

Section 13: Protected Health Information (PHI)

This section asks you to indicate if you propose to review and/or record PHI prior to obtaining consent.

13. Protected Health Information (PHI)

[User Guide](#)

* Indicate how you intend to use potential subjects' Protected Health Information (PHI):	
<input type="radio"/> I will review, but not record, PHI prior to consent.	
<input type="radio"/> I will record PHI prior to consent.	
<input checked="" type="radio"/> I do not intend to use PHI prior to consent.	
<input type="radio"/> I will record PHI without consent. (decedent research, database repository, chart review)	

If you propose to use PHI prior to documenting consent, you must upload a waiver form: <https://irb.duhs.duke.edu/forms/waiver-documentation-informed-consent>

An IRB may waive the requirement for the investigator to obtain a signed and dated consent form for some or all subjects, if it finds either:

- (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

or

- (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Please note that studies involving FDA-regulated products must meet additional criteria. Please see the policy on waiving consent for more information:

<https://irb.duhs.duke.edu/policies-and-regulations/policies/waiver-documentation-consent>