



## Noncompliance: Investigations and Determinations

### Policy

It is the policy of Children's Hospital to comply with all applicable local, state, and federal regulations in the conduct of clinical research studies. Principal investigators (PIs) and Department/Division Chiefs or any staff member are required to report regulatory noncompliance to either the Chair of the Committee on Clinical Investigation (CCI), the Director of Clinical Research Compliance, or to the Vice President of Research Administration (Institutional Official ) and to participate in institutional efforts to address and resolve noncompliance. The CCI, CCI Chair, Director of Clinical Research Compliance and Institutional Official are responsible for investigating and assessing noncompliance, reporting to the CCI and requesting further remedies from the CCI itself. The Committee on Clinical Investigation (CCI) will make the final determination that an event is serious or continuing noncompliance. The "Reporting Policy" will be followed for all reportable events.

### Purpose

The Purpose of this policy is to outline the procedure for reporting and investigating noncompliance with human research protection requirements.

### Definitions

**Noncompliance** is defined as any violation of any regulation that governs human subject research, any deviation from the study protocol approved by the CCI; or any violation of any conditions imposed by the CCI on the approval of the study or conduct of the research.

**Minor noncompliance** is a noncompliant event that does not impact the subject safety, compromise the integrity of study/data, violate a subject's rights or welfare or affect the subjects willingness to participate in the research.

**Serious Noncompliance** is a noncompliant event that may impact the subject safety, increase risks to the subjects, affect the integrity of the data, violate a subject's rights or welfare or affect the subject's willingness to participate in the study.

**Continuous noncompliance** is defined as a series of more than one noncompliant event, in reasonably close proximity, that indicates the need for evaluation of the methods and systems used to protect human subjects. Continuous noncompliance need not involve a sequence of similar events if the events, taken as a whole, indicate that examination of the methods and systems used is warranted.

## Procedures

Principal Investigators are responsible for promptly reporting in writing all suspected incidents of noncompliance. Investigators may make an initial report in person, but must follow up with a written report. In addition any person may report suspected noncompliance, in person or in writing. The reports should be sent to the CCI Chair, the Director of Clinical Research Compliance or the Institutional Official. Any allegation regarding noncompliance, or any concern about human subject protections will be fully investigated. If at any time during an investigation there are concerns regarding scientific misconduct, it will immediately referred to the Vice President of Research Administration, who also serves as the Institutional Official

### **CCI Chair and Director of Clinical Research Responsibilities**

The CCI Chair and/or the Director of Clinical Research Compliance are responsible for obtaining as much information as possible from the individual who initially reports the event. The Chair and the Director are then to meet to discuss the following:

- The incident and the facts presented to date
- Identification of those individuals involved in the incident or likely to be involved in the investigation and resolution of the incident. If necessary a meeting should be scheduled as soon as possible after the incident is reported (within 72 hours, when feasible) to begin to discuss and resolve the incident. Attendees may include the investigator(s), the investigator's Department/Division Chief, the CCI Chair, the Director of Clinical Research Compliance, the General Counsel, the Institutional Official, and any other staff member thought to be involved in the noncompliance incident and required resolution.
- Whether there are sufficient facts to demonstrate serious or continuing noncompliance that is reportable in accordance with the Reporting Policy. If so this will be immediately reported to the CCI who, based on a completed investigation, will make a final determination. If the CCI determines it is serious or continuing noncompliance the Reporting Policy will be followed. (In most cases, more information will be required before a determination is made that the event is either serious or continuing noncompliance.)
- The Chairman may
  - determine that the incident is minor noncompliance and requires either no further action, or compliance with a corrective action plan that is acceptable to the chair and agreed upon by the investigator
  - require that preliminary steps be immediately taken to further investigate and begin to correct the noncompliant incident and report to the CCI.
  - determine the incident seems to represent serious or continuing noncompliance and recommend to the CCI that the protocol be suspended or terminated in whole or in part. This step may be taken as a final measure, or as an interim measure where

investigatory conclusions, although incomplete, are conclusive enough in pertinent part to just CCI action.

### **Committee On Clinical Investigation Responsibilities**

The CCI is responsible for making a final determination as to whether serious or continuing noncompliance has occurred. The CCI is to receive notification of any incident that the Chair has determined that a potential incident of serious or continuing noncompliance exists. This should occur at the earliest possible time which is usually the next scheduled meeting. The CCI should be advised by the Director of Clinical Research Compliance or the CCI Chair about the actions taken thus far and determine further actions to be taken. All members will be given a summary of the incident prepared by the Director of Clinical Research Compliance and important supporting documents. The CCI, directly or through a delegate, such as the Director of Clinical Research Compliance or a subcommittee formed for the purpose, may request any documents it deems necessary to conduct the investigation. As determined by the specifics of the situation, the CCI reserves the right to conduct any type of investigation deemed necessary in order to obtain the required information. Moreover, the CCI may delegate any component of the investigation to those individuals best suited to perform the functions of the investigation. At any time during the investigation the CCI may take any one or more of the following actions.

- Suspend or terminate the protocol
- Designate an individual or a subcommittee to review and investigate the incident and provide information and recommendations for resolution back to the CCI
- Require additional information
- Require modifications to the protocol and/or consent form
- Require that subjects currently or previously on protocol be notified of the non-compliance when such information might relate to their willingness to continue to take part in the research.
- Require that subjects be re-consented
- Modify the continuing review schedule
- Require remedial education
- Require oversight by a senior investigator
- Monitor the informed consent process
- Require immediate or periodic audits by EQUiP
- Referring concerns or findings to areas of the organization that administer other policies, laws, and regulations implicated by the noncompliance;

- Any other action deemed necessary by the CCI.

The Committee will be continually updated as information becomes available until final resolution. If it determined the incident represents serious or continuing noncompliance the "Reporting" policy will be followed.

### **Investigator Responsibilities (if applicable)**

Investigators are responsible for reporting non-compliance on their protocols. Investigators may choose to voluntarily initiate a suspension or termination until the potential issue is investigated and/or resolved. Investigators will also be informed, in writing, when allegations of noncompliance are made on their protocols. Investigators are required to fully cooperate with any fact finding and subsequent investigation, and maintaining all potentially useful records pending investigation, even if regulations or other policies would otherwise permit destruction of those records. The investigator is responsible for responding promptly, in writing, to all issues and questions raised. This may include an explanation of the noncompliance event, answers to questions raised by the CCI, and a plan of action to ensure that similar incidents do not occur in the future. Investigators are responsible for complying fully with all directives of the CCI, whether investigatory or remedial. If the CCI has determined that subjects must be contacted with regards to the noncompliance incident, the investigator will be responsible for doing so if the CCI so directs.

### **Institutional Official Responsibilities**

The Institutional official is responsible for submitting a report on behalf of the institution in accordance with the "Reporting" Policy.

### **The Final Report**

For incidents determined to be serious or continuing noncompliance, the reporting policy will be followed. A file of the noncompliance incident, regardless of the ultimate determination, will be maintained in the Clinical Investigation office.

## **Related Content**

## **Document Attributes**

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