TITLE: Human Protections Administrator		POLICY/PROCEDURE NUMBER: IRB 1.2	
Author:	Jana L. Lacera, RN, MSA, CDM	Applicable To:	CHS CIRB
Supersedes:		Issued By:	CHS CIRB
Date Originated:	2/25/05	Date Effective:	2/2023
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	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:

The Human Protections Administrator (HPA) is the administrative coordinator of the Community Healthcare System Central Institutional Review Board (CHS CIRB) review process, serves as the Office of Human Research Protection's (OHRP) primary contact for issues related to CHS CIRB review, and communicates CHS CIRB policies and procedures to Board members, investigators and their staff. The HPA is responsible for ensuring that administrative policies and procedures related to the ethical review of human subject's research in the Community Healthcare System are consistently carried out. Additionally, the HPA assures compliance with Federal regulations and state laws.

The HPA is directly responsible for:

1. Managing policies and procedures of the CHS CIRB and monitoring its performance.
2. Complying with all applicable provisions of the CHS CIRB Federal Wide Assurance.
3. Serving as a knowledgeable point of contact for OHRP.
4. Serving as a member of the CHS CIRB.
5. Ensuring system-wide communication and guidance on human subject's protection.
6. Possessing knowledge about the requirements of Federal regulation, applicable state and local laws, the CHS CIRB Federal Wide Assurance, and CHS CIRB policies and procedures for the protection of human subjects.
7. Educating CHS CIRB members, investigators and their staff on behalf of CHS CIRB on issues related to human subjects protection.
8. Acting as a resource to the system research committees regarding Federal regulation, applicable state and local laws and the CHS CIRB policies and procedures for the protection of human subjects

The HPA has oversight responsibility for:

1. Coordinating full committee CHS CIRB meetings and ensuring that a quorum is present, including one non-scientist.
2. Ensuring that CHS CIRB records and correspondence are maintained appropriately and are available upon request to authorized Federal officials.
3. Ensuring that changes in approved research, during a period in which approval has been granted, are not initiated without prior CHS CIRB approval
4. Auditing research sites that are conducting CHS CIRB approved protocols and taking corrective action to assure compliance with CHS CIRB policies and procedures, Federal regulations, and applicable state and local laws.
5. Ensuring the prompt reporting to CHS CIRB and appropriate agencies of any breaches of protocol or Federal regulations, or unanticipated injuries or problems involving risks to the research subjects.

6. Maintaining copies of all research proposals reviewed, scientific evaluation, approved sample consent documents, progress reports submitted by investigators, reports of injuries to subjects, records of continuing review activities, correspondence between the CHS CIRB and investigators.
7. Maintaining file copies of all CHS CIRB meeting minutes and correspondence.

The HPA is responsible to:

1. Completing the training modules for the HPA on the OHRP website.
2. Maintaining a membership in a related professional organization, i.e., PRIM&R
3. Completing ongoing education regarding current trends or changes in regulations that govern human research subject's protections.
4. Maintaining a file documenting the completion of these requirements.

ACCEPTED BY:

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Nancy Moser
Vice President, Corporate Compliance & Risk Management

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Andrej Zajac, M.D.
Chair, CHS CIRB

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Kristin M. Wadkins BSN, RN
Manager, IRB/Regulatory Compliance
Human Protections Administrator, CHS CIRB

Reviewed and Approved by CHS CIRB: 6/7/05, 6/2009, 4/2013, 1/2016, 11/2017, 2/11/2020, 2/2023

DATE REVISED:

REVIEWED BY:

Date	Initials
6/2009	JL
3/2013	JL
1/2016	JL
11/2017	JL
2/2020	JL
2/2023	KW