Section 14: Consent Process

In this section, you will describe your plan for obtaining appropriate informed consent from your research participants.

IMPORTANT:
For all studies involving human subjects that are not Duke patients, you must give a notice of privacy practices (NOPP) to participants and record signatures of acknowledgement of receipt during the consent process. Please mention this in your Research Summary and upload the appropriate documents. These documents can be found here:
research.duke.edu/campus-oversight-organization/information-notice-privacy-practices

You will also upload your consent forms in this section. They must be MS Word documents and follow the specific format outlined by the IRB. A sample on the approved template (Form M0345) can be found here:
https://irb.duhs.duke.edu/forms/duhs-sample-consent

Note: Please do not edit the section of the footer that contains the Protocol ID, Continuing Review and Reference Date fields. Those fields will be used to stamp the final consent form when it is approved by the IRB. If you want to add an internal version date, please put it in the header.

You also need to provide the following information:

- Who will conduct the consent process with prospective participants? Give the person's role in this study (PI, Study coordinator, etc.)
- Who will provide consent or permission? (Select all that apply)
    - Participant
    - Parent(s) or Legal Guardian(s)
    - Legally Authorized Representatives (LAR)
- How much time will the prospective participant (or legally authorized representative) have between being approached about participating in the study and needing to decide whether or not to participate?
- If you are not giving the person overnight to consider whether or not to participate, please justify.
- Where will the consent process occur?
    - Needs to be private
- What steps will be taken in that location to protect the privacy of the prospective participant?

- How much time will be allocated for conducting the initial consent discussion, including presenting the information in the consent document and answering questions, with each prospective participant?
- What arrangements will be in place for answering participant questions before and after the consent is signed?
- Describe the steps taken to minimize the possibility of coercion or undue influence.
- What provisions will be in place to obtain consent from participants who do not read, are blind, or do not read/understand English?