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Next

## 25-2. HIPAA Authorization Waiver Request

Completion of this section is required based on the response provided to question 25-1.3.2

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### 25-2.1\* Waiver of HIPAA authorization requested for:

Select all that apply:

- Entire project
- Survey portion only
- Recruitment portion only
- Specific subject group only
- Other portion or aspect of the project

If other, please specify:

### 25-2.2\* To ensure that this research use of the PHI involves no greater than minimal risk to privacy, describe the plan to protect patient-subject identifiers from improper use or disclosure.

NOTE - QUESTIONS ARE SIMILAR TO, BUT NOT THE SAME AS, SECTION 10-3 ON INFORMED CONSENT WAIVER.

Answer as appropriate. Answers should be consistent with other parts of the application, such as 05-1, 11, 11-1, and others.

### 25-2.3\* To ensure that this research use of PHI involves no greater than minimal risk to privacy, describe the plan to destroy patient-subject identifiers at the earliest opportunity consistent with the research. Indicate at what point in the research the patient-subject identifiers will be destroyed. If applicable, provide a health, research or legal justification for retaining the identifiers.

Answer as appropriate, consistent with eResearch pages 11 and 11-1. This question asks that you DESCRIBE YOUR PLAN.

### 25-2.4\* To ensure that this research use of the PHI involves no greater than minimal risk to privacy, provide assurance that this information will not be reused or disclosed to any other person or entity (i.e., outside the research study team), except as required by law, for authorized oversight of the research study, or for other research for which the IRB has granted a waiver of the HIPAA authorization.

"So assured" is an appropriate answer. This question asks only that you PROVIDE ASSURANCE.

### 25-2.5\* Why could this research not practicably be conducted unless the waiver of HIPAA authorization is granted [45 CFR 164.512 (i)(2)(ii)(B)]?

Answer as appropriate, consistent with 10-3.2, 2nd sub-question.

Why would it NOT be worthwhile at any point to contact potential subjects and obtain written HIPAA authorization for the research use? You do not need to assert obtaining authorization would be impossible, but you do need to provide a stronger justification than that waiver is convenient.

Consider also that HIPAA authorization CAN be obtained by mail without direct interaction. Postage costs would be less than \$1/subject INCLUDING sending them a pre-stamped return envelope. Depending on the number of subjects, this may NOT be "time and cost prohibitive." A POSSIBLE JUSTIFICATION for a small-cohort waiver might be that you would expect most people would \*not\* return the authorization form and thus you would lose out on a significant fraction of the data; in that case, how important is the more complete dataset?

**25-2.6\* Why could this research not practicably be conducted without access to and use of the PHI [45 CFR 164.512(i)(2)(ii)(C)]?**

Answer as appropriate, consistent with 25-1.2 ("minimum necessary PHI") and 10-3.2, 3rd sub-question.

If this is a MiChart medical record review, this answer should include why it is NOT PRACTICABLE to obtain data without direct PHI access through Data Office for Clinical and Translational Research <https://research.medicine.umich.edu/office-research/data-office-clinical-and-translational-research> (including their free "self-serve" tool DataDirect) because Data Office services are intended to make "medical record research without PHI access" MORE feasible.

**25-2.7\* Will data containing PHI be shared outside of the U-M covered component? (If yes review the guidelines from UM HIPAA office)**

Yes  No [Clear](#)

Answer YES if some U-M study team members accessing PHI are NOT part of Michigan Medicine.

Answer YES if PHI (including in Limited Data Set form) is sent to external collaborators.

Disclosures of PHI (sharing outside the U-M covered component) relying on a Waiver of Authorization must be tracked. U-M Privacy Office suggests tracking in a patient's medical record or via UMHS web Disclosure log. For more information, see UMHS Policy 01-04-335 (link requires level-2 or UMHS VPN).



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