

TITLE: Physician and Non-Physician Investigator Initiated Research/Projects		POLICY/PROCEDURE NUMBER: IRB 9	
AUTHOR:	Jana L. Lacera, RN, MSA, CDM	APPLICABLE TO:	All Investigators
SUPERSEDES:	None	ISSUED BY:	CHS CIRB
DATE ORIGINATED:	July 6, 2011	DATE EFFECTIVE:	5/2023
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- CFNI Munster, Indiana     
 Community Hospital Munster, Indiana     
 St. Catherine Hospital East Chicago, Indiana     
 St. Mary Medical Center Hobart, Indiana

**POLICY STATEMENT/PURPOSE:**

To provide a process for the facilities within the Community Healthcare System to review and approve or disapprove of research/projects proposed Physician Investigators (PI), and Non-Physician Investigators (NPI).

All research/projects proposed by Investigators; i.e., QA/QI medical records review, Doctoral dissertations; Master’s theses, student projects, internally initiated research/projects, etc, must undergo this review process.

The System recognizes that some research/projects involve activities that in a different context might meet the definition of human subjects research. As a rule, when those activities are conducted solely to fulfill a course requirement, an element of the definition of research (the intent to develop or contribute to generalizable knowledge) is usually absent, and therefore the activity is not human subjects research. However, it is also the case that some research/projects place the individuals conducting the research/projects and their “subjects” at risk. When these activities do not require Community Healthcare System Central Institutional Review Board (CHS CIRB) oversight, the individual departments are responsible for overseeing the activities and for ensuring that the Investigator is adequately trained and that their planned research/project activities are designed with appropriate and adequate safeguards in place in order to ensure that the activities are conducted ethically.

Research that has been approved by the CHS CIRB may be subject to further appropriate review and approval or disapproval by officials of the institution, but those officials may not approve the research if it has not been approved by the CHS CIRB.

**DEFINITIONS:**

**Affiliation Agreement:** The agreement entered into by the Community Healthcare System facility and the school that the NPI attends. The agreement must be reviewed by legal counsel and signed by the Chief Nursing Officer (CNO) or the Vice President (VP) of the Division where the proposed research/project will be conducted. The original, signed Agreement will be maintained as per the entities internal policies.

Failure to comply with the terms of the Agreement by the entity entering into the Agreement or the NPI will nullify all approvals to conduct research and/or a project.

**Community Healthcare System Central Institutional Review Board:** An independent body that reviews research and consent forms to determine if the rights and welfare of subjects are protected. The composition of the IRB must conform to the Code of Federal Regulations at 45 CFR § 46.107 and 21 CFR § 56.107.

Responsibilities of the CHS CIRB include:

- Reviews complete research/project proposal;
- Determines if the research/project proposal is human subjects research;

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- Determines if the research/project is QA/QI, Exempt, Expedited or requires full board review; and
- Determines if the research/project requires further CHS CIRB oversight.

**Employee investigator:** An employee of the Community Healthcare System whose intent is to conduct research/project within the system. This employee is now functioning as an Investigator and not as an employee. Therefore, they will not have the same access to medical records, the patients, etc., as they would as an employee. The employed Investigator must undergo the same approval process as the non-employee Investigator with the exception of; 1) attend an orientation by Human Resources and 2) sign another CFNI Confidentiality Statement.

**Mentor:** An appropriately credentialed employee of the CHS who is assigned to the Investigator for the duration of the research/project. Responsibilities of the Mentor include:

- Guides the Investigator through the approval process;
- Assists with the orientation of the Investigator regarding administrative policies, standards' and practices of the facility;
- Directs the Non-Employee Investigator to Human Resources;
- Monitors the Investigator during the course of the research/project;
- Facilitates communication regarding the progress of the Investigator to the department manager and the school (if applicable);
- Alerts the school (if applicable) if the Investigator is seen to pose an immediate threat to the health and welfare of its patients, staff members, visitors, or operations. The Mentor will immediately remove the Investigator from the department pending further investigation.
- Obtains access to EPIC if necessary.

**Non-Physician Investigator:** any person (who is not a physician) whose intent is to conduct a research/project within the Community Healthcare System.

**Physician Investigator:** any physician employed by the Community Healthcare System whose intent is to conduct a research/project within the Community Healthcare System.

**Non-employee, non-physician investigator:** an investigator whose intent is to conduct a Project within the Community Healthcare System and is not an employee of the System. The investigator may not conduct a research study with the System unless affiliated with a school and is given prior authorization from the administration of the department where the research/project will be conducted.

**PROCEDURE FOR AN NPI:**

1. The research/project may be denied at any point during the review process.
2. The NPI will obtain a Documentation of Approval Form; Addendum A. It is the responsibility of the NPI to obtain the necessary signatures as they move through the approval process. The signature of the Immediate Supervisor will indicate their approval and ability to provide support for the research/project.

EXCEPTION: The PGY-1 Pharmacy Residents will not need to complete an Approval Form.

3. The NPI will submit the research/project proposal to the Immediate Supervisor where the research/project will be conducted. The Immediate Supervisor, in consultation with the Department Director, will determine if the Division/Department is able to provide the necessary resources to support the research/project.
  - The Education Department can verify if there is a valid Affiliation Agreement with the facility.
4. The Immediate Supervisor may assign a Mentor to the NPI.
5. The NPI will submit the research/project proposal to the Office of the Community Healthcare System Central IRB (CHS CIRB). Submission documents may be accessed on the Intranet → Departments → CFNI → CHS CIRB or on the Internet at [www.comhs.org](http://www.comhs.org)

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**NOTE:** The Documentation of Approval Form must accompany the CHS CIRB Submission Form. The NPI must complete the Education Module required by the CHS CIRB prior to submitting the proposal to the CHS CIRB office.

6. The CHS CIRB will notify the NPI within 5 business days in writing of their determination. Determinations will be classified as;
  - Not human subjects research. No further CHS CIRB review required;
  - Exempt Review; No further CHS CIRB review required;
  - Expedited Review; or
  - Requires full board review

**NOTE:** The CHS CIRB will request a Study Status Update for Not Human Subjects Research, Exempt and Expedited research to be able to track all projects conducted within the System. In addition, the CHS CIRB may, at its discretion, request periodic status reports. All research that is reviewed by the full board will adhere to the federal regulations regarding continuing review.

7. If the research/proposal has been approved, the Non-Employee NPI, will be directed to Human Resources:
  - Completes the process for non-employees who support and/or provide services within the facility
  - Receives a temporary identification badge
  - Receives computer or EPIC access, if appropriate

#### **PROCEDURE FOR A PHYSICIAN INVESTIGATOR**

1. The research/project may be denied at any point during the review process
2. The PI will submit the research/project proposal to the Office of the Community Healthcare System Central IRB (CHS CIRB). Submission documents may be accessed on the Intranet → Departments → CFNI → CHS CIRB or on the Internet at [www.comhs.org](http://www.comhs.org)
3. The CHS CIRB will notify the PI within 5 business days in writing of their determinations. Determinations will be classified as;
  - Not human subjects research. No further CHS CIRB review required;
  - Exempt Review; No further CHS CIRB review required;
  - Expedited Review; or
  - Requires Full Board Review

**NOTE:** The CHS CIRB will request a Study Status Update for Not Human Subjects Research, Exempt and Expedited research to be able to track all projects conducted within the System. In addition, the CHS CIRB may, at its discretion, request periodic status reports. All research that is reviewed by the full board will adhere to the federal regulations regarding continuing review.

#### **REFERENCE(S):**

Addendum A: Documentation of Approval (s)  
 Application for Non-Physician Investigator (NFI) Research/Projects Form  
 Clinical Research Policies and Procedures  
 Community Healthcare System Central IRB Policies and Procedures  
 Policy HR242: Non-Employees: Contractors, Students, Vendors, Volunteers

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ACCEPTED BY:

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Nancy Moser, BSN, JD  
Vice President, Corporate Compliance and Risk Management

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Andrej Zajac, M.D.  
Chair, CHS CIRB

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

DATE(S) REVISED: 11/2017, 7/ 2021, 4/2022, 5/2023

REVIEWED BY: CHS CIRB 2/13/2013, 1/2016, 3/2020, 8/2021, 5/2022, 5/2023

Date	Initials
1/2016	JL
11/2017	JL
3/2020	JL
7/2021	JL
4/2022	JL
5/2023	KW