

**Community Healthcare System Central IRB
Request for a De-Identified or Limited Data Set
(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).

SECTION I: Project Information

De-Identified Data Set

Limited Data Set

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
	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No

Who will use the collected PHI?

Name/Title	Employed by CHS
	<input type="checkbox"/> Yes <input type="checkbox"/> No

	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No

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

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

<input type="checkbox"/>	CHS Electronic Medical Record/EPIC
<input type="checkbox"/>	CHS Picture Archiving & Communication System (PACS) for digitize radiologic images and reports
<input type="checkbox"/>	Cancer Registry
<input type="checkbox"/>	Computer/Database (electronic record)
<input type="checkbox"/>	Hospital Administrative/Billing records
<input type="checkbox"/>	Quality Improvement records
<input type="checkbox"/>	Drug and alcohol treatment records
<input type="checkbox"/>	Behavioral Health records
<input type="checkbox"/>	Psychotherapy notes
<input type="checkbox"/>	AIDS/HIV information
<input type="checkbox"/>	Genetic information
<input type="checkbox"/>	Data previously collected for research purposes
<input type="checkbox"/>	Other: Click or tap here to enter text.

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

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

Select the specific HIPAA identifiers that will be accessed and/or collected:

<input type="checkbox"/>	Names
<input type="checkbox"/>	Street address
<input type="checkbox"/>	City or State *
<input type="checkbox"/>	Zip code *
<input type="checkbox"/>	Geocode *
<input type="checkbox"/>	Date of Birth *

<input type="checkbox"/>	Ages related to person 90 or older
<input type="checkbox"/>	Admission/Discharge date *
<input type="checkbox"/>	Date of Death *
<input type="checkbox"/>	Dates of Service *
<input type="checkbox"/>	Telephone numbers
<input type="checkbox"/>	Fax numbers
<input type="checkbox"/>	Electronic mail addresses
<input type="checkbox"/>	Social security numbers
<input type="checkbox"/>	Medical Record numbers
<input type="checkbox"/>	Health plan beneficiary numbers
<input type="checkbox"/>	Account numbers
<input type="checkbox"/>	Certificate/License numbers
<input type="checkbox"/>	Vehicle identifiers and serial numbers
<input type="checkbox"/>	Device identifiers and serial numbers
<input type="checkbox"/>	Web Universal Resource Locators (URLs)
<input type="checkbox"/>	Internet Protocol (IP) address numbers
<input type="checkbox"/>	Biometric identifiers (finger, voice prints)
<input type="checkbox"/>	Full face photographic images and any comparable images
<input type="checkbox"/>	Any other unique identifying number, characteristic, or code: Describe: Click or tap here to enter text.

If only identifiers with an asterisk (*) have been checked, the data being requested is a “limited data set”. If use or disclosure of a “limited data set” is being requested, a **Data Use Agreement will be required. Contact the CHS Contract Specialist to begin the process to obtain a DUA.**

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.

<input type="checkbox"/>	Access limited to only individuals who need to know the information in the performance of their job.
<input type="checkbox"/>	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.
<input type="checkbox"/>	Physical safeguards where only study staff has access to areas with study information. Describe the physical safeguards in place (e.g., <i>locked cabinets, locked filing room, and security system</i>): Click or tap here to enter text.

<input type="checkbox"/>	Other: Click or tap here to enter text.
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SECTION IV: INVESTIGATOR ASSURANCE

By submitting this form, I assure that:

<input type="checkbox"/>	The data set has been adequately de-identified as recognized by the HIPAA Privacy Rule. The Certificaiton of De-Identification accompanies this submission.
OR	
<input type="checkbox"/>	The data set has been converted into a limited data set and the Data Use Agreement accompanies this submission.
<input type="checkbox"/>	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 Person requesting review

Print Name

Date

FOR CHS CIRB OFFICE USE ONLY

CHS CIRB /HIPAA Privacy Board Determinations:

De-Identified Data Set

<input type="checkbox"/>	The data set has been adequately de-identified as recognized by the HIPAA Privacy Rule. The Certification of De-Identification has been received by the CHS CIRB. The data set may be used and disclosed for research.
<input type="checkbox"/>	The data set has not been adequately de-identified and may not be used or disclosed in its current form.
<input type="checkbox"/>	The Certification of De-Identificaiton has not been received by the CHS CIRB. The data set may not be used or disclosed until the CHS CIRB receives the certification.

Limited Data Set

<input type="checkbox"/>	The data set has been adequately converted to a limited data set as recognized by the HIPAA Privacy Rule. A signed Data Use Agreement has been received by the CHS CIRB. The data set may be used and disclosed for research.
<input type="checkbox"/>	The data set has not been adequately converted to a limited data and may not be used or disclosed in its current form.
<input type="checkbox"/>	The Data Use Agreement has not been received by the CHS CIRB. The data set may not be used or disclosed until the CHS CIRB receives the signed DUA.

Signature of CHS CIRB Chair/Designee

Date