Community Healthcare System CIRB
Short Form Application for Physician and Non-Physician Investigator (NPI) Research/Projects
(Form Date 4/2023)

DATE SUBMITTED: Click here to enter a date.	**IRB use only:** CHS CIRB Number: Date received:

Purpose: To determine if there is a requirement for CHS CIRB oversight of non-government funded or non-regulated studies involving little or no risk. Even if it is determined that the research/project does not require oversight, the research/project will be reviewed by the CHS CIRB office to assure that the research/project is compliant with the Privacy Rule pursuant to the Health Insurance Portability and Accountability Act (HIPAA).

NOTE: All questions must be answered in full. The response "see attached" will not be accepted and the forms returned for clarification.

NOTE: The Education Module Affirmation Statement along with required documentation must be completed and submitted with this application for all research/projects. The Documentation of Department Approval must be submitted for all Non-Physician Investigator initiated research/projects.

FDA regulated research cannot use this form to make application or request exemption from oversight.

Site (s) where research will be performed. Check all that apply:

☐ Community Hospital
☐ Saint Mary Medical Center
☐ Saint Catherine Hospital
☐ CSRC
☐ Other (specify)

Part A – Investigator/Coordinator Information

- Principal Investigator:
  - Employed by Community Healthcare System: ☐ Yes ☐ No
- Sub-Investigators and/or other study personnel (if applicable):
  - Employed by Community Healthcare System: ☐ Yes ☐ No

- Phone number of Principle Investigator:
- E-Mail address of Principle Investigator:

Part B – Protocol/Project Information

NOTE: All related documents will be collectively referred to as the "project".

Title of the Project:
Attach a copy of your proposal.

Version Date: Click here to enter a date.

What is the purpose of the project?
☐ Medical Records Review ☐ Retrospective ☐ Prospective
☐ QA/QI
☐ Doctoral Dissertation
☐ Required Student Project
☐ Internally Initiated Research/Project
☐ Case Study
☐ Other: List:

School Affiliation **(if applicable)**:
Advisor:
Phone Number:
Email Address:
Is there a valid Affiliation Agreement with the School? Yes ☐ No ☐

Name of the department (s) where the project take place?
☐ List (specify)

If applicable, what will be the responsibilities/duties of the department staff in relation to the project? Will their participation require any training? Provide an explanation:

Planned start date: Click here to enter a date.

Planned end date: Click here to enter a date.

Hypothesis or goal: What is the purpose of the project? Provide an explanation of the proposed objectives.

Subject Population: Provide a description of the proposed target population including any inclusion or exclusion criteria.

How will you gain access to the target population? (Referral, Medical Records search, direct contact in the department etc.) Provide an explanation of recruitment strategies.
Will the project require written informed consent? ☐Yes ☐No

If yes, provide an explanation of how the subject will consent to participate in the project. Attach a copy of the consent document.

If no, provide an explanation as to why consent is not being obtained. Is the PI requesting a Waiver of Consent or Waiver of Documentation of Consent?

Part C: Treatment of Data

Instructions: This section **MUST** be completed if you are requesting to access, use, and/or disclose Community Healthcare System patient personal health information (PHI).

List the names and titles of all individual(s) authorized by the investigator who will be responsible for querying medical records and/or database to obtain the protected health information:

Name/Title	Employed by CHS
	☐ Yes ☐ No
	☐ Yes ☐ No
	☐ Yes ☐ No

Who will use the collected PHI?

Name/Title	Employed by CHS
	☐ Yes ☐ No
	☐ Yes ☐ No

SECTION II: Review of the following protected health information (PHI)

Select the source(s) to be accessed to obtain the PHI:

☐	CHS Electronic Medical Record/EPIC
☐	CHS Picture Archiving & Communication System (PACS) for digitize radiologic images and reports

☐	Cancer Registry
☐	Computer/Database (electronic record)
☐	Hospital Administrative/Billing records
☐	Quality Improvement records
☐	Drug and alcohol treatment records
☐	Behavioral Health records
☐	Psychotherapy notes
☐	AIDS/HIV information
☒	Genetic information
☐	Data previously collected for research purposes
☐	Other: Click or tap here to enter text.

List the specific health information to be accessed and/or collected:

☐	Health history
☐	Diagnosis: Specify condition or Diagnosis code: Click or tap here to enter text.
☐	Laboratory test results
☐	Medications
☐	Radiographic images and/or results
☐	Surgical procedures
☐	Treatment outcomes
☐	Healthcare provider reports and notes
☐	Other: Describe: Click or tap here to enter text.

SECTION III: Privacy and Confidentiality

Researchers are reminded that subject identifiers and the means to link subject names and codes with research data should not be stored on unencrypted moveable media (e.g., laptops, compact discs, jump drives)

What steps have been taken to ensure that the PHI will not be reused or disclosed inappropriately to any other person or entity? Check all that apply.

☐	**Access limited** to only individuals who need to know the information in the performance of their job.
☐	**Electronic safeguards** where only study staff has access to electronic study information. Describe the electronic safeguards in place (e.g., password protection, data encryption, firewall, and automatic shutdown of unused screen, electronic system will not transmit data outside the covered entity.): Click or tap here to enter text.
☐	**Physical safeguards** where only study staff has access to areas with study information. Describe the physical safeguards in place (*e.g., locked cabinets, locked filing room, and security system*): Click or tap here to enter text.
☐	Other: Click or tap here to enter text.

Disclosure Tracking

A covered entity is any healthcare plan, provider, or service that transmits health care information in an electronic form (e.g., electronic medical record). Community Healthcare System is a covered entity. PHI disclosed outside of the covered entity for the purpose of research must be tracked as required by HIPAA regulations.

Will you be sharing PHI (health information plus one or more of the 18 HIPAA identifiers) with anyone outside of Community Healthcare System? ☐Yes ☐ No
If Yes, what health data will be shared, which identifier(s) will accompany the data, and who will receive it? Enter contact name and address for receiving entity.
If Yes, indicate your plan for compliance with Accounting of Disclosures Requirements (must check one): ☐ This study will enroll fewer than 50 subjects. The person or general role of the person responsible for entering each subject into the HIPAA Accounting Tracking Form is:

☐ This study will enroll 50 or more subjects. The Alternative Tracking form will be used. Send the completed form along with a copy of this Request form to the CHS CIRB office.

<u>SECTION VI:</u> REQUEST FOR WAIVER OR ALTERATION OF HIPAA AUTHORIZATION (complete ONLY when requesting a Waiver as part of a protocol submission application)

Subject permission cannot be waived to retain **<u>identifiable</u>** private information and **<u>identifiable</u>** biospecimens for future research purposes.

<u>TYPE OF WAIVER REQUESTED</u>

☐	**Full Waiver**	• Are requested for complete access, use, and creation of records containing PHI, but only as described in the IRB approved application/protocol; • Are limited to a specific study; • Cover the entire duration of the study; and • The investigator will not be obtaining subject Authorization.
☐	**Partial Waiver**	Partial Waivers occur when the IRB determines that a covered entity does not need Authorization for all PHI uses and disclosures. They are usually limited to use and disclosure by a researcher to review PHI in order to contact a prospective subject(s) with whom the researcher does not have a prior relationship or to conduct screening procedures. Choose Partial Waiver if you will be obtaining consent and a signed HIPAA Authorization from participants once they have been identified.
☐	**Alteration of Waiver**	A request that removes some, but not all, PHI or alters the requirements for an Authorizations. Situations requiring an alteration vary, but most often involve verbal Authorization and use of an information sheet.

IF REQUESTING A <u>FULL WAIVER:</u> Check all that apply:

☐	The protocol summary assures that only existing data/specimens will be used and that those data/specimens will be only those that were collected during a time period between two specified dated in the past. From date: Click or tap here to enter text. to date: Click or tap here to enter text.

☐	Sample size is so large that including only those samples/records/data for which a signed HIPAA Authorization can be obtained would prohibit conclusions to be drawn or bias the sample such that conclusions would be skewed.
☐	Patients are no longer being followed and/or are lost to follow-up.
☐	The study in question has already obtained subject authorization for storage of the data/specimens in a research database/repository and for their use in future research related to the area of research covered by the database/repository.
☐	Other:

IF REQUESTING <u>PARTIAL WAIVER:</u> Check all that apply:

☐	Requesting a Partial waiver to access and use information about the potential subjects' past and present health to determine eligibility.
☐	Requesting a Partial waiver for CHS researcher to access and use demographic and/or contact information to contact subjects to determine if they are willing to participate in this research study.
☐	Requesting a Partial waiver for any other use and/or disclosure for only part of the research project. **Explain:**

For the purposes of this waiver, explain why the identifiers that were selected above in **SECTION II** are needed to meet the research objectives. Check all that apply:

☐	The identifiers obtained under this waiver are needed to link patients with their EMR data (*e.g. medical record number*)
☐	The identifiers obtained under this waiver are needed to meet the research objectives in order to determine the correct patient population (inclusion/exclusion criteria) for this project (e.g., dates, such as date of diagnosis or date of procedure):
☐	The identifiers obtained under this waiver are needed to contact potential participants for this project (e.g., name and mailing address/email address for sending recruitment materials)
☐	The identifiers obtained under this waiver will be stored within: (describe means of storage): Click or tap here to enter text. to document and track unique patients. (e.g., name, date of birth, zip code, medical record number,

	dates of service, and brief medical history. This information will not be used for screening or contacting patients for future research without IRB approval.)
☐	Other: Click or tap here to enter text.

Plan to destroy identifiable information:

☐	All identifiers (or links between identifiers and data) collected under his waiver will be destroyed at the earliest opportunity consistent with the conduct of the research. **Identify the procedure** to be used to destroy the PHI collected under this waiver *(e.g., electronic paper, audio/video, photography, and other*) and **the approximate timing**: Click or tap here to enter text.
☐	Identifiers collected for this project **will not** be destroyed. Provide an explanation as to when you will destroy the subject identifiers. If lont-term retention of identifiable data is planned, provide a research or health justification for the long-term retention or explain the state or federal law that requires you to retain the identifiers: Click or tap here to enter text.
☐	Other: Click or tap here to enter text.

NOTE: If this is a **partial waiver** being used for recruitment purposes only, your answer(s) should only address a plan for the destruction of PHI collected prior to consent and for those potential subjects who do not enroll.

NOTE: If you will retain identifiers after the end of the required record retention applicable to your study, you must provide a health, research and/or regulatory/legal justification for retaining the identifiers.

SECTION VII: INVESTIGATOR ASSURANCE

By submitting this form, I assure that I agree to the following: (All must be checked)

☐	The research could not practicably be conducted without the waiver or alteration;
☐	The PHI for which use or disclosure is requested is the minimum necessary to conduct the research activities noted above;
☐	I will account for any disclosure of PHI to a non-CHS Workforce Member as part of this research activity;

☐	If, at any time, I want to reuse this information for other purposes or to disclose the information to additional individuals or entities, I will seek prior approval from the CHS CIIB; and
☐	I am aware of the legal, regulatory, and ethical requirements to protect human subjects, including protection of their personal privacy and the privacy of all information identifying and/or relating to them, and agree to comply with all such human subjects' protections.

_____

Signature of Investigator Print Name Date

Attachments:

- ☐ Documentation of Approval Form
- ☐ Documentation of CHS CIRB Education
- ☐ CV and Credentials for investigators and study personnel
- ☐ IRB Approval Letter (if applicable)
- ☐ Proposal
- ☐ Consent (if applicable)
- ☐ Data Collection Tool (s)
- ☐ Instructions, Surveys, questionnaires, assessment tools, etc.
- ☐ Patient/staff education material

Confidentiality Statement

I understand that I am obligated to refrain from any access to, use of or sharing of protected information that is not directly related to my responsibilities or research as an investigator within the Community Healthcare System. This includes, but is not limited to, the health, demographic or financial information of all patients and/or employed staff. Non-patient information that includes, but is not limited to, client and Hospital proprietary information are also privileged and confidential and therefore should not be accessed or divulged unnecessarily. Breach of this obligation is a violation of the Health Insurance Portability and Accountability Act (HIPAA) privacy regulations and can include civil and criminal penalties. I also understand that an intentional breach of this obligation will result in the termination of any further privileges to conduct research within the Community Healthcare System.

I understand that I will submit any changes or modifications to the research regarding the manner in which data is collected, analyzed or distributed to the Community Healthcare System Central Institutional Review Board for review and approval prior to implementation.

I have received a copy of the Community Foundation of Northwest Indiana policy on Confidentiality. I have been given the opportunity to ask questions and those questions have been answered to my satisfaction and understanding.

_____

Printed name (Principal Investigator)

_____ _____

Signature Date

_____ _____

Printed name (Sub-Investigator) Date

_____

Signature

For Office Use Only
CHS CIRB Review Determination

	Yes	No	Date	Comments
Not Human Subjects Research				
QA/QI				
CHS Engaged in Research				
Exempt				
Limited Review				
Expedited				
Full Board				
	Yes	**No**	**Date**	**Comments**
All required documentation received				
CITI training completed				
Approval Granted				
Investigator Notified				

Signature CHS CIRB Reviewer **Date**

FOR CHS CIRB OFFICE USE ONLY
CHS CIRB /HIPAA Privacy Board Determinations:

☐	The CHS CIRB, acting as the Privacy Board, has determined that the request for a waiver/alteration of waiver of HIPAA Authorization satisfies the criteria set forth at 45 CFR164.512(i)(2)(ii);
☐	The use or disclosure of the PHI involves no more than minimal risk to the privacy of individuals based on the presence of the following elements: a. An adequate plan to protect health information identifiers from improper use and disclosure: and b. An adequate plan to destroy identifiers at the earliest opportunity consistent with conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so); and; c. Adequate written assurances that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.
☐	The research could not practicably be conducted without the waiver or alteration; and
☐	The research could not practically be conducted without access to and use of the PHI.
☐	The PHI made available is the minimum necessary for the research.
☐	An IRB ☐ Full Waiver or ☐ Partial Waiver or ☐ Alteration **is granted** by ☐ Full IRB review or ☐ Expedited IRB Review
☐	A Waiver/Alteration of Waiver **is not granted** by the CHS CIRB.
☐	Suggested action: Click or tap here to enter text.

_____ _____

Signature of CHS CIRB Chair/Designee Date