Written Documentation of Informed Consent

At least one option must be used to meet the requirement for documentation of informed consent. Select the method the investigator will use to document informed consent.

- *Refer to the Consent Process page of the study application, which will provide information about how the investigator will document informed consent.*

☐ Informed Consent will be documented in writing with a consent document.

- *If subject to FDA regulation, the participant or participant's legally authorized representative should date the document when signed.*

☐ Informed Consent will be documented in writing with a short form.

- *The short form must be signed by the participant or participant's legally authorized representative and the witness.*
- *The written summary (of the information presented orally) must be signed by the witness and the person obtaining consent.*
- *The participant or the participant's legally authorized representative must be provided both a copy of the short form and a copy of the written summary.*
- *If subject to FDA regulation, the participant or participant's legally authorized representative should date the document when signed.*

If this is not a VA study, please skip the following question:

○ Yes
○ No Is the consent in VA Format (10-1086) including PI name and title of study in the header?
Clear