### Consent for adult subjects with potentially diminished capacity

The capacity of prospective adult subjects with the potential for having a diminished ability to provide consent will be ascertained by the study team. The prospective participant’s ability will be assessed during a brief conversation whose objective will be to gain a general sense of the individual’s ability to comprehend and communicate. If the individual potentially has the capacity to provide consent, the team will use a talk back procedure to confirm that the prospective subject understands the required elements of consent. The investigative team member will explain the consent form information and request that the subject explain back the information. The consent elements will include the following:

* 1. The purpose of the research study. We will explain that the study is trying to determine/understand XXXXXXX. We will ask the prospective participant to explain in their own words what the study is about.
  2. Study procedures will be explained with the aid of a picture book (or other study aid) that depicts the study visit and at-home procedures. We will then ask them to explain in their own words what each procedure will be like.
  3. The investigative team member will clearly explain that the prospective subject does not have to participate in the study, that they can change their mind about being in the study at any time, and that no one will be disappointed, upset or consider it a failure if they decide they do not want to continue with the study. Prospective participants will be asked to explain in their own words that they understand that they do not have to take part in the study and that there will be no consequences if they choose not to participate.
  4. The investigative team member will explain that subjects’ information will be kept private to the best of our ability. We will explain the risks of each procedure. We will also explain (describe the potential study benefits), but that it is also possible that they may not benefit from taking part in the study. Participants will be asked to explain in their own words what they understand about the risks and benefits of the study.

If subject does not have the capacity to understand one or more of the required elements of consent, then the prospective subject will not be able to consent. The subject’s legally authorized representative must then provide informed consent on the subject’s behalf. If the subject does not have a legally authorized representative, then the adult with diminished capacity’s healthcare representative may consent for them. The healthcare representative is determined in the following order - spouse, adult child who is not the child of the spouse, parent, adult sibling, and then adult grandchild (based on PA Act 169 (Advanced Directives)).

### Assent procedures for adults who do not have the capacity to consent

Whenever possible the investigators will obtain the assent of age who are not capable of consenting for themselves. When assent is obtained, it will be documented in the consent form. To have the capacity to assent, the subject must be able to understand the general purpose of the research and the nature of the procedures and must be able to understand the concept of voluntariness. If the capability of some of the participants is limited so that they cannot reasonably be consulted, assent will not be obtained; the investigators will document it on the consent form.