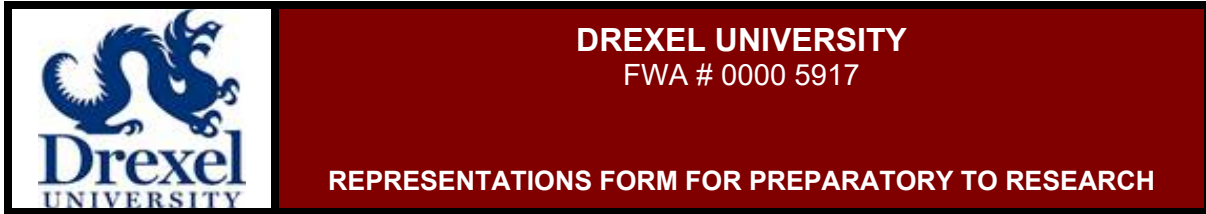


Project #:

Protocol #:



The Privacy Regulations issued under the Health Insurance Portability and Accountability Act (“HIPAA”) require researchers who intend to perform a review preparatory to research to make certain representations *before* using or disclosing protected health information (“PHI”) in such a review.

Applicability:

I acknowledge that the HIPAA Privacy Rule imposes restrictions on the use of protected health information (PHI) in activities preparatory to research, defined as:

- the development of research questions,
- the determination of study feasibility (in terms of the available number and eligibility of potential study participants),
- the development of eligibility (inclusion and exclusion) criteria, and
- the determination of eligibility for study participation of individual potential subjects.

I therefore agree that:

1. Under this certification, I am permitted to use PHI only for the purposes of preparing a research protocol for grant preparation or IRB review or for those preparatory to research activities listed above.
2. I will use only the PHI that is necessary to prepare a research protocol for grant preparation or IRB review or for those preparatory to research activities listed above.
3. I will not remove any PHI, abstracted in the course of my review of PHI, from covered entities of Drexel University or Paladin. The Paladin covered entities include the Hahnemann University Hospital and St. Christopher’s Hospital for Children. Furthermore, I will not disclose the abstracted PHI under any circumstances to anyone outside of the workforce of the Drexel University or Paladin medical record custodians during the preparatory to research phase. Abstraction staff will either be workforce of the medical record custodian (Drexel for Drexel records and Paladin for Paladin records) or retained as workforce by the custodian for the abstraction using a Business Associates Agreement (BAA).
4. The preparatory to research process will no longer permit recruitment and patient contact prior to IRB involvement. This change protects all participants from accidental contact and recruitment by non-clinical enterprise employed staff.

Please type all responses.
Handwritten responses will be returned to the applicant.

1. PROJECT DETAILS AND SIGNATURES		
1.1 Project Title		
<i>Project Title (The title must exactly match the grant title):</i>		<i>Sponsor:</i>
<input type="text"/>		<input type="text"/>
1.2 Principal Investigator		
<i>Principal Investigator Name:</i>		<i>Degree:</i>
<input type="text"/>		<input type="text"/>
<i>Phone Number:</i>	<i>Fax Number:</i>	<i>Pager or Cell Number:</i>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<i>Drexel email address:</i>		<i>Department:</i>
<input type="text"/>		<input type="text"/>
<i>College or School:</i>		
<input type="text"/>		
<i>Position:</i> <input type="checkbox"/> Faculty / <input type="checkbox"/> Staff / <input type="checkbox"/> Investigator / <input type="checkbox"/> Other (describe below):		
<input type="text"/>		
List Names of all other research staff who will access PHI		
<i>Name:</i>		<i>Position title:</i>
<input type="text"/>		<input type="text"/>
<i>Name:</i>		<i>Degree:</i>
<input type="text"/>		<input type="text"/>
<i>Name:</i>		<i>Degree:</i>
<input type="text"/>		<input type="text"/>
<i>Name:</i>		<i>Degree:</i>
<input type="text"/>		<input type="text"/>

COMPLETE ALL SECTIONS THAT APPLY TO YOUR REQUEST

I. Records located within or owned by <u>Drexel University</u> (Fill out details below as to records located/housed by Drexel)		
<i>Date of Records From:</i> <input type="text"/>	<i>Date of Records To:</i> <input type="text"/>	<i>Number of Records to be Reviewed:</i> <input type="text"/>
<i>Types of PHI you wish to review (Provide below or on a separate page a description of the PHI you will review from the medical records):</i> <input type="text"/>		
<i>Sources of PHI (Identify the sources of PHI. e.g., medication lists, history and physical, etc.):</i> <input type="text"/>		
<i>Source of Electronic Records (Identify any PHI to be received electronically):</i> <input type="text"/>		

II. Records located within or owned by <u>Hahnemann University Hospital:</u> (Fill out details below as to records located/housed by HUH)		
<i>Date of Records From:</i> <input type="text"/>	<i>Date of Records To:</i> <input type="text"/>	<i>Number of Records to be Reviewed:</i> <input type="text"/>
<i>Types of PHI you wish to review (Provide below or on a separate page a description of the PHI you will review from the medical records):</i> <input type="text"/>		
<i>Sources of PHI (Identify the sources of PHI. e.g., medication lists, history and physical, etc.):</i> <input type="text"/>		

Source of Electronic Records (Identify any PHI to be received electronically):

--

III. Records located within or owned by St. Christopher's Hospital for Children
(Fill out details below as to records located/housed by SCHC)

Date of Records From:

--

Date of Records To:

--

Number of Records to be Reviewed:

--

Types of PHI you wish to review (Provide below or on a separate page a description of the PHI you will review from the medical records):

--

Sources of PHI (Identify the sources of PHI. e.g., medication lists, history and physical, etc.):

--

Source of Electronic Records (Identify any PHI to be received electronically):

--

The Researcher makes the following representations

- The use or disclosure of PHI is solely for review of PHI necessary to prepare for Research protocol or similar purposes preparatory to research.
- The PHI will not be removed from the site by the researcher or research staff.
- No PHI to be used to contact prospective research subjects.
- The PHI is necessary for the research purposes.

Name of the PI (typed):

--

Original Signature of PI:

Date:

--

<i>Drexel HIPAA Privacy Officer's Name and Signature (If necessary):</i>	
<input type="text"/>	
<i>Signature:</i>	<i>Date:</i>
<input type="text"/>	<input type="text"/>
<i>HUH HIPAA Privacy Officer's Name and Signature (If necessary):</i>	
<input type="text"/>	
<i>Signature:</i>	<i>Date:</i>
<input type="text"/>	<input type="text"/>
<i>St. Christopher Privacy Officer's Name and Signature (If necessary):</i>	
<input type="text"/>	
<i>Signature:</i>	<i>Date:</i>
<input type="text"/>	<input type="text"/>

Version 6: March 14, 2018