



## HIPAA Summary Form

This form must be in the current version and typewritten

**This form must be opened and saved using Adobe or software that allows for digital signature.**

### Section A: Administrative Information

1.	Principal Investigator Name	The Principal Investigator must sign Section E of this form.
2.	Project Title	
3.	<p>From which of the following institutions will you obtain Protected Health Information (PHI)?</p> <p>Please note: When health information is collected directly from the participant in a research study through interviews, questionnaires or surveys, and if the research team will never access medical records to verify that information, HIPAA oversight by the IRB is not required.</p> <p>(Select all that apply)</p> <p><input type="checkbox"/> Detroit Medical Center</p> <p><input type="checkbox"/> John D. Dingell VA Medical Center</p> <p><input type="checkbox"/> Karmanos Cancer Institute</p> <p><input type="checkbox"/> Wayne State University Practice Plan</p> <p>(specify): _____</p> <p><input type="checkbox"/> Other (specify): _____</p>	

4.	Which method(s) of HIPAA documentation are you requesting to use in this study? (Select all that apply)		
<input type="checkbox"/> Written HIPAA Authorization (See NOTE 1 below)	<input type="checkbox"/> Waiver of Authorization (See NOTE 2 below)	<input type="checkbox"/> Limited Data Set (See NOTE 3 below)	
<p><b>NOTE 1:</b> Written HIPAA Authorization is obtained during the informed consent process. Authorization is appropriate if the following condition is met:</p> <ul style="list-style-type: none"> <li>The research team will use PHI and obtain informed consent for participation in this study.</li> </ul>			
<p><b>NOTE 2:</b> A Waiver of Authorization is required if <u>one</u> of the following conditions is met:</p> <ul style="list-style-type: none"> <li>The research team will use PHI, but will not obtain informed consent.</li> <li>The research team will access PHI for research purposes prior to the informed consent process. This includes accessing medical records to identify persons who are eligible to recruit for this study. <i>Note: The PI must still obtain written HIPAA Authorization during the informed consent process.</i></li> <li>The research team will de-identify health information for all aspects of this study, and will not use or disclose any PHI.</li> <li>The PI has attached documentation by a statistician, independent of the research team, that the risk of identification of an individual by the use of PHI is minimal. <i>Note: Documentation should include the methods and justification for determining that risk of identification is minimal.</i></li> </ul> <p>In addition:</p> <ul style="list-style-type: none"> <li>The PI must request a waiver of consent using the applicable IRB forms.</li> <li>Age is PHI for persons over 89 years of age. If requesting a Waiver of Authorization, you must collapse age into decades for participants over 89. If age is not collapsed into decades, written HIPAA Authorization must be obtained from participants over 89.</li> </ul>			
<p><b>NOTE 3:</b> A Limited Data Set may be used if the following condition is met:</p> <ul style="list-style-type: none"> <li>PHI used and/or disclosed in this study is limited to addresses greater than street (which includes city, state, zip code), elements of dates, and/or any other unique identifying numbers, characteristic or codes (i.e. linked study identification numbers).</li> </ul> <p>In addition:</p> <p>If the PI will disclose the Limited Data Set to a recipient outside of Wayne State University, the Detroit Medical Center, John D. Dingell VA Medical Center, Karmanos Cancer Institute, then a Data Use Agreement (DUA) between Wayne State University and the outside entity must be obtained. The WSU Office of Business Innovation and Technology Commercialization executes all DUAs. Visit their <a href="#">Material Transfer Agreements website</a> for additional information.</p> <p><a href="#">Click Here to see the Data Use Agreements and Limited Data Sets Guidance Tool for more information</a></p>			

## Section B: Participant Recruitment and Use of PHI

5.	<p>Will someone with a clinical relationship contact or refer potential participants to your study?</p> <p><b>NOTE:</b> A person with a clinical relationship should first introduce a study to potential participants. This person does not have to be a member of the research key personnel. Research that is not in a clinical setting, does not involve face-to-face recruitment (i.e. advertisements), or does not involve direct contact with participants (i.e. previously collected data), may not require that a person with a clinical relationship introduces the study.</p>	<input type="checkbox"/> Yes – <b>answer 5a.</b> <input type="checkbox"/> No – <b>answer 5b.</b>
	<p>a. State who will introduce the study to potential participants and their clinical relationship(s).</p>	
	<p>b. Justify why someone with a clinical relationship will not introduce the study to potential participants.</p>	
6.	<p>Which of the following Protected Health Information (PHI) items obtained from Wayne State University, the Detroit Medical Center, John D. Dingell VA Medical Center, Karmanos Cancer Institute are being USED for research purposes? <b>(Select all that apply and include for the HIPAA Authorization PHI that will be USED section)</b></p> <p><b>NOTE: Research uses include screening for eligibility, data collection, data analysis, and follow-up contact.</b></p>	
<input type="checkbox"/> Name (including Initials)		
Address:		
<input type="checkbox"/> Street Address		
<input type="checkbox"/> City, State, and/or Zip Code		
<input type="checkbox"/> Elements of Dates (Birth Date, Admission Date, Date of Service, Date of Death, etc.)		
<input type="checkbox"/> Telephone Number		
<input type="checkbox"/> Fax Number		
<input type="checkbox"/> E-Mail Address		
<input type="checkbox"/> Social Security Number		
<input type="checkbox"/> Medical Record Number		
<input type="checkbox"/> Health Beneficiary Number		
<input type="checkbox"/> Account Numbers (Credit Card, etc.)		
<input type="checkbox"/> Certificate/License Numbers		
<input type="checkbox"/> Vehicle Identification/Serial Numbers		
<input type="checkbox"/> Device Identification/Serial Numbers		
<input type="checkbox"/> Website URLs		
<input type="checkbox"/> Internet Protocol (IP) Addresses		
<input type="checkbox"/> Biometric Identifiers (Voice, Fingerprints, etc.)		
<input type="checkbox"/> Full Face Images		
<input type="checkbox"/> Any Other Unique Identifying Numbers, Characteristic or Code (Linked Study Identification Numbers, etc.)		

## Section C: Disclosure of PHI

7.	Will PHI be DISCLOSED to sponsors, companies hired to provide study related services, or research institutions outside of Wayne State University and its affiliates (Detroit Medical Center, John D. Dingell VA Medical Center, Karmanos Cancer Institute)?  NOTE: PHI is always available to federal agencies that monitor research upon request, and it is not necessary to consider them when answering this question. These agencies include the Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA), the Office for Civil Rights (OCR), and the Veteran's Administration (VA) (if applicable).	<input type="checkbox"/> No – go directly to Q#10 <input type="checkbox"/> Yes
8.	List all sponsors, companies hired to provide study related services, or research institutions outside of Wayne State University and its affiliates that will receive PHI. <p style="text-align: center;">Note this entities must also be listed for the for HIPAA Authorization</p>	
	a. Describe how data will be sent: <b>NOTE: Describe actual methods and include a plan for coding and/or encryption to maintain confidentiality.</b>	
9.	Which of the following Protected Health Information	

<p>(PHI) items are being DISCLOSED to sponsors, companies hired to provide study related services, or research institutions outside of Wayne State University and its affiliates?</p> <p><b>(Select all that apply include for the HIPAA Authorization PHI that will be DISCLOSED section)</b></p>	<p><b>Justify the disclosure of each selected item below.</b></p>
<input type="checkbox"/> Name (including Initials)	
<p>Address:</p> <input type="checkbox"/> Street Address <input type="checkbox"/> City, State, Zip Code	
<input type="checkbox"/> Elements of Dates (Birth Date, Admission Date, Date of Service, Date of Death, etc.)	
<input type="checkbox"/> Telephone Number	
<input type="checkbox"/> Fax Number	
<input type="checkbox"/> E-Mail Address	
<input type="checkbox"/> Social Security Number	
<input type="checkbox"/> Medical Record Number	
<input type="checkbox"/> Health Beneficiary Number	
<input type="checkbox"/> Account Numbers (Credit Card, etc.)	
<input type="checkbox"/> Certificate/License Numbers	
<input type="checkbox"/> Vehicle Identification/Serial Numbers	
<input type="checkbox"/> Device Identification/Serial Numbers	

<input type="checkbox"/> Website URLs	
<input type="checkbox"/> Internet Protocol (IP) Addresses	
<input type="checkbox"/> Biometric Identifiers (Voice, Fingerprints, etc.)	
<input type="checkbox"/> Full Face Images	
<input type="checkbox"/> Any Other Unique Identifying Numbers, Characteristic or Code (Linked Study Identification Numbers, etc.)	

## Section D: Waiver of HIPAA Authorization

10.	Is a Waiver of HIPAA Authorization being requested for the proposed study?	<input type="checkbox"/> No – go directly to Q#16 <input type="checkbox"/> Yes
11.	Describe how the proposed use and/or disclosure of PHI presents no more than minimal risk to the privacy of participants:	
12.	Explain why the research could not practicably be conducted without the Waiver of Authorization:	
13.	Explain why the research could not practicably be conducted without access to, and use of PHI:	
14.	Describe the steps taken to protect identifying information (or links to identifiers) from improper use or disclosure:	

15.	Describe the plans for destroying identifying information (or links to identifiers). Specify when identifying information will be destroyed. Provide justification if identifying information is retained:	
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**Section E: Principal Investigator’s Signature for HIPAA Submission**

This section is to be completed by the Principal Investigator ONLY

**Principal Investigator’s Waiver of HIPAA Authorization Statement**

**As Principal Investigator my signature above is also an attestation of the following regarding the request for Waiver of HIPAA Authorization.**

As Principal Investigator, I assure that the information I obtain as part of this research will not be reused or disclosed to any other person or entity other than those listed on this form, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI is approved by the Wayne State University IRB. If at any time I want to reuse this information for other purposes or disclose the information to other individuals or entities, I will seek approval from the Wayne State University IRB.

- Yes
- No
- N/A, Waiver of HIPAA Authorization is not requested.

**Principal Investigator’s Signature for HIPAA Submission**

**As Principal Investigator, my signature is attesting to the accuracy of this submission and requesting approval/authorization for USE and/or Disclosure of Protected Health Information as indicated for this form.**

Name of Principal Investigator: \_\_\_\_\_

\_\_\_\_\_  
Signature of Principal Investigator

\_\_\_\_\_  
Date



## Section F: Detroit Medical Center (DMC) Protected Health Information (PHI) Use and Disclosure

The Wayne State University IRB/Privacy Board does not review Section D of the HIPAA Summary Form. Access to Detroit Medical Center (DMC) Protected Health Information (PHI) requires DMC review. The DMC Clinical & Translational Research Office uses Section D as part of their review.

If you have questions related to Q#16-21, please contact the DMC Clinical & Translational Research Office for assistance: <https://www.dmc.org/ResearchReviewProcess>

16.	Are you accessing Protected Health Information (PHI) from the DMC EMR/Medical Records for your research?	<input type="checkbox"/> Yes - answer question 17. <input type="checkbox"/> No – <b>STOP, the form is complete</b>
17.	Are you requesting an <b>automated</b> extract of DMC Protected Health Information (PHI)?	<input type="checkbox"/> Yes If Yes, answer question 18. <input type="checkbox"/> No If No, proceed to question 19.
18.	Indicate where the information is being housed and transmitted:	
	18a.) A database housed within the DMC?	<input type="checkbox"/> Yes - answer question 18b. <input type="checkbox"/> No - answer question 18c
	18b.) Describe the location where the data will be housed:	
	18c.) Transmitted to an external organization (eg. Wayne State University, Karmanos), an external database or system?	<input type="checkbox"/> Yes - answer question 18d. <input type="checkbox"/> No
	18d.) Describe the location where the data will be transmitted:	
19.	Are you <b>manually</b> extracting DMC Protected Health Information (PHI)?	<input type="checkbox"/> Yes - answer question 20. <input type="checkbox"/> No – <b>STOP, the form is complete</b>
20.	For the <b>initial</b> manual PHI extraction, indicate where the information will be stored :	

	20a.) A database housed within the DMC?	<input type="checkbox"/> Yes - <i>answer question 20b.</i> <input type="checkbox"/> No - <i>answer question 20c.</i>
	20b.) Describe the location where the data will be stored:	
	20c) An external organization (eg. Wayne State University, Karmanos), an external database or system?	<input type="checkbox"/> Yes - <i>answer question 20d.</i> <input type="checkbox"/> No
	20d.) Describe the location where the data will be stored:	
	20e.) Are you <b>transmitting</b> the <b>manually</b> extracted PHI to an external organization (eg. Wayne State University, Karmanos), an external database or system?	<input type="checkbox"/> Yes <input type="checkbox"/> No
21.	Indicate who will be extracting the data?	<input type="checkbox"/> DMC Research Team <input type="checkbox"/> WSU Research Team <input type="checkbox"/> DMC Information Services <input type="checkbox"/> DMC Finance <input type="checkbox"/> Other: _____