**Purpose:** This template may be used to record and document the informed consent process.

**Responsibility:** To be used by Principal Investigator and study team members who are delegated to obtain informed consent.

**Procedure:**

* This template contains two types of text: instruction/explanatory and example text.
* **Instruction/explanatory text** are indicated by italics and should be deleted. Footnotes to instructional text should also be deleted. This text provides information on the content that should be included.
* **Example text** is included to further aid in document development and should either be modified or deleted. Example text is indicated in [brackets in regular font]. Within example text, a need for insertion of specific information is notated by <angle brackets>. Example text can be incorporated as written or tailored to a particular document. If it is not appropriate to the document, however, it too should be deleted.

**Documentation of Informed Consent Template**

**Participant/ID:**

**Protocol #:**

**Study Title:**

**Principal Investigator:**

**Consent Version Date:**

**Additional Consent Versions (sub-study, etc.):**

**Consent Obtained By:**

**Other Person(s) Present (specify relationship to subject):**

**Date of Consent:**

**Re-Consent? (Yes/No):**

|  |  |  |
| --- | --- | --- |
| **Topic** | **Yes/No** | **Initials of Person Verifying** |
| **Information presented** **in the language (\_\_\_\_\_\_\_\_\_) understandable to the subject.** |  |  |
| Discussed, explained, and reviewed the consent form with subject. |  |  |
| Subject was given time to review the consent form and to discuss participation in this study with family members/others. |  |  |
| All of the subject’s questions were answered/concerns addressed. Document below in Comments/Notes section.  |  |  |
| Subject did not have any questions/concerns. |  |  |
| The subject agreed to participate in the study and signed and dated a valid consent form prior to the start of any study procedures. |  |  |
| A copy of the signed and dated consent form was given to the subject. |  |  |
| The original signed and dated consent form was placed in the research record. |  |  |

**Signature/Initials:** **Date:**

**Additional Comments to Clarify the Consenting Process (questions/concerns discussed and consent reaffirmed):**

|  |  |  |  |
| --- | --- | --- | --- |
| Date | Time | Comments/Notes | Staff Initials |
|  |  |  |  |
|  |  |  |  |