**Children's Hospital and Health System, Inc.**
**Administrative Policy and Procedure**

# SUBJECT – Research Noncompliance

## POLICY

Children's Hospital and Health System has a strong commitment to maintaining a high level of integrity in the conduct of research. This policy is intended to carry out Children's Hospital and Health Systems (CHHS) responsibilities under applicable federal and state laws and regulations, and CHHS policies.
(**Research Misconduct is covered under CHHS Policy "Misconduct in Research Practices.")**

## INDEX



## I. APPLICABILITY AND DEFINITIONS

### A. APPLICABILITY

This policy applies to any person employed by or otherwise affiliated with CHHS who is the subject of or becomes aware of apparent research noncompliance in connection with research subject to review by the Institutional Review Board (IRB) of Children's Hospital of Wisconsin (CHW).

This policy and procedure does not apply to authorship or collaboration disputes. This policy and procedure does not apply to allegations of research misconduct (fabrication, falsification, or plagiarism in performing

or reporting research results), which is covered in a separate policy "Misconduct in Research Practices and can be found at Q:\P&P - Administrative\Misconduct in Research Practices.doc or at http://intranet.chw.org/PandPs/Misconduct%20in%20Research%20Practices.pdf.

## B. DEFINITIONS

### 1. Research Noncompliance

Conducting research in a manner that fails to comply with applicable federal or state laws or regulations or CHHS policies governing such research. This can include, but is not limited to, inappropriate subject recruitment procedures in human research, inadequate or non-existent procedures for informed consent in human research, inadequate supervision of research involving devices, drugs or procedures, failure to follow recommendations made by the Institutional Review Board to ensure safety of subjects and minimize risk, failure to report adverse events or protocol changes to the CHW IRB.

### 2. Continuing Noncompliance

A pattern of noncompliance that, in the judgment of the IRB Chair or convened IRB, indicates a lack of understanding of the regulations or institutional requirements that may affect the rights and welfare of participants, would have been foreseen as compromising the scientific integrity of a study such that important conclusions could no longer be reached, suggests a likelihood that non-compliance will continue without intervention, or frequent instances of minor noncompliance. Continuing non-compliance also includes failure to respond to a request to resolve an episode of non-compliance.

### 3. Serious Noncompliance

An action or omission in the conduct or oversight of research involving human subjects that affects the rights and welfare of participants, increases risks to participants, decreases potential benefits or compromises the integrity or validity of the research.

### 4. Research Record

Record of data or results regarding the research project, and includes, but is not limited to, research proposals, laboratory records (both physical and electronic), progress reports, research consent forms, CHW IRB documents, clinical research forms, tracking logs, sponsor required study records, abstracts, theses, presentations, internal reports and journal

articles. In some cases, copies of the clinical record become part of the research record.

### 5. Inquiry

An inquiry is preliminary information-gathering and fact-finding to determine whether an allegation or an apparent instance of noncompliance merits an investigation being conducted.

### 6. Investigation

An investigation is a formal development of a factual record and examination of relevant facts to determine whether or not research noncompliance or questionable research practices have occurred.

### 7. Findings of Research Noncompliance

A finding of research noncompliance requires that there is a violation of applicable federal or state laws or regulations or CHHS research policies.

## II. RESPONSIBILITY TO REPORT NONCOMPLIANCE OR QUESTIONABLE RESEARCH PRACTICE

All observed, suspected, or apparent research noncompliance or questionable research practices should be reported promptly to the Director of Corporate Compliance, who shall serve as the Research Integrity Officer (RIO) or his or her designee. Reporting such concerns will not jeopardize the employment of the individual who brought the complaint. CHHS prohibits retaliation against a person who, acting in good faith, reports or provides information about suspected noncompliance or questionable research practices. If an individual is unsure whether a suspected incident fails within the definition of research noncompliance, he or she may meet with or contact the RIO to discuss the suspected research noncompliance or questionable research practice informally, which may include discussing it anonymously and/or hypothetically.
At any time, the RIO is available for confidential discussions and consultations about concerns of possible misconduct.

## III. REVIEW PROCESS

### A. PRELIMINARY ASSESSMENT

Upon receipt of an allegation, the RIO will access information to determine whether the complaint involves, in all or in part, allegations of research noncompliance or questionable research practices. Adherence to federal and state laws and regulations, and CHHS research policies will be assessed.

## B. INQUIRY

If the RIO determines that the criteria for an inquiry are met, he or she will immediately initiate the inquiry process. The inquiry may or may not require a full review of research records related to the allegation.

1. At the beginning of the inquiry, the RIO will take all reasonable and practical steps to obtain custody of the research records needed to conduct the inquiry.

2. Inquiries will begin with written notification to the researcher. An open meeting with the researcher or other appropriate individuals may also occur if necessary. The inquiry may include review of relevant documents and interviews with appropriate staff.

3. The researcher will be given the opportunity to comment on the draft report findings. Draft copies of the report will be reviewed by appropriate members of CHHS management before issuance of the final report.

4. The distribution of the final report will be as follows; the President of CHHS, Corporate Vice President and General Counsel, Vice President of Children's Research Institute, CHW Chief Medical Officer, IRB Chair for human subjects concerns and other executive and managerial personnel of CHHS, and appropriate managerial personnel of the researcher's employer if not CHHS, as the RIO deems appropriate.

Unless the President has further concerns, the RIO's recommendation regarding the finding will be final.

## C. INVESTIGATION PROCEDURES

1. At the beginning of an investigation, the RIO will take reasonable steps to obtain custody of all research records that have not been previously gathered.
2. Written notification of an investigation will be sent to the researcher.

3. The RIO will convene an investigation committee that will include a representative from legal services, the Vice President of Research Administration and, at the RIO's discretion, any other individuals with expertise related to the investigation.
4. The investigation may include review of relevant documents and interviews with appropriate staff.
5. All significant issues should be pursed until the RIO is reasonably certain that all available and appropriate information has been gathered.
6. Once completed, draft report findings will be discussed with impacted individuals before issuance of a final report. The researcher will be given the opportunity to comment on the draft report findings. Draft copies of the report will be reviewed by appropriate members of CHHS management before issuance of the final report.
7. The distribution of the final report will be as follows; President of CHHS, Corporate Vice President and General Counsel, Vice President of Children's Research Institute, Chief Medical Officer, HRRB Chair for human subjects concerns, other impacted executive and managerial personnel of CHHS, and appropriate managerial personnel of the researcher's employer if not CHHS.

## IV. AFFILIATE INTERACTIONS

There will be instances and circumstances when issues involving research noncompliance will require collaborative resources and consistent communication between CHHS Research Compliance and other institutions. This may occur when the study is under the purview of the CHHS Institutional Review Board but involves MCW or other affiliate faculty and/or staff as part of the research team.

## V. NOTIFICATION TO EXTERNAL AGENCIES

The RIO will comply with the applicable notice requirements and regulations of governmental and funding agencies.

## VI. INVESTIGATIONAL OUTCOME

In cases in which research noncompliance are verified.

1. Written plan of corrective action for the researcher that appropriately addresses the findings of noncompliance is to be implemented immediately. The corrective action plan will be reviewed, acknowledged and monitored by CHW IRB office.
2. CHW IRB may suspend or terminate approval for research studies in a particular area if evidence of continuous or serious noncompliance is found.
3. Notices of suspension or termination of research will immediately be sent to the researcher and, if appropriate, to governmental and funding agencies.

## VII. SAFEGUARDS

A. In the course of conducting inquiries or investigations, the following safeguards will be applied:
    1. Precautions will be taken to avoid unresolved personal, professional or financial conflicts of interest on the part of those involved in the inquiry or investigation.
    2. The identity of researchers, complainants, and research subjects will be protected throughout the proceedings.
    3. Except as required in the reporting provisions above, only those directly involved in an inquiry or investigation or with a need to know will be made aware that the process is being conducted or have access to records or evidence, including the identity of researchers, complainants, or research subjects.
    4. Where appropriate, efforts will be made to protect and restore the reputations of the researcher(s) when allegations are not confirmed.
    5. Where appropriate, efforts will be made to protect and restore the reputations of a complainant and to counter any retaliation against the complainant.

(signed copy on file)

Peggy Troy, President
Children's Hospital and Health System