**Section A: Administrative Information**

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

**Section B: Participant Recruitment and Use of PHI**

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| **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 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 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**

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| **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 to Question 10**  **Yes- go to Question 8**  **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), and the Office of Civil Rights (OCR).** |
| **8. List all sponsors, companies hired to provide study related services, or research institutions 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 confidentiality.** |
| **9. Which of the following Protected Health Information(PHI) items are being DISCLOSED to 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**  **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 D: Disclosure of PHI**

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| 10. Is a Waiver of HIPPA Authorization being requested for the proposed study?  No- go to Question 16  Yes |
| 10.A Why is a Waiver of HIPPA Authorization being requested?  To screen medical records for eligible potential participants  To obtain data for a retrospective chart review study  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: |

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| 16. **Waiver Agreement- Submitting this form to the IRB is the assurance the following will occur.** |
| 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. |

***NOTE:*** *Access to Detroit Medical Center-Children’s Hospital of Michigan (DMC-CHM)Protected*

*Health Information (PHI) requires DMC review.*

*If you have questions contact the DMC Clinical & Translational Research Office for assistance:*

[***https://www.dmc.org/ResearchReviewProcess***](https://www.dmc.org/ResearchReviewProcess)

**IRB USE ONLY**

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| **Waiver of HIPAA Authorization Documentation** |
| Granted for screening of eligible potential participants only  Granted for the entire study  Not granted  NA – Waiver of HIPAA Authorization not requested  Other: |
| The research could not practicably be conducted without the waiver or alteration.  True  False |
| The research could not practicably be conducted without access to and use of PHI.  True  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).  True  False  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.  True  False  There is adequate written assurance PHI will not be reused or disclosed. |

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| **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: |

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| Reviewer Comments: |