TITLE: Non-Compliance/Complaint : Investigating Allegations and Reporting		POLICY/PROCEDURE NUMBER: IRB 4	
AUTHOR:	Jana L. Lacera, RN, MSA, CDM	APPLICABLE TO:	CHS CIRB, Investigators, Clinical Research Staff
SUPERSEDES:	None	ISSUED BY:	CHS CIRB
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X	CFNI Munster, Indiana	X	Community Hospital Munster, Indiana	X	St. Catherine Hospital East Chicago, Indiana	X	St. Mary Medical Center Hobart, Indiana

POLICY STATEMENT/PURPOSE:

"Suspension or termination of IRB approval of research. An IRB shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action, and shall be reported promptly to the investigator, appropriate institutional officials, and the Department or Agency head." 45 CFR 46.113 (analogous to FDA regulation 21 CFR 56.113

To exercise this statutory authority, the CHS CIRB shall review all allegations of non-compliance or complaints regarding human subjects' regulations and review any study that has been associated with unexpected serious harm to research subjects.

The CHS CIRB will take appropriate action to insure the safety and welfare of human research subjects. These actions may range from corrective or educational measures for the researcher to terminating CHS CIRB approval for all active studies of a researcher.

The CHS CIRB Chair or Co-chair has the authority to suspend or terminate approval of any or all study activities before there is a convened meeting of the CHS CIRB if he/she determines that any delay would place participants at excessive risk. The chair must notify the CHS CIRB of his/her action at the next scheduled meeting.

The CHS CIRB will take appropriate action to insure that all inquires, investigations, and resolutions be conducted in a confidential manner.

This policy and procedure does not address allegations of research misconduct, e.g., fabrication, falsification, or plagiarism. Refer to Policy IRB 3: Scientific Misconduct in Research

DEFINITIONS:

Allegation: An assertion made by a second party that must be proven or supported with evidence to either confirm or deny. Allegations of non-compliance or study complaints may come to the attention of the CHS CIRB by:

- New submissions;
- Continuing review;
- Internal audits;
- FDA or OHRP inspections;
- Adverse event or safety reports;
- Sponsor Site Monitoring Reports;

- Reports from collaborators, employees, research subjects, family members, community members, and anonymous sources.

Institutional Officials: For the purposes of this policy/procedure, the institutional officials shall include the Signatory Official named on the FWA and the Chief Executive Officers of Community Hospital, St. Catherine Hospital and St. Mary Medical Center.

Investigator imposed suspension or termination: The determination by the investigator to suspend or terminate some or all activities of a research study. It is the responsibility of the investigator to notify the CHS CIRB and the sponsor. The CHS CIRB is not obligated to report this event to the appropriate federal agencies.

Non-Compliance: Failure to comply with relevant Federal, State, or local laws or regulations, the Good Clinical Practice Act, CHS CIRB policies and procedures, or determinations of the CHS CIRB.

Non-Compliance: Non-Serious and Non-Continuing: Isolated, unintentional deviations from the approved research protocol and unapproved changes to research practices that do not increase risk to subjects. This may include but are not limited to:

- Revising the advertisement used to recruit subjects without prior CHS CIRB approval;
- Failure to notify the CHS CIRB before an investigator is added to, or removed from, an ongoing study;
- Minor, non-substantive, changes in wording of a consent form.

Non-Compliance: Serious and/or Continuing: Practices that appear to: (1) Cause injury (physical, psychological, emotional, etc.) or any other unanticipated problems involving risks to subjects and/or others, or (2) constitute serious or repeated non-compliance with relevant Federal, State, or local regulations, the Good Clinical Practice Act, CHS CIRB policies and procedures, or determinations of the CHS CIRB. Repeated non-compliance that, in the opinion of the CHS CIRB, Chair, Co-Chair or designee, suggests the likelihood that non-compliance will continue without intervention. This may include, but is not limited to:

- Failure to obtain CHS CIRB approval for research involving human subjects;
- Inadequate or non-existent procedures for informed consent;
- Inadequate supervision in research involving drugs, devices or procedures;
- Failure to follow recommendations made by the CHS CIRB to insure the safety of subjects;
- Failure to report adverse events or proposed protocol changes to the CHS CIRB;
- Failure to provide ongoing progress reports or timely renewal of the protocol.;
- Repeated use of a Humanitarian Use Device for an unapproved indication without prior CHS CIRB approval.

Sponsor imposed suspension or termination: The determination by the sponsor to suspend or terminate some or all activities of a research study. It is the responsibility of the sponsor to notify the investigator, OHRP and FDA of any suspension or termination of a research study. It is the responsibility of the investigator to notify the CHS CIRB.

Study Complaint: Occurs when an individual expresses dissatisfaction with some aspect of the research. A minor complaint is one that does not involve non-compliance. Examples of study complaints may include but are not limited to;

- The reimbursement to research subjects is not delivered as scheduled.
- A potential subject feels he or she was excluded from a study inappropriately.
- A subject feels that the study is not being conducted in the manner that was described in the investigational consent.

Suspension: A determination made by the CHS CIRB Human Protections Administrator, Chair, Co-Chair, Institutional Officials, CHS CIRB, to temporarily cease some or all activities in a currently approved research study. Any determination to suspend research activities will immediately be reported to the investigator, appropriate institutional officials, the appropriate federal agencies and the CHS CIRB at its next regularly scheduled meeting.

Termination: A determination by the CHS CIRB to permanently withdraw approval for some or all activities of a currently approved research study. Any determination to terminate some or all research activities will immediately be reported to the investigator, appropriate institutional officials, the appropriate federal agencies and the CHS CIRB at its next regularly scheduled meeting.

Unexpected Serious Harm to Subjects or Others**:** Any event that:

- Is unforeseen;
- Caused harm or placed a person at increased risk of harm, and
- Is related to the research procedures.

Preliminary Determination of Suspension Not Merited or Suspension Merited

The allegation of non-compliance or the complaint is reviewed by the CHS CIRB office within two (2) working days of receipt of the allegation.

The CHS CIRB office will begin the documentation using the Non-Compliance/Complaint Investigation form.

The initial determination to suspend or not to suspend research activities will be based on preliminary review of available information, communication with the principal investigator(s) and associated clinical research staff.

The CHS CIRB office will discuss the allegations and the preliminary findings with the Chair and other institutional officials as is deemed necessary to render a determination to suspend or not to suspend the research activities at this point in the investigation.

If the determination is made that **suspension is not merited**, any further communications or actions will remain between the CHS CIRB office, the Chair and the investigator(s). Any further action will be based on the nature of the non-compliance/complaint. A Corrective Action Plan will be devised to assure that the non-compliance/complaint will not reoccur. This may include:

- Required training with respect to Human Subjects Research and the regulatory requirements for the conduct of such research;
- More frequent auditing of the study and/or research department;
- No further action required.

If the determination is made that **suspension is merited**, the CHS CIRB office in conjunction with the Chair, investigator(s) and others as deemed necessary will continue to investigate the allegation to determine if the situation merits a designation of serious or continuing non-compliance. The investigator(s) will be required to produce all records related to the study in question for auditing purposes.

- The CHS CIRB office will notify the appropriate institutional officials and regulatory agencies of the suspension and that an investigation is in progress.

Inquiry

The CHS CIRB office will continue the investigation within five (5) working days of the initial receipt of the allegation. The purpose of the inquiry is fact-finding, and may involve examination of study records and discussion with the research team, other personnel, research participants, witnesses, the complainant (if not anonymous), and others as deemed necessary.

The CHS CIRB office will document and compile the information and present the findings to the Chair and others as deemed necessary to render a determination of non-serious/non-continuing or serious/continuing.

Resolution of Investigation

If the determination is made that the allegation is **non-serious and non-continuing,** the CHS CIRB office, Chair, Co-Chair and others as deemed necessary, will devise a Corrective Action Plan to assure that the non-compliance/complaint will not reoccur. This may include:

- Required training with respect to Human Subjects Research and the regulatory requirements for the conduct of such research;
- More frequent auditing of the study and/or research department;
- Other actions as deemed appropriate.

If the determination is made that the allegation is **serious and/or continuing,** the Chair will:

- The Chair will readdress the possible need for suspension of study activities for the study in question, as well as for other studies conducted by the same investigator, pending further review by the CHS CIRB.
- The investigation summary will be placed on the agenda at the next scheduled meeting of the CHS CIRB.
- A written report summarizing the investigation findings will be sent to the investigator(s) involved in the noncompliance/complaint activities.
- The investigator(s) will be provided with an opportunity to discuss the investigation summary at the next scheduled meeting of the CHS CIRB.
- Prior to the next scheduled meeting, the CHS CIRB will review all of the documentation associated with the investigation. The board may then address the allegations to the investigator(s) at the next scheduled meeting.
- Once the CHS CIRB has completed its investigation, a vote will be taken to determine whether noncompliance of a serious and/or continuing nature has occurred. If non-compliance is found, the CHS CIRB will devise and vote on a Corrective Action Plan.

The Corrective Action Plan may include, but is not limited to:

- Suspension or termination of the investigator(s) research study(s);
- Required training with respect to Human Subjects Research and the regulatory requirements for the conduct of such research;
- Imposition of changes in such research study(s) to further protect human subjects;
- Imposition of restrictions as a condition for the continuation of research by the investigator(s);
- Segregation of data collected during the period of non-compliance/complaint;
- Disallowance of the publication of data collected during the period of non-compliance/complaint;
- Oversight monitoring by the Human Protections Administrator and/or office of Corporate Compliance;
- Any other action deemed appropriate by the CHS CIRB.

The investigator(s) will be notified in writing of the CHS CIRB determination and the Corrective Action Plan within five (5) working days of the convened meeting.

The investigator(s) will respond to the CHS CIRB in writing to the determination and Corrective Action Plan regarding the actions that he/she intends to implement in response to the Corrective Action Plan within ten (10) working days of receipt.

Note: Failure to respond within the prescribed time frame may result in the automatic suspension of all research activities with which the investigator(s) is associated.

Appeals Process

The purpose of an appeal is to give the researcher an opportunity to request reconsideration of the CHS CIRB determination under limited circumstances. Grounds for appeal are limited to:

- New information not reasonably available during the investigation;
- Request for extended time period to respond to Corrective Action Plan;
- Sanction exceeds the severity of the violations.

No other grounds will be considered.

The investigator(s) shall have the right, within thirty (30) days after his/her receipt of the CHS CIRB determination and Corrective Action Plan, to request a reconsideration of the decision as to either the finding of non-compliance or the corrective actions imposed.

The appeal will be forwarded to the Chair. The Chair may or may not reconsider the decision of the CHS CIRB. The Chair, at their discretion, may have further discussion with the investigator(s), institutional officials, and/or the CHS CIRB.

The decision of the Chair shall be final in all respects and the investigator(s) shall have no further right of consideration or appeal.

Dissemination of Findings

Copies of the documentation associated with the inquiry, investigation or subsequent appeals will be filed in the Quality Section of the study binder and in the CHS CIRB office.

The CHS CIRB office will log the information into the Non-Compliance Data Base.

The CHS CIRB office will notify in writing the appropriate institutional officials and regulatory agencies throughout the entire investigation of the following:

- Name of institution conducting the research;
- Title of the research project and/or grant proposal in which the non-compliance, suspension or termination occurred;
- Name of the principal investigator on the protocol;
- Number of the research project assigned by the CHS CIRB
- Number of any applicable federal award(s) (grant, contract, or cooperative agreement);
- A detailed description of the incident that resulted in the non-compliance, suspension or termination;
- Actions the CHS CIRB is taking or plans to take to address the non-compliance (e.g., educate the investigator(s) and/or staff, conduct random audits of the investigator(s)' conduct random audits of the investigator(s), suspend enrollment, and inform enrolled subjects.

CROSS REFERENCE(S):
Policy: Scientific Misconduct in Research IRB 3
Non-Compliance/Complaint Investigation Form

REFERENCE(S):
45 CFR 46.113
21 CFR 56.113
21 CFR 56.108(b)
OHRP Compliance Oversight Activities: Significant Findings and Concerns of Noncompliance 10/12/2005
OHRP's Compliance Oversight Procedures for Evaluating Institutions 10/19/2005

Office for Human Research Protections
Division of Compliance Oversight
1101 Wootton Parkway
Suite 200
Rockville, MD 20852
1-866-447-4777

Food and Drug Administration
For Drug Products
Division of Scientific Investigations (HFD-45)
Ofice of Compliance
Center for Drug Evaluation and Research
7520 Standish Place
Rockville, MD 20855
1-301-594-0020
Fax: 1-301-594-1204

For Biologic Products:
Bioresearch Monitoring Branch (HFM-664)
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research
1401 Rockville Pike, Room 400S
Rockville, MD 20852-6347
1-301-827-6347
Fax: 1-301-827-6748

For Medical Devices:
Division of Bioresearch Monitoring (HFZ-310)
Office of Compliance
Center for Device and Radiological Health (CDRH)
2094 Gaither Road
Rockville, MD 20850
1-240-276-0125
Fax: 1-240-276-0128

ACCEPTED BY:

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DATE(S) REVISED: 6/2010, 11/2017

REVIEWED BY: CHS CIRB 1/10/2007, 6/2010, 7/2013, 6/14/2016, 2/11/2020

Date	Initials
6/28/2010	JL
3/2013	JL
5/2016	JL
11/2017	JL
2/2020	JL