West Michigan Cancer Center IRB
Request for Waiver of Informed Consent and Waiver of Authorization to Use and Disclose Protected Health Information for Research Purposes

Investigators seeking a waiver of participants’ informed consent (under the Common Rule) and a waiver of participants’ authorization (under the Privacy Rule) must request and justify such waivers to the West Michigan Cancer Center Institutional Review Board (WMCC IRB) by completing the following questions:

Principal Investigator’s Name: ________________________________

Study Title: ___________________________________________________________________________________

1. Co-Investigators, research team members, or others who will need access to protected health information (PHI):

<table>
<thead>
<tr>
<th>Name and Degree</th>
<th>Role on Project</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Name(s) of Covered Entity(ies) and location(s) where PHI will be accessed or obtained:

3. Does the use or disclosure of the PHI involve greater than minimal risk* to the privacy of the potential research participants? □ No □ Yes

If yes, please explain:

4. Date range of required data: __________________ through __________________ (mm/dd/yyyy) (mm/dd/yyyy)

5. Type of data to be collected (choose all that apply):

- □ Personal data (name, address, primary care physician)
- □ Medical history
- □ Demographic data (age, gender, vital status)
- □ Billing data
- □ Laboratory data
- □ Coded encounter data
- □ Images
- □ Reports, clinic/office notes
- □ Other, specify_____________________________

*“Minimal risk” means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations.
6. Check any of the following identifiers (i.e., PHI) that will be recorded with or linked by code to the data:

- Name
- Social Security Number
- Medical record number
- Account number
- Date of birth
- Procedure/Service date
- Admission/Discharge date
- Street address
- City/County/Zip Code
- Telephone number
- Fax number
- E-mail address
- Web URLs
- Vehicle identifier/Serial number/License plate
- Internet protocol (IP) address
- Health plan beneficiary number
- Certificate/License number
- Medical device identifier/Serial number
- Biometric identifiers (finger/voice prints)
- Full face photo/Image
- Any other unique identifying number, characteristic or code (except Study ID)

6. Explain why the research could not practicably be conducted without this Waiver of Informed Consent and Waiver of HIPAA Authorization. Select all that apply:

- The research involves no more than minimal risk (e.g., chart reviews) and does not require any other reason to contact potential participants
- It is not possible to contact all of the potential participants associated with the data or specimens to obtain consent or authorization
- The design of the study does not allow the possibility of obtaining consent or authorization
- The potential study population is so large that it would not be feasible to obtain consent or authorization
- Requiring consent or authorization may introduce systemic bias into the data
- The risk of contacting the subjects is greater than the risk of the study procedures
- Other: _________________________________________________________

7. Explain why the research could not practicably be conducted without access to and use of the PHI being requested. Select all that apply:

- PHI is required to determine eligibility
- PHI must be accessed to gather the required elements needed to meet study objectives
- PHI is required for distribution of survey materials to potential participants
- Other: ______________________________________________________________________
- Not applicable – No PHI is being requested

9. Describe your plan to access the requested information. Select all that apply:

- Direct access to Covered Entity’s paper-based medical records
- Direct access to Covered Entity’s electronic medical records
- Direct access to Covered Entity’s operational databases (e.g., registry)
- Receipt of reports/data from the Covered Entity (e.g., HIM department, Quality & Safety department)
- Treating physicians will provide a list or otherwise identify potentially eligible research participants
- Other: ______________________________________________________________________
10. Describe your plan to protect the PHI from improper use and disclosure. Select all that apply:

☐ Data containing PHI will only be accessible by authorized study personnel (see Item #1)
☐ Investigators will de-identify the extracted study data (e.g., data collection form) by assigning a unique study number to each patient via a correlation tool (i.e., code/key sheet)
☐ Data containing PHI* (e.g., code/key sheet, source reports) will be securely stored in a separate location from extracted (i.e., de-identified) study data and other patient records. *Indicate if electronic or paper (or both):
   ☐ Electronic files containing PHI will be protected with a unique password and stored on the secure/encrypted network/system belonging to ______________
   ☐ Paper data containing PHI will be maintained in locked storage located ______________
☐ Data containing PHI will be transmitted via secure (i.e., encrypted) e-mail or transported directly (i.e., with no stops) to/between authorized study personnel and stored securely thereafter or immediately destroyed
☐ If researcher discloses PHI to a third party (e.g., research sponsor, data analyst, centralized database, etc.), researcher has received written assurances that the third party will maintain confidentiality of the PHI
☐ Other: ____________________________
☐ Not applicable – No PHI is involved
☐ Not applicable – Data provided by the Covered Entity will already be de-identified and investigator does not have the ability to re-identify the data subjects

11. Will the PHI be destroyed at the completion of the study?

☐ Yes  If yes, describe your plan to destroy the identifiers. Select all that apply:
   ☐ Paper-based PHI will be shredded
   ☐ Electronic PHI will be securely deleted/permanently erased (i.e., “wiped”) from the computer system(s) or devices
   ☐ Other: __________________________________________
☐ No  If no, explain why the PHI must be retained, including whether the data is needed for a health or research purpose, legal or institutional requirements, or other reason: ______________________________________________________________________

☐ Not applicable – No PHI is involved or only de-identified data will be received (and investigator does not have the ability to re-identify the data subjects)

12. Explain why subjects’ rights and welfare will not be adversely affected by this Waiver of Informed Consent and Waiver of HIPAA Authorization. Select all that apply:

☐ This research is a retrospective chart review of standard medical exams/procedures that have already been performed; therefore; results of this study will not affect clinical decisions about the subject’s care
☐ Survey materials clearly state that by completing/submitting the survey, the subject has agreed to participate in the research
☐ A summary of study results or other pertinent information will be provided to subjects. Please describe plan for sharing: ______________________________________________________________________

☐ No PHI is being requested or only de-identified data will be received (and investigator does not have the ability to re-identify the data subjects)
☐ Other: __________________________________________
As Principal Investigator, I affirm that (please check box after reading statement):

☐ The research could not practicably be carried out without the Waiver of Informed consent;
☐ The research could not practicably be carried out without the Waiver of HIPAA Authorization;
☐ The research could not practicably be conducted without access to and use of PHI;
☐ The use or disclosure of PHI involves no more than minimal risk because of an adequate plan

I assure the IRB that the protected health information which I have detailed in this Waiver of Informed Consent and/or Authorization will not be reused (i.e., used other than as described in this request) or disclosed to any person or entity other than those listed above, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by West Michigan Cancer Center IRB. I also assure West Michigan Cancer Center IRB that the information that I provide in this application is accurate and complete, and that the PHI that I request is the minimum amount of identifiable health information necessary for my research project.

___________________________  __________________________
Principal Investigator’s Signature  Date