eResearch M REGULATORY MANAGEMENT SAND

Edit: Application - HUM00008837

Note *(0 Notes Total)* Add

25-2. HIPAA Authorization Waiver Request

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

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.

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.

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.

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)]?

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)]?

25-2.7* Will data containing PHI be shared outside of the U-M covered component?

○ Yes ○ No Clear