

Geisinger

Review of Protected Health Information (PHI) Preparatory to Research 45 CFR 164.512

This form serves to notify the Geisinger Institutional Review Board (GIRB) of a researcher's intent to request review of protected health information (PHI) without subject consent/authorization to prepare a research study, **including conducting feasibility analyses**. This is referred to as "Preparatory to Research" by the HIPAA regulations. This includes researchers employed by the Covered Entities below:

- Geisinger Medical Center
- Geisinger Clinic
- Geisinger Wyoming Valley Medical Center and Geisinger South Wilkes-Barre, (hereinafter referred to as "Geisinger NorthEast")
- Geisinger Holy Spirit Hospital
- Geisinger Commonwealth School of Medicine

This allows use of PHI to design a research study or to assess the feasibility of conducting a study. In order to comply with the Privacy Rule/HIPAA, PHI may not be removed from the Covered Entities without prior review by the Geisinger Institutional Research Review Board (GIRB).

(Complete all Sections)

Researcher:	CRC/PM:
Department:	Phone:
Phone:	E-mail:
Fax:	
E-mail:	

1. Working Title of the Project:

2. Brief Description of the Project:

3. Purpose of the Data Pull:

4. **Description of records and PHI to be accessed by the study team or a data broker/custodian – Selection Criteria (e.g.; rheumatoid arthritis patients seen in the Rheumatology Clinic). Describe how potential subject population will be identified and what data sources will be used. Provide sufficient detail on how diagnoses or procedures or other inclusion/exclusion criteria are to be defined:**

5. **Dates of required records:**
 from _____ through _____ [cannot be any later than the date on which the form is signed by the Researcher].

6. **Approval Priority (please check one):**

- Urgent (1-2 days)
- Routine (3-5 days)

7. **Anticipated sources of information (check all that apply):**

- Paper medical records
- Electronic Health Record (EHR)
- Clinical Decision Intelligence System (CDIS)
- Departmental Database/Personally Maintained
- GHP Claims Data
- Other, please explain:

A. Request for de-identified or aggregated data only

- I am not receiving data with PHI directly. A Data Custodian will be accessing PHI on my behalf for research protocol development and/or feasibility.

B. Request for data with PHI

Data fields required - Elements of PHI to be received (check all that apply):

<input type="checkbox"/> Names	<input type="checkbox"/> Vehicle identifiers and serial numbers, including license plate numbers
<input type="checkbox"/> Geographic subdivisions smaller than a state	<input type="checkbox"/> Device identifiers and serial numbers
<input type="checkbox"/> Dates (except year)	<input type="checkbox"/> Web addresses – universal resource locators (“URLs”)
<input type="checkbox"/> Telephone numbers	<input type="checkbox"/> Internet protocol (“IP”) address numbers
<input type="checkbox"/> Fax numbers	<input type="checkbox"/> Biometric identifiers, including fingerprints and voice prints
<input type="checkbox"/> E-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"/> Full face photographic images and any comparable images <input type="checkbox"/> Other unique identifying number, characteristic, or code (except a re-identification code) – Explain: _____
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C. Attestation and Signature

I understand that the approval of this request is contingent upon my agreement that:

- 1) Receipt of data set is sought solely to prepare a research protocol or for similar purposes preparatory to research; and
- 2) No PHI will be removed from the Covered Entities; and
- 3) No PHI will be shared with individuals who are not employees of the Covered Entities; and
- 4) The data set may be utilized only for the purpose stated above.

I certify that I will use data set in compliance with the principles stated above.

Signature of Researcher

Date

Send the form to the IRB Office bkent@geisinger.edu

Date
Authorized Signer
