TITLE: Education and Training of CHS CIRB Members, Investigators and Clinical Research Staff		POLICY/PROCEDURE NUMBER: IRB 18	
AUTHOR:	Jana L. Lacera, RN, MSA, CDM	APPLICABLE TO:	CHS CIRB, Investigators and Clinical Research Staff
SUPERSEDES:		ISSUED BY:	CHS CIRB
DATE ORIGINATED:	10/17/05	DATE EFFECTIVE:	7/2021
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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:
The Code of Federal Regulations, 45 CFR § 46.107 (a), requires that "In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and the practice. The IRB shall therefore include persons knowledgeable in these areas." This same statement is made in, 21 CFR § 56.107 (a).

The Code of Federal Regulations, 21 CFR § 312.53(a), requires that investigators be "qualified by training and experience as appropriate experts to investigate the drug (or device)". The International Conference on Harmonization Good Clinical Practices, (IHC GCP) guideline adds that the investigator "should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial and should meet all qualifications specified by the applicable regulatory requirements."

The Code of Federal Regulation, 42 § 50, Subpart F, requires that investigators receive education and training relating to the policies that govern the disclosure and reporting of financial conflicts of interest. The regulations are applicable to each institution that applies for or receives Public Health Service (PHS) funding by means of a grant or cooperative agreements. The CHS CIRB will hold its members, investigators and senior/key personnel to the same standards of disclosure and reporting.

The CHS CIRB, therefore, will expect that certain minimum educational requirements be met by its members, alternate members, investigators and their clinical research staff to ensure the adequate protection of human subjects. Educational activities supported by the Community Healthcare System include both **required** training, which must be completed by all CHS CIRB members and alternates, investigators and their clinical research staff, and a variety of **ongoing** activities that compliment the required training.

Documentation of credentials and training for the CHS CIRB members will be maintained in the office of the Director of the CHS CIRB. Documentation of credentials and training for the investigators and clinical research staff will be maintained in their respective research departments.

Orientation of members and alternate members – **Required**
Each new member of the CHS CIRB will be provided with orientation and training. The member will also be required to submit a current Curriculum Vitae or Resume. The training module will include but is not limited to:

1. Letter of Introduction and Instructions
2. Proof of equivalent training from:
    - The Collaborative Institutional Training Initiative (CITI);
    - Good Clinical Practice NIDA – Clinical Trials Network Education; and/or
    - Good Clinical Practice - Investigator Version – TransCelerate

- NOTE: All training must have been completed within one year from the date on the Affirmation Statement.

3. Orientation Affirmation Statement
4. Financial Conflict of Interest Disclosure Statement
5. Confidentiality Statement for CHS CIRB Members
6. The Belmont Report
7. The Declaration of Helsinki
8. The Institutional Review Board Guidebook, Chapter III from the OHRP
9. ICH Topic E (R1) Guideline for Good Clinical Practice; 1. Glossary, 2. The Principles of OCH GCP and 3. Institutional Review Board/Independent Ethics Committee (IRB/IEC)
10. CHS CIRB Fact Sheet: Using a Systematic Approach to Reviewing Research Application Material
11. Institutional Policies:
    - IRB 1: Purpose, Structure and Responsibilities of the Community Healthcare System Central Institutional Review Board
    - IRB 2: Conflict of Interest
    - IRB 3: Scientific Misconduct in Research
    - IRB 17: Education and Training of CHS CIRB Members, Investigators and Clinical Research Staff
    - IRB 21: Non-Compliance/Complaint: Investigating Allegations and Reporting
    - HIP 1.06: Confidentiality

<u>Continuing education of members and alternate members</u>
Continuing education will be provided to include but not limited to:

1. Newsletters
2. Material provided at CHS CIRB meetings including new or updated policies, current information on the protection of human subjects, etc.
3. A lending library of books, videos, etc., on various topics related to human subjects protection
4. Access to the libraries within the System

<u>Orientation of Investigators and Clinical Research Staff – **Required**</u>
All investigators and their clinical research staff that are involved with human subject research must complete the minimum institutional requirements for education in human subject protection prior to participating in the conduct of research. This will include the Principal Investigator as well as the co-investigators and clinical research staff listed on the Protocol Submission Form. The education module distributed by the research department may include but is not limited to:

1. Letter of Introduction and Instructions
2. Orientation Affirmation Statement
3. Proof of training from:
    - The Collaborative Institutional Training Initiative (CITI);
    - Good Clinical Practice NIDA – Clinical Trials Network Education; and/or
    - Good Clinical Practice - Investigator Version – TransCelerate
    - NOTE: All training must have been completed within one year from the date on the Affirmation Statement
4. Financial Conflict of Interest Disclosure Statement
5. Confidentially Statement for Investigators/Clinical Research Staff
6. Humanitarian Use Device education if the research department participates in HUD studies
7. Any additional credentialing or education as mandated in Policy: MS 10.14: Credentialing for Investigational Procedures

<u>Continuing education of Investigators</u>
Continuing education will be provided to include but not limited to:

1. Newsletters
2. Material provided by mail including new or updated policies, current information on the protection of human subjects, etc.
3. A lending library of books, videos, etc., on various topics related to human subjects protection
4. Access to the e-libraries within the System

CROSS REFERENCE(S):
Policy: IRB 1, Purpose, Structure, and Responsibilities of the Community Hospital Central Institutional Review Board
Policy: IRB 2, Conflict of Interest
Policy: IRB 3 Scientific Misconduct in Research
Policy: IRB 7, Submission of a Research Study for Initial Review
Policy: IRB 4: Non-Compliance/Complaint: Investigating Allegations and Reporting
Policy: IRB 18: Education and Training of CHS CIRB Members, Investigators and Clinical Research Staff
Policy: IRB 5: Principal Investigator Responsibilities
Policy: HIP 1.06: Confidentiality
Policy: MS 10.14: Credentialing for Investigational Procedures

REFERENCE(S):
The Code of Federal Regulations, 45 CFR § 46, 21 CFR § 56.107 (a).
The International Conference on Harmonization Good Clinical Practices

ACCEPTED BY:

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DATE(S) REVISED: 6/2009, 8/2012, 4/2013, 7/2017, 11/2019, 6/9/2021

REVIEWED BY: Initial review and approval by CHS CIRB on 5/10/2006, 6/9/2009, 9/2012, 4/2016, 8/2017, 10/2019, 7/2021

Clinical Research: 10/2019

Date	Initials
6/2009	JL
8/2012	JL
4/2013	JL
3/2016	JL
7/2017	JL
9/2019	JL
6/2021	JL