**MODIFY TO FIT YOUR STUDY CONSENT PROCESS**

**(remove or edit all sections in red that are not applicable, including removing this header)**

**Informed Consent & HIPAA Authorization Process Documentation**

|  |  |
| --- | --- |
| Protocol: |  |
| Participant ID: |  |
| Visit Date: |  |
| PI/Designee: |  |

Prior to giving verbal/written informed consent and HIPAA authorization the participant (check all that apply):

Reviewed the currently approved/stamped Research Information Sheet/Consent Form with the researcher.

Discussed study participation with researcher including:

* + Purpose of the study
  + Risks/benefits
  + Alternatives
  + Who to call with questions
  + Withdrawal rights

Had the opportunity to ask questions and discuss the study with anybody they believe could help them make the decision regarding participation.

Agreed to participate in the study and personally signed and dated the consent form.

Informed consent and HIPAA authorization was conducted prior to any research-related procedures.

**Notes about the consent process** (e.g. what questions/concerns did the participant have, any special circumstances):

PI/Designee Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Possible additional information to collect during the consent process if approved in the protocol (modify above as needed):**

* The consent process was witnessed by an impartial witness.
* Translated consent forms were used and an interpreter was present.
* The participant agreed to optional portions of the study (e.g. audio or videotaping, sub-studies).
* Assent was obtained from child participant.
* A consent comprehension quiz was used to ensure participant’s understanding of the study.

**If approved for a remote consent process, please modify accordingly. Example language:**

* The approved IRB consent form was mailed/faxed/emailed to the participant.
* The participant had ample time and opportunity to review the consent form in advance, and then discuss it and ask any questions together with the investigator.
* List possible platforms for consent discussion (e.g. phone, Zoom, etc.).
* The participant signed the consent form and mailed/faxed/emailed it back to the researcher.
* The researcher signed the consent form and provided a copy of the fully executed consent form to the participant.