TITLE: Quality Assurance Activities: Audits and Monitors		POLICY/PROCEDURE NUMBER: IRB 1.5	
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Supersedes:		Issued By:	CHS CIRB
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Page 1 of 3			

	CFNI		Community Hospital		St. Catherine Hospital		St. Mary Medical Center
X	Munster, Indiana	X	Munster, Indiana	X	East Chicago, Indiana	X	Hobart, Indiana

POLICY/PROCEDURE STATEMENT/PURPOSE:

To ensure compliance with the federal regulations and CHS CIRB policies and procedures for the protection of human subjects; the CHS CIRB may conduct routine, targeted or random audits of all active CHS CIRB approved research protocols.

The CHS CIRB will notify the Investigator prior to conducting any Site Visits for monitoring purposes.

Internal Monitoring

1. The CHS CIRB, can at its discretion, convene an internal review committee or consult with outside agencies to review its human protections program. This review may include auditing files, attending CHS CIRB meetings, interviewing staff or CHS CIRB members and contacting investigators or members of the research teams.
2. The CHS CIRB office will conduct ongoing quality monitors to verify CHS CIRB policies and procedures with written guidance, new regulations governing human subjects research and the compliance activities of the federal oversight agencies.
3. The CHS CIRB office will intermittently conduct quality monitors to ensure the efficient operation of the department.

Random Audits

1. Random audits of CHS CIRB research activities may be conducted and involve some or all of the following:
    a. Examining investigator research records.
    b. Contacting research subjects.
    c. Requiring a third person, not directly affiliated with the project, to observe the informed consent process or research procedures.
    d. Verifying from sources other than the investigators that no changes in the project have occurred (i.e., research personnel, study coordinators, etc.).
    e. Other monitoring or auditing activities deemed appropriate by the CHS CIRB.

Targeted Audits

1. The CHS CIRB may conduct targeted audits if the CHS CIRB has reason to believe that a research activity is not being carried out as approved. Auditing activities may include some or all of the actions outlined above. Targeted audits may, for example, be initiated by:
    a. Complex projects involving unusual levels of types of risk to subjects.
    b. Receipt of a complaint by a subject or sponsor.

c. Failure to follow federal regulations or CHS CIRB policies/procedures.
d. Projects conducted by investigators who previously have failed to comply with the requirement of the federal regulations or the requirements or determinations of the CHS CIRB
e. Projects where concern about possible material changes occurring without CHS CIRB approval have been raised based upon information provided in continuing review reports or from other sources.
f. Reports of a serious or fatal adverse event or multiple reports of protocol deviations.

Safety Monitoring

1. The CHS CIRB may request additional safety monitoring or reporting for certain high risk studies beyond what is proposed by the investigator or the sponsor. Upon initial and/or continuing review, the CHS CIRB will notify the investigator of any additional safety monitoring or reporting requirements.
2. The Investigator will submit a copy of the final report of all site audit visits by the sponsor of the study to the CHS CIRB for review.
3. The Investigator will submit a copy of the Data Safety Monitoring Board's findings and recommendations for each active study to the CHS CIRB for review.

Reporting of Audits

1. Findings that adversely affect the risks or benefits of the research or continuing non-compliance with the federal regulations or institutional policies and procedures will be reported immediately to the Chair of the CHS CIRB and the Institutional Official. These may include but are not limited to:
   a. Incomplete documentation.
   b. Compromised security of the patient record, storage or accountability records of the investigational devices or drugs.
   c. Not using the most recent CHS CIRB approved Informed Consent.
2. Actions taken as a result of this review may include, but are not limited to:
   a. Submission of progress reports more frequently than initially specified.
   b. Suspension or termination of the project.
   c. Documentation placed in the Investigator's credentialing file in the Medical Staff Office.
   d. Other action deemed appropriate by the co-Chairs and the Institutional Official.
3. The Co-Chairs will decide if the findings of the audit should be presented to the full CHS CIRB.
4. Investigations of those audits that uncover allegations of Scientific Misconduct will be conducted according to the policy "Scientific Misconduct in Research".

Investigator Responsibilities:
1. Implement processes to improve areas of non-compliance identified in the site audit report, i.e., staff education, improvements to internal processes.
2. Respond in writing to the CHS CIRB regarding any actions taken to improve non-compliance issues.

Department Responsibilities:
1. Complete site audit and monitor to submit to the CHS CIRB.
2. Complete and send to the investigator all findings and recommendations from the CHS CIRB.
3. Assist the investigator in responding to the findings and provide recommendations if necessary.

CROSS REFERENCE:
Policy IRB 3: Scientific Misconduct in Research
Policy IRB 21: Non-Compliance/Complaint: Investigating Allegations and Reporting
Non-Compliance/Complaint: Investigating Allegations and Reporting Form

ACCEPTED BY:

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DATE REVISED: 6/2009, 3/2013, 11/2017

REVIEWED BY: CHS CIRB 8/9/05, 6/2009, 11/2017, 2/11/2020, 2/14/2023

Date	Initials
6/2009	JL
3/2013	JL
2/2016	JL
11/2017	JL
2/2020	JL
2/2023	KW