ Hospital (TCH) is committed to maintaining integrity and transparency in research. As such, TCH expects all individuals involved in research activities within the institution to adhere to the highest standards of research integrity to protect the accuracy and reliability of the research record and published results. Allegations of research misconduct may come from any source including investigators, study participants and their

families, TCH personnel, other institutional committees, the hospital's Research Subject Advocate (Director of Social Services), anonymous sources, or the public. Informal inquiries or consultations with the IRB Office or other institutional officials regarding potential research misconduct do not, by themselves, constitute formal allegations of research misconduct. Allegations of research misconduct should be directed (preferably in writing) to the Research Integrity Officer as soon as misconduct is suspected. This policy applies to all research conducted within the institution, regardless of the funding source. All aspects of an investigation must be completed within 180 days of commencement including transmitting the institutional record, including the final investigation report and decision, by the Institutional Deciding Official to the U.S. Department of Health and Human Services Office of Research Integrity (ORI) in accordance with 42 CFR 93.311 for PHS-funded research.

4.0 OVERVIEW

4.1 Allegations of research misconduct may be made by anyone, whether associated with the institution or not, and may be made anonymously.

4.2 Allegations can be made through one of the following avenues:

- 4.2.1 Complaint or Concern Form
- 4.2.2 Email: IRB_Office@thechristhospital.com
- 4.2.3 Mail: IRB, 2139 Auburn Avenue, Room 3140, Cincinnati, Ohio 45219
- 4.2.4 Telephone:
  - 4.2.4.1 IRB Office at 513-585-2298
  - 4.2.4.2 Patient Relations at 513-585-1200
  - 4.2.4.3 TCH Compliance Hotline at 1-800-398-1496.

4.3 To the maximum extent possible, within the law, and the need to conduct a thorough inquiry or investigation, all participants in the process must keep all information regarding the allegations and any proceedings under this policy confidential until the process, including any disciplinary action, has concluded and all avenues of appeal (if pursued) have been exhausted.

4.4 A finding of research misconduct requires that:

- 4.4.1 There is a significant departure from accepted practices of the relevant research community;
- 4.4.2 The misconduct be committed intentionally, knowingly, or recklessly; and
- 4.4.3 The allegation be proven by a preponderance of evidence.

4.5 A response to an allegation of research misconduct will usually consist of several phases, including:

- 4.5.1 Inquiry assessing whether the allegation has substance and if an investigation is warranted.
- 4.5.2 Investigation involving the formal development of a factual record, and the examination of that record leading to (1) dismissal of the case or (2) a recommendation for a finding of research misconduct or other appropriate remedies.

4.5.3 Adjudication during which recommendations are reviewed and appropriate corrective actions determine. Adjudication is separated organizationally from inquiry and investigation.

4.5.4 Appeal, if applicable:

4.5.4.1 The decision on an allegation(s) may be appealed to the IDO by the respondent(s) or complainant(s) based on new information not already considered during the inquiry, or evidence that a substantial procedural irregularity occurred during the inquiry phase within 7 days of receipt of the final inquiry report

4.5.4.2 Appeals are separated organizationally from inquiry and investigation.

4.6 The institution will promptly take reasonable and practical steps to:

4.6.1 Obtain and inventory all relevant research records and other evidence,

4.6.2 Sequester those materials in a secure manner, and

4.6.3 Maintain the chain of custody and integrity of the records throughout the proceeding.

4.7 If additional respondents are identified during an inquiry or investigation, the institution is not required to conduct a separate inquiry for each new respondent. However, each additional respondent must be provided notice of and an opportunity to respond to the allegations.

4.8 In instances when allegations involve Public Health Service (PHS)-funded research carried out at multiple institutions, TCH institution shall conduct its research misconduct proceedings independently. The Research Integrity Officer must communicate to the inquiry and investigation committee members that their review and findings should focus only on the allegations involving PHS-funded research at their own institution (Ref. Guidance for Public Health Service Policies on Research Misconduct, Multiple Institutions, page 4.)

4.9 The institution will address any potential, perceived or actual, professional, or financial conflicts of interest between any person(s) conducting the research misconduct proceedings and the complainant, respondent, or witnesses.

4.10 The institutional record and all sequestered evidence must be securely maintained for seven years after the completion of the institutional or HHS (U.S. Department of Health and Human Services) proceeding, whichever is later, unless custody is transferred to HHS or the Research Integrity Officer advises otherwise. (Ref. Guidance for Public Health Service Policies on Research Misconduct, Research Records, page 9.)

5.0 RESPONSIBILTY & PROCEDURE

5.1 Principal Investigator (PI)

5.1.1 Bears the ultimate responsibility for the conduct of a research project and is expected to adhere to the highest standards of research integrity to protect the accuracy and reliability of the research record and published results, and

5.1.2 Must comply with the requirements of The Christ Hospital's Federalwide Assurance, the FDA, state laws, and with the determinations of the IRB as outlined in minutes, guidelines, and other correspondence.

5.2 **Institutional Deciding Official (IDO) / Institutional Official**

5.2.1 Has ultimate authority for research misconduct proceedings.

5.2.2 Designates a Research Integrity Officer to be responsible for administering this policy for the institution.

5.2.3 Makes final institutional decisions and adjudication related to all allegations of research misconduct. The determination must be provided in writing including:

5.2.3.1 Whether the institution found research misconduct and, if so, who committed the misconduct; and

5.2.3.2 A description of relevant institutional actions to be taken.

5.2.4 Takes administrative actions that are, in the IDO's judgment, appropriate to protect research funds, materials, equipment, records, or the legitimate interests of research subjects, patients, clients, or research animals. Such administrative actions will not be deemed disciplinary in nature.

5.2.5 Rules on any appeals from Respondents or Complainants.

5.2.6 Works with other institutional officials to help restore the reputation of a Respondent found not to have committed misconduct.

5.3 **IRB Administrator**

5.3.1 When made aware of an allegation of misconduct, immediately notifies the IRB Chair and works with the Chair to compile any required background file information.

5.3.2 Provides administrative support to the Research Integrity Officer including, but not limited to, documentation, record keeping, and preparation of determination letters.

5.3.3 On behalf of the Research Integrity Officer, files an annual report on research misconduct with the Office of Research Integrity containing information specified by the Research Integrity Officer on institutional compliance with federal regulations on research misconduct.

5.4 **Research Integrity Officer (RIO) / IRB Chair**

5.4.1 <u>Risk to Public Health/Safety</u>

If public health or safety is at risk at any time during an inquiry or investigation, the Research Integrity Officer immediately notifies the applicable federal agency if the following special circumstances arise:

5.4.1.1 Agency resources or interests are threatened;

5.4.1.2 Research activities should be suspended;

5.4.1.3 A reasonable indication of possible violations of civil or criminal law exists;

5.4.1.4 Federal action is required to protect the interests of those involved in the investigation;

5.4.1.5 The research institution believes the inquiry or investigation may be made public prematurely so that appropriate steps can be taken to safeguard evidence and protect the rights of those involved; and/or

5.4.1.6 The research community or public should be informed.

5.4.2 Inquiry Phase

(Must be completed with 90 days of initiation unless circumstances warrant a longer period.)

5.4.2.1 Assesses whether the allegation has substance and if an investigation is warranted. An investigation is warranted if the allegations meet the definition of research misconduct and preliminary information-gathering and fact-finding indicates the allegation may have substance.

5.4.2.2 Refers all complaints that do not meet the definition of research misconduct to the appropriate department.

5.4.2.3 If needed, utilizes one or more subject matter experts to assist them in the inquiry.

5.4.2.4 Conducts interviews with witnesses or respondents to provide additional information for the institution's review as described in 42 CFR 93.310(g).

5.4.2.5 Pursues all significant issues diligently and pursues relevant leads including any evidence of additional instances of possible research misconduct. If additional allegations are raised, the respondent(s) must be notified in writing of the additional allegations raised against them.

5.4.2.6 Prepares a written preliminary inquiry report, including the following information:

5.4.2.6.1 The names, professional aliases, and positions of the respondent and complainant;

5.4.2.6.2 A description of the allegation(s) of research misconduct;

5.4.2.6.3 The composition of the inquiry committee, if used, including name(s), position(s), and subject matter expertise;

5.4.2.6.4 Inventory of sequestered research records and other evidence and description of how sequestration was conducted;

5.4.2.6.5 Transcripts of any transcribed interviews;

5.4.2.6.6 Timeline and procedural history;

5.4.2.6.7 Any scientific or forensic analyses conducted;

5.4.2.6.8 The basis for recommending that the allegation(s) warrant an investigation;

5.4.2.6.9 The basis on which any allegation(s) do not merit an investigation;

5.4.2.6.10 Any comments on the inquiry report by the respondent or the complainant;

5.4.2.6.11 Any potential evidence of honest error or difference of opinion;

5.4.2.6.12 Any institutional actions implemented, including communications with journals or funding agencies;

5.4.2.6.13 For research receiving PHS support, detailed information on the PHS support, including, for example, grant numbers, grant applications, contracts, and publications listing PHS support; and

5.4.2.6.14 If the inquiry takes longer than 90 days to complete, documents reasons for exceeding the 90-day period.

5.4.2.7 Notifies the IDO and any applicable Department Director if the inquiry into the allegation determines that there is sufficient evidence to proceed to an investigation.

5.4.2.8 Provides the respondent(s) written notice of the inquiry outcome including the inquiry report and a copy of, or supervised access to, the research records and other evidence that was considered or relied on and a copy of this standard operating procedure. The respondent(s) must submit any comments on the inquiry report within 14 days of receipt.

5.4.2.9 Provides the complainant(s) with the relevant sections of the inquiry report specific to their allegation(s), or written notice of the inquiry outcome. The complainant(s) must submit any comments on the inquiry report within 14 days of receipt.

5.4.2.10 Provides the IDO with the final inquiry report.

5.4.2.11 Prepares the final inquiry report, including any revisions to the inquiry report and the written response(s) from the respondent(s) and complainant(s).

5.4.2.12 Forwards the final inquiry report to the respondent(s) and IDO.

5.4.2.13 Provides the complainant(s) with the relevant sections of the inquiry report specific to their allegation(s), or written notice of the inquiry outcome.

5.4.2.14 Notifies the funding agency/sponsor of an allegation of research misconduct within 30 days of determining that there is sufficient evidence to proceed with an investigation.

Multiple Agencies: If more than one agency/sponsor is involved in funding activities relevant to the allegation, a lead agency/sponsor should be designated to coordinate responses to allegations of research misconduct. Each agency/sponsor may implement administrative actions in accordance with applicable laws, regulations, policies, or contractual procedures.

5.4.2.15 If the research receives PHS support, provides the following information to the Office of Research Integrity whenever requested:

5.4.2.15.1 The institutional policies and procedures under which the inquiry was conducted; and

5.4.2.15.2 The research records and other evidence reviewed, and copies of all relevant documents.

5.4.2.16 Retains detailed documentation of all inquiries as described in by 42 CFR 93.318 3.318.

5.4.3 Investigation Phase

5.4.3.1 Consults Risk Management to ensure that all applicable legal and institutional policy requirements are satisfied.

5.4.3.2 Ensures that misconduct proceedings are not tainted by inappropriate conflicts of interest.

5.4.3.3 Promptly sequesters all data or other materials relevant to the complaint, on or before the date on which the respondent(s) is notified of the allegations.

5.4.3.4 Promptly locates and secures the originals of all research records and other relevant materials if it is believed that such records may become relevant in the course of an inquiry or investigation of alleged research misconduct.

5.4.3.5 Provides supervised access to the research records and other materials to (1) any investigative bodies looking into the complaint, (2) the respondent(s), and (3) any other person who has a legitimate reason to require access.

5.4.3.6 Contacts the appropriate officials to locate and secure all research records relevant to the complaint if research records exist outside of the institution.

5.4.3.7 Assists the appropriate officials in carrying out the investigation, including assembling evidence and conducting interviews.

5.4.3.8 Prepares an assessment report and provides the report to the IDO for consideration and adjudication.

5.4.4 Following Adjudication by IDO

5.4.4.1 After the IDO completes adjudication, the Research Integrity Officer forwards the IDO decision notifying the agency/sponsor of any correction actions taken or planned.

5.4.4.2 When an investigation is complete, the Research Integrity Officer will forward to the agency/sponsor a copy of:

5.4.4.3 The evidentiary record,

5.4.4.4 The investigative report,

5.4.4.5 Recommendations made to the IDO, and

5.4.4.6 The subject's written response to the recommendations (if any).

5.4.5 Appeals for PHS-Supported Research

5.4.5.1 If a respondent appeals the institution's finding(s) of research misconduct or institutional actions, the Research Integrity Officer must promptly notify the Office of Research Integrity.

5.4.5.2 If the institution has not transmitted its institutional record to the Office of Research Integrity prior to the appeal, the Research

Integrity Officer must wait until the appeal is concluded to transmit the institutional record. The Research Integrity Officer must ensure that the complete record of the appeal is included in the institutional record consistent with 45 CFR 93.220(a)(5).

5.4.5.3 If the institution has transmitted its institutional record to the Office of Research Integrity in accordance with 42 CFR 93.316 prior to the appeal, the Research Integrity Officer must provide the Office of Research Integrity a complete record of the appeal once the appeal is concluded.

5.4.6 Annual Report to Office of Research Integrity: Certifies the content of the annual report and ensures the report is submitted as required.

6.0 REFERENCES

6.1 **IRB Standard Operating Procedure**
SOP 3.08 - Complaints and Inquiries for Research Participants, Investigators, Research Staff, and the Community

6.2 **Code of Federal Regulations**
42 CFR Part 93, Public Health Service Policies on Research Misconduct

6.3 **U.S. Department of Health and Human Services Office of Research Integrity**
Guidance for Public Health Service Policies on Research Misconduct 42 CFR Part 93 (2024):

6.3.1 Institutional Records (2025)
6.3.2 Research Records (2025)
6.3.3 Multiple Institutions (2025)

6.4 **AAHRPP Domains and Elements**
Element III.2.C