Reporting

Policy

Children's Hospital complies with all applicable local, state, and federal regulations that pertain to reporting requirements. These regulations require that the following be reported:

- Unanticipated problems that involve risks to participants or others;
- Suspension or termination of Committee on Clinical Investigation (CCI) approval of research; and
- Serious or continuing noncompliance with regulations or the requirements of the CCI.

The specific procedures for investigating and making pertinent determinations concerning those situations are addressed in the following Clinical Investigation policies:

- ***Noncompliance: Investigations and Determinations***
- ***Adverse and Unexpected Events and Unanticipated Risks to Research Subjects and Others***
- ***Suspensions and Terminations,***

Children's Hospital assurance of compliance is restricted to federally funded research. The same criteria and process for conducting investigations, making determinations about reporting, and actions taken will apply to all research regardless of funding source. If an event involves research that is not federally funded. The report will be sent to the President of Children's Hospital in leiu of OHRP or any of the federal agencies. All other reporting requirements listed below will remain the same as pertinent. The Committee on Clinical Investigation reserves the right to voluntarily reporting any event that is not associated with federal funding to OHRP.

Purpose

To outline the steps to be taken when an event is determined to be reportable.

Procedures

All reporting actions are to occur within the minimal amount of time necessary to conduct complete and conclusive investigations, with a final report goal of no more than 30 days from the time an event is identified and an initial report made. If additional time is necessary to complete the final report, the time frame is to the extent practicable to be specified in the initial report. If federally funded, the Institutional Official will submit any report on behalf of the institution. The Director of Clinical Research Compliance will be responsible for submitting any other reports to the President of Children's Hospital.

Reportable Events

The Committee on Clinical Investigation (CCI) determines that an event represents an unanticipated problem that involves risks to participants or others;

The Committee on Clinical Investigation (CCI) suspends or terminates research; or

The Committee on Clinical Investigation(CCI) determines that an event represents serious or continuing noncompliance.

Report Content

Following a complete investigation of the situation or incident, the Director of Clinical Research Compliance is to prepare a final report that includes the following:

- An overview of the situation or incident
- A description of the manner in which the investigation was conducted
- The findings of the investigation
- A full explanation as to why and how the incident occurred
- The actions taken, including any corrective actions
- Any sanctions taken

The CCI, CCI Chair, the Institutional Official, the General Counsel, and any other individual(s) deemed appropriate by the CCI are to review the report. The CCI makes the final determination regarding the report's content

Report Recipients

A copy of the final report will be shared with government agencies or the President of Children's Hospital as applicable, sponsors to the extent legally and contractually required, and with any others in the sole discretion of the CCI and the Institutional Official. Possible recipients of the full report, excerpts or summaries, include:

- Office of Human Research Protections (OHRP) if federally funded, or the President of Children's Hospital if not federally funded
- Food and Drug Administration (FDA) when the research is subject to regulation by the FDA
- Funding agency when funded by a government entity (e.g., the Departments of Defense, Education, and Justice require copies of such reports)
- Licensing and accrediting bodies, where the report or some portion thereof implicates standards or regulations administered by those bodies
- CCI Chair and members
- Principal investigator (PI)
- PI's Department Chair or supervisor
- Grants and Contracts Office, when the research is funded by a grant or contract
- Any other external sponsor, when the research is sponsored
- Other Children's Hospital Departments who require notification (i.e. Pharmacy, GCRC, office of Sponsored programs, Department Chairs. Chiefs)

- Harvard Medical School, where the findings are requested and relevant to violations of academic standards

A copy of the report is to be placed in the protocol file, as well as any other files that are maintained during an investigation to determine whether an event is reportable.

Related Content

None Identified

Document Attributes

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