

Eastern Michigan University
University Human Subjects Review Committee (UHSRC)
HIPAA SUMMARY FORM

Date Submitted: _____

Title of Project _____

Principal Investigator _____

Department _____

Phone _____ Fax _____ Email _____

Co-PI/Project Director _____

If a **student project**, list faculty _____

1. Protected Health Information: Identify which of the following participants' Protected Health Information (PHI) items are being used for research purposes from medical records and/or databases created from medical records. Indicate whether the PHI will be used and/or disclosed. (Check all that apply)

Used? Disclosed?

- | | | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | Name |
| <input type="checkbox"/> | <input type="checkbox"/> | Social Security Number |
| <input type="checkbox"/> | <input type="checkbox"/> | Elements of dates associated with personal identity (such as birth date, admission date, date of service, date of death, etc.)* |
| <input type="checkbox"/> | <input type="checkbox"/> | Address: Street |
| <input type="checkbox"/> | <input type="checkbox"/> | Address: City, State, and/or Zip |
| <input type="checkbox"/> | <input type="checkbox"/> | Phone number |
| <input type="checkbox"/> | <input type="checkbox"/> | Fax number |
| <input type="checkbox"/> | <input type="checkbox"/> | Email Address |
| <input type="checkbox"/> | <input type="checkbox"/> | Medical Record number |
| <input type="checkbox"/> | <input type="checkbox"/> | Health Beneficiary number |
| <input type="checkbox"/> | <input type="checkbox"/> | Account Numbers (credit card, etc.) |
| <input type="checkbox"/> | <input type="checkbox"/> | Certificate/License Numbers |
| <input type="checkbox"/> | <input type="checkbox"/> | Vehicle and Serial Numbers (including license plate numbers) |
| <input type="checkbox"/> | <input type="checkbox"/> | Device IDs and Serial Numbers |
| <input type="checkbox"/> | <input type="checkbox"/> | Web URLs |
| <input type="checkbox"/> | <input type="checkbox"/> | Internet Protocol (IP) Addresses |

- | | | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | Biometric Identifiers (voice and fingerprints) |
| <input type="checkbox"/> | <input type="checkbox"/> | Full Face Photographs (and comparable images) |
| <input type="checkbox"/> | <input type="checkbox"/> | Any unique identifying numbers, characteristic or code* |

*These items may be considered part of a “limited data set.” Use of data under the provisions of a “limited data set” requires the signing of a **Data Use Agreement**. If you are using a “limited data set” as defined under HIPAA, please attach your Data Use Agreement.

Check here if not applicable:

Provide written justification for disclosure of name, address, SSN, medical record number or health beneficiary number.

Check here if not applicable:

Justification for disclosure: <input style="width: 100px; height: 15px;" type="text"/>
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2. Use of PHI from individuals older than 89 years of age

Yes **No**

- | | | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | Are individuals greater than 89 years of age eligible for participation in the study? |
|--------------------------|--------------------------|---|

Yes **No**

- | | |
|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> |
|--------------------------|--------------------------|

If Yes to item above: is the year of birth collapsed into decades?
 Note: If the year of birth is not collapsed into decades, authorization must be obtained from all participants over 89.

3. De-identification of dataset

HIPAA regulations do not apply if Protected Health Information (PHI) is de-identified. If the PHI can or will be de-identified for all aspects of this study, check the appropriate box.

Yes **No**

- | | | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | Method 1: Elimination of all 18 elements identified in Question 1, above. If any boxes are checked in question 1, this method does not apply. |
| <input type="checkbox"/> | <input type="checkbox"/> | Method 2: Documentation by a statistician, independent of the research team, that the risk of identification of an individual by the use of PHI is very small. If using Method 2, provide documentation of the determination and justification of that assessment. |

If health information has been de-identified by Method 1 or 2 above, HIPAA regulations do not apply, and completion of the remainder of this form is not required. Please sign the form and submit to the UHSRC with your Application Form, to verify that PHI is not being collected.

If PHI is being collected, HIPAA regulations DO apply in addition to those of the Common Rule (45 CFR 46). Please answer the following questions to determine the level of protection required for research participants.

4. Participant recruitment

From which institutions are you obtaining Protected Health Information (PHI)?

Who with a clinical relationship to the potential participant is contacting/referring them for participation in the study/project?

Name/Position	Precise clinical relationship with the potential participant
a.	
b.	
c.	
d.	
e.	
f.	
g.	

5. Disclosure of PHI

Yes No
 Will PHI be sent outside of EMU?

If yes, where will the PHI be sent? (If no, please note that subsequent release of data outside of EMU requires approval by the UHSRC through submission of either a study modification form or a new protocol.)

And, if yes, how will the PHI be sent? (Describe actual methods and include a plan for coding and/or encryption)

6. Access to Protected Health Information (PHI)

Select one of the 3 methods below for documentation for use and disclosure of PHI.

Yes No N/A

a. **Limited Data Set:** A Limited data set involves the following three identifiers only: (1) Locations larger than a specific street address; (2) Elements of dates; (3) Unique codes. **If yes, attach a copy of all Data Use Agreements**

b. **Written “Authorization” from the Patient/Participant.** If yes, submit a copy of the HIPAA Authorization.

c. **Waiver of Authorization.** If yes, complete Section 7, below.

7. Request for HIPAA Waiver of Authorization (COMPLETE THIS SECTION ONLY WHEN QUESTION 6 C IS ANSWERED YES, ABOVE)

With limited exceptions, federal regulations require that authorization to use PHI be obtained from all human research participants. However, the UHSRC is allowed to waive authorization to access PHI if the following conditions are met. If you wish to request a waiver of authorization, please provide the following justifications.

a. Describe how the proposed use and disclosure of PHI from data/documentation/ record presents no more than minimal risk to the privacy of participants.

b. Explain why the research could not practicably be conducted without the waiver of authorization.

- c. Describe the steps taken to protect the identifiers (or links) from improper use or disclosure.

[Redacted]

- d. Describe the plans for destroying identifiers (or links) and specify when this will occur. If there is a justification for retaining the identifiers, please provide detailed information.

[Redacted]

Only sign here if a “Waiver of Authorization” is being requested

Waiver Agreement: 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 UHSRC. 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 UHSRC.

[Redacted]

[Redacted]

Name of Principal Investigator Requesting Waiver

Date

Signature

Submit form along with your *Request for Human Subjects Approval Form* to the Graduate School – one signed paper copy and send as email attachment to human.subjects@emich.edu.

Investigator Signature

Date