

Note (0 Notes Total) Add

25-3. Certification for Review of Data Preparatory to Research

Completion of this section is required based on the response provided to question 4-1.1 and/or 25-1.3.2.

25-3.1* Affirm that the PHI will be used only for one or more of the following purposes:

Purpose

- To determine whether the proposed project is feasible, or to assist in the design of the project. *In either case, the study team will not record any PHI reviewed for this purpose into a dataset that may later be used for the project itself.*
- To ask potential subjects whether they want to consider participating in the study. *In this case, the study team will record only name and contact information and will not use this information for any other activity.*

25-3.2* Confirm that no PHI will be removed from the U-M covered component during this review preparatory to research. This information may not be sent off-site to anyone, even a sponsor or consultant or vendor helping with or monitoring the study. Note: individuals outside the U-M covered component, including sponsors, consultants, and monitors, may review the information on-site.

25-3.3* Will individuals outside the U-M covered component review the information on-site?

Yes No [Clear](#)