IRB Administration Office
Foust Hall 104
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Mt. Pleasant, MI 48859
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# HIPAA Summary Form

## Section A: Administrative Information

| | |
|---|---|
| 1. Principal Investigator | Principal Investigator's Signature |
| 2. Project Title | |
| 3. From which of the following institutions will you obtain Protected Health Information (PHI)?<br>☐ DMC-CHM ☐Other: _____ | |
| 4. Which method(s) of HIPPA documentation are you requesting to use in this study?<br>☐ Written HIPPA Authorization<br>☐ Waiver of Authorization<br>☐ Limited Data Set | |

## Section B: Participant Recruitment and Use of PHI

5. Will someone with a clinical relationship contact or refer potential participants to your study?
☐ Yes - answer Question 5.A)
☐ No – answer Question 5.B)

NOTE: A person with a clinical relationship should first introduce a study to potential participants. This persondoesnot 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 introduce the study.

5. A) State who will introduce the study to the potential participants and their clinical relationship(s)

5. B) Justify why someone with a clinical relationship will not introduce the study to the potential participants.

6. Which of the following Protected Health Information(PHI) items obtained from the Detroit Medical Center are being USED for research purposes? (Select all that apply)

NOTE: Research uses include screening eligibility, data collection, data analysis, and follow-up contact.

☐ Name (including initials)
☐ Street Address
☐ City, State, and/or Zip Code
☐ Elements of Dates (Birth Date, Admission Date, Date of Service, Date of Death)
☐ Telephone Number
☐ Fax Number
☐ E-Mail Address
☐ Social Security Number
☐ Medical Record Number

☐ Health Beneficiary Number
☐ Account Numbers (Credit Card, etc.)
☐ Certificate/License Numbers
☐ Vehicle Identification/Serial Numbers
☐ Device Identification/Serial Numbers
☐ Website URLs
☐ Internet Protocol (IP) Addresses
☐ Biometric Identifiers (Voice, Fingerprints, etc.)
☐ Full Face Images
☐ Any Other Unique Identifying Numbers, Characteristics 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 Central Michigan University and its affiliates (Detroit Medical Center)?

☐ No – go directly to Question 10
☐ Yes

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 of Civil Rights (OCR), and the Veteran's Administration (VA) (if applicable).

8. List all sponsors, companies hiredto provide study relatedservices, or researchinstitutions outside of Central Michigan University and its affiliates that will receive PHI:

8. A) Describe how data will be sent:

NOTE: Describe actual methods and include a plan for coding and/or encryption to maintain to maintain confidentiality.

9. Which of the following Protected Health Information(PHI) items are being DISCLOSEDto sponsors, companies hired to provide study related services, or research institutions outside of Central Michigan University and its affiliates?

☐ Name (including initials)
☐ Street Address
☐ City, State, and/or Zip Code
☐ Elements of Dates (Birth Date, Admission Date, Date of Service, Date of Death)
☐ Telephone Number
☐ Fax Number
☐ E-Mail Address
☐ Social Security Number
☐ Medical Record Number
☐ Health Beneficiary Number
☐ Account Numbers (Credit Card, etc.)
☐ Certificate/License Numbers
☐ Vehicle Identification/Serial Numbers
☐ Device Identification/Serial Numbers
☐ Website URLs

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|---|
| ☐ Internet Protocol (IP) Addresses<br>☐ Biometric Identifiers (Voice, Fingerprints, etc.)<br>☐ Full Face Images<br>☐ Any Other Unique Identifying Numbers, Characteristics or Code (Linked Study Identification Numbers, etc.) |

**Section D: Disclosure of PHI**

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| 10. Is a Waiver of HIPPA Authorization being requested for the proposed study?<br>☐ No – go directly to Question 16<br>☐ Yes |
| 10. A) Why is a Waiver of HIPPA Authorization being requested?<br>☐ To screen medical records for eligible potential participants<br>☐ To obtain data for a retrospective chart review study<br>☐ Other (specify): _____ |
| 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 Wavier 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 of 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: |

| Waiver of Agreement – must be signed to receive a Waiver of HIPPA Authorization |
|---|
| I assure that the information I obtain as part of this research will not be reused or disclosed to any other person or entity 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 Central Michigan 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 Central Michigan University IRB.<br><br>Signature of Principal Investigator Date |

**Section E: Detroit Medical Center (DMC) Protected Health Information (PHI) Use and Disclosure**

The Central Michigan University IRB/Privacy Board does not review Section E of the HIPAA Summary Form. Access to Detroit Medical Center-Children's Hospital of Michigan (DMC-CHM) Protected Health Information (PHI) requires DMC review. These are questions that you will provide responses to on the DMC Clinical & Translational Research Office HIPAA document.

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

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| 16. Are you accessing Protected Health Information (PHI) from the DMC EMR/Medical Records for your research?<br>☐ Yes – answer Question 17<br>☐ No – **STOP**, this form is complete |
| 17. Are you requesting an **automated** extract of DMC Protected Health Information (PHI)?<br>☐ Yes – answer Question 18<br>☐ No – proceed to Question 19 |
| 18. Indicate where the information is being housed and transmitted: |
| 18. A) A database housed within the DMC?<br>☐ Yes – answer Question 18.B)<br>☐ No – answer Question 18.C) |
| 18. B) Describe the location where the data will be housed: |
| 18. C) Transmitted to an external organization or an external database or system?<br>☐ Yes – answer Question 18.D)<br>☐ No |
| 18. D) Describe the location where the data will be transmitted: |
| 19. Are you **manually** extracting DMC Protected Health Information?<br>☐ Yes – answer Question 20<br>☐ No – **STOP**, the form is complete |
| 20. For the **initial** manual PHI extraction, indicate where the information is stored: |
| 20. A) A database housed within the DMC?<br>☐ Yes – answer Question 20.B)<br>☐ No – answer Question 20.C) |
| 20. B) Describe the location where the data with be stored: |
| 20. C) An external organization or an external database or system?<br>☐ Yes – answer Question 20.D)<br>☐ No |
| 20. D) Describe the location where the data will be stored: |
| 20. E) Are you transmitting the manually extracted PHI to an external organization?<br>☐ Yes<br>☐ No |
| 21. Indicate who will be extracting the data?<br>☐ DMC Research Team<br>☐ CMU CHM Research Team<br>☐ DMC Information Services<br>☐ DMC Finance<br>☐ Other: |

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| Waiver of HIPAA Authorization Documentation |
|---|
| ☐ Granted for screening of eligible potential participants only<br>☐ Granted for the entire study<br>☐ Not granted<br><br>☐ NA – Waiver of HIPAA Authorization not requested<br>☐ Other:_____ |
| The research could not practicably be conducted without the waiver or alteration.<br>☐ True<br>☐ False |
| The research could not practicably be conducted without access to and use of PHI.<br>☐ True<br>☐ False |
| There is an adequate plan to destroy identifiers at the earliest opportunity consistent with the conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so).<br>☐ True<br>☐ False<br>☐ There is adequate justification to keep identifiers |
| There are adequate written assurances (i.e., the Waiver of Agreement is signed) that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule. |

| IRB/Privacy Board HIPAA Determination | |
|---|---|
| The proposed use of PHI is: ☐ Approved ☐ Approved Pending Revisions ☐ Not Approved ☐ Other:_____ | |
| HIPAA Reviewer's Signature: | Date: |
| HIPAA Reviewer's Printed Name: | |

| Reviewer Comments: |
|---|
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