**MODIFY TO FIT YOUR STUDY CONSENT PROCESS**

**(To be used when a Legally Authorized Representative (LAR) is consenting on behalf of the participant.**

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

**Informed Consent & HIPAA Authorization Process Documentation**

|  |  |
| --- | --- |
| Protocol Study#: |  |
| Participant ID: |  |
| Date of consent documentation: |  |
| PI/Designee conducting consent process: |  |

If applicable, list the methods used to evaluate the participants capacity to consent:

* Include methods such as, standardized assessments, post consent quiz or alternative procedures for evaluating the presence of decision-making capacity.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Participant ID) was determined to be

Able

Unable

to provide informed consent for this research study by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(PI/consenting designee).

If unable include:

Thus, consent was sought from \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (name of LAR)

Specify relationship to participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please indicate who provided consent:

The decision-maker designated by the patient in a Living Will or Durable Power of Attorney for Health Care (“Advance Directive”)

A judicially-appointed guardian if the court order explicitly grants the guardian clinical decision-making authority pursuant to [14 V.S.A. § 3069 (c ) (2](https://legislature.vermont.gov/statutes/section/14/111/03069))

If the patient has not designated a decision-maker in his/her Advance Directive, consent may be obtained from a spouse, civil union partner, adult child, adult sibling, or other family member/friends. Providers should exercise their professional judgement when determining which family member(s) should be consulted as the patient’s surrogate decision-maker. In general, when determining who should serve as the surrogate decision-maker, providers should assess which individuals best knows what the patient would want in a given circumstance (i.e. the individual best equipped to offer a substituted judgement)

The LAR was fully informed about the study and was provided a written research information sheet/consent form. During the consent process the research team:

Discussed the protocol:

* + 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 allow participation in the study and personally signed and dated the consent form on behalf of the participant as their legally authorized representative.

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

Authorization was obtained prior to the collection of protected health information.

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

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