TITLE: Institutional Official		POLICY/PROCEDURE NUMBER: IRB 1.1	
AUTHOR:	Jana L. Lacera, RN, MSA, CDM	APPLICABLE TO:	CHS CIRB
SUPERSEDES:	None	ISSUED BY:	CHS CIRB
DATE ORIGINATED:	8/2010	DATE EFFECTIVE:	2/2023
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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:

Each institution engaged in human subject's research conducted or supported by one of the federal departments or agencies that have adopted the Common Rule must designate an institutional official (IO) to execute the assurance of compliance. The IO is delegated the legal authority to represent the Community Healthcare System Central Institutional Review Board (CHS CIRB) and all components listed on the Federalwide Assurance (FWA). It is the responsibility of this official to ensure that the institution develops, implements, and maintains an effective Human Research Protections Program (HRPP) that complies with the requirements of the Common Rule, Title 45 Code of Federal Regulations, Part 46.

The IO will be appointed by the President and CEO and will be approved by the Community Foundation of Northwest Indiana (CFNI)

SCOPE:

At a minimum, specific responsibilities of the IO include:

1. Ensuring the development and implementation of policies and procedures governing all of the institution's research projects involving human subjects, research investigators, and research personnel who conduct such research and IRBs;
2. Designating one or more IRBs to be responsible for oversight of the institution's human research;
3. Ensuring that the institution's IRBs are provided with sufficient meeting space;
4. Ensuring that the institution's IRBs receive sufficient resources, including technology and staff, to support their substantial review and record keeping responsibilities;
5. Ensuring that institutional programs function in accordance with all federal, state, and local laws and regulations that govern human subjects protection in the conduct of research;
6. Ensuring the implementation of appropriate procedures for notifying institutional officials and researchers with oversight responsibility about 1) any unanticipated problems involving risks to subjects or others; 2) any serious or continuing noncompliance with the requirements of the Common Rule or the requirements or determinations of the IRB; and 3) any suspension or termination of IRB approval; and
7. In coordination with appropriate institutional officials with oversight responsibility, ensuring prompt notification of FDA, any sponsoring federal department or agency, and the assurance granting office (e.g., OHRP) of such incidents in accordance with federal regulations.

Additional responsibilities may include:

1. Establishing effective lines of communication with the institution's highest officials and its governing body to ensure an understanding of their legal and ethical responsibilities for protecting human research subjects;
2. Promoting an institutional culture that values human subjects protection as a primary ethical value and personal responsibility;
3. Fostering understanding of, and compliance with, human subjects protection requirements throughout the institution;
4. Ensuring the establishment of initial and continuing education requirements relative to human subjects protection issues for research investigators, study coordinators, research staff, IRB members and IRB staff;
5. Ensuring the provision of resources sufficient to maintain effective initial and continuing education programs relative to human subjects protection issues;
6. Ensuring that open channels of communication linking the institutions IRB(s), IRB staff, research investigators, study coordinators, research staff, administrative staff, and any other relevant parties are maintained;
7. Monitoring the operation and administration of the institutional Human Research Protection Program (HRPP) including the institution's IRBs;
8. Arranging for internal and/or external, periodic, independent assessments or audits of the institution's HRPP in terms of regulatory compliance and overall effectiveness;
9. Providing the individual institution's board of directors (MRF) and the system's board of directors (CFNI) with periodic reports that summarize the activities of the institution's HRPP; and
10. Serving as a knowledgeable point of contact for federal regulatory agencies or assigning another individual to serve in his/her capacity.

REFERENCE(S):
45 CFR 46.103
21 CFR 56.108 (b)

ACCEPTED BY:

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DATE(S) REVISED:

REVIEWED BY: CHS CIRB: 8/2010, 1/2014, 1/2017, 2/11/2020, 2/14/2023
CFNI Board of Directors: 8/2010

Date	Initials
1/2014	JL
1/2017	JL
2/2020	JL
2/2023	KW