Community Healthcare System Central IRB
Notice of Review Preparatory to Research
(Form date 3/2022)

Date Submitted: Click or tap here to enter text.	**IRB use only: Date Received** **IRB Number:**

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

This constitutes a **notice** to the CHS CIRB, not a request for the investigator to review PHI Preparatory to Research. Approval is not required, therefore a letter acknowledging the activity will be sent to the investigator.

SECTION I: Project Information

Title of Study or brief description of the Preparatory to Research activity: Click or tap here to enter text.

Investigator Name and Title: Click or tap here to enter text.

Investigator's email address: Click or tap here to enter text.

Contact Person Name and Title: Click or tap here to enter text.

Contact Person's email address Click or tap here to enter text.

Is the investigator employed (Workforce Member) by the Community Healthcare System (CHS)?
☐ Yes ☐ No
If "Yes", in what capacity? Click or tap here to enter text.

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

Indicate the purpose for the use/disclosure of PHI:

☐	Prepare protocol/grant
☐	Develop a research hypothesis
☐	Determine number of available potential subjects
☐	Screening/determining eligibility/recruitment of potential research subjects (includes creating a list of potential subjects and contacting patients to determine interest in participation) – can only be done once IRB approval of the study has been secured

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

Select the source(s) to be accessed:

☐	CHS Electronic Medical Record/EPIC
☐	CHS Picture Archiving & Communication System (PACS) for digitized 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:

☐	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.

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 No,** proceed to Section III.
If Yes, enter contact name and address for receiving entity. Click or tap here to enter text.
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 Notice of Review form to the CHS CIRB office.

SECTION III: INVESTIGATOR ASSURANCE

By submitting this form, I am representing and agreeing that: (All must be checked)

☐	The use or disclosure is requested solely to review PHI necessary to conduct Preparatory to Research as noted above;
☐	The PHI for which use or disclosure is requested is the minimum necessary for the Preparatory to Research as noted above;
☐	I may identify **(but not contact)** the names of potential research subjects;
☐	No PHI will be removed from CHS in the course of the review. If I am a CHS Workforce Member, I am allowed to view PHI via CHS standard remote access processes, but if I do so, I agree that I will not print, download, copy, save or retain the PHI including any temporary files stored on a device;
☐	If applicable, I will account for any disclosure of PHI to a non-CHS Workforce Member while that member is on site at a CHS Facility;
☐	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 CIRB;

☐	I am aware of the legal, regulatory, and ethical requirements to protect human subjects, including protection of their personal privacy and agree to comply with all such human subjects protections.

_____ _____

Signature of Person requesting review Print Name Date

FOR CHS CIRB OFFICE USE ONLY

CHS CIRB /HIPAA Privacy Board Determinations:

☐	The CHS CIRB has determined that the Preparatory to Research activities described above meet the criteria set forth at 45 CFR §164.512(i)(1)(ii).
☐	The CHS CIRB has determined that the Preparatory to Research activities described above **not meet** the criteria set forth at 45 CFR §164.512(i)(1)(ii).
	Suggested Action:

_____ _____

Signature of CHS CIRB Chair/Designee Date