**MODIFY TO FIT YOUR STUDY CONSENT PROCESS**

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

**Consent & Authorization Process Documentation**

Protocol:

Subject ID:

Visit Date:

PI/Designee:

A capacity to consent evaluation was completed measuring the subjects understanding, appreciation, reasoning, and ability to express a choice about participating in the study.

The methods used to evaluate capacity to consent included:

* Put methods here including any standardized assessments administered

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (subject name) was determined to be

Able

Unable

to provide informed consent for this research study by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (staff name).

If unable include:

Thus, consent was sought from \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (name of surrogate decision maker; specify relationship to subject a surrogate decision maker) acting as a surrogate decision maker. The process of identifying the surrogate decision maker included:

* Specify the process used
* Specify if the subject was informed of the decision to seek surrogate consent

The surrogate decision maker was fully informed about the study and was provided a written research information sheet/consent document. During the consent process the surrogate decision maker

* Discussed the protocol with the researcher including:
  + Purpose of the study
  + Risks/benefits
  + Alternatives
  + Who to call with questions
  + Withdrawal rights
* Asked questions; and
* Had the opportunity to discuss the study with anybody they believed could help them make the decision regarding participation of the subject.
* Consulted with family and/or or other health care providers as desired.

Informed consent was conducted prior to any research-related procedures. Permission was obtained prior to the collection of limited (leave “limited” if obtaining verbal authorization) protected health information.

Other Comments:

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

Note: If applying verbal process, you must submit a request for Alteration of HIPAA and a Waiver of Documentation of Consent. Forms located here https://www.uvm.edu/rpo/human-subjects-research#IRB\_Waiver\_Alteration

(please delete this footer before use)