Guidance - Assessment of Capacity to Consent

Capacity to consent is defined as the ability to provide legally effective consent to enroll in a research study. When an adult does not have the capacity to consent to participate in the research, they cannot take part without the consent of their legally authorized representative (LAR). Ultimately the investigator is responsible for ensuring that all prospective subjects understand the required information in the consent form sufficiently to provide informed consent. The investigator must develop a plan to determine whether or not the prospective adult has the capacity to consent and if they do not.

Many individuals who lack the competence to consent to treatment still retain the capacity to consent to research. For example, an adult with diminished capacity may lack the ability to manage the complexity of their required healthcare or consent to a randomized clinical trial. However, they may have the ability to understand the purpose, procedures and other elements of consent for a minimal risk research study, such as one involving a blood draw or questionnaire.

When an investigator is studying a group of individuals that typically have diminished capacity to consent, additional materials such as PowerPoint, video or pictures can be used to assist individuals' understanding of the required elements of consent. The capacity to consent should be evaluated on an individual basis to avoid incorrect assumptions as to an individual's ability to make decisions.

Assessment of Capacity to Consent

EXMPLES:

Talk Back:
After reviewing the consent form, the investigators can use Talk Back to assess comprehension. Questions should be open-ended and should not involve 'yes' or 'no' questions. When there are areas of misunderstanding, the person obtaining consent should review and re-explain that aspect of consent.

Question **examples**:

- What did you understand to be the purpose of the research?
- What will you be asked to do in this research study?
- What are the risks of the study?
- What is the chance that you'll get the study drug/placebo?
- Will you have to pay for the study drug?
- What should you do if you change your mind about taking part in the research study?

Quiz / Questionnaires:
A post-consent quiz or questionnaire can be used to assess subject comprehension. There are a variety of standard tools that have been developed that can be adapted to the complexity of the study.

Professional Evaluation:
The study investigators may ask a physician/psychologist outside the research team to evaluate the potential participant's decisional capacity.

Consenting Plan for adults with potentially diminished capacity

EXAMPLE:

The capacity of prospective adult subjects with the potential for having a diminished ability to provide consent will usually be ascertained by the investigator or 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. If the study has IRB-approval for use of a Legally Authorized Representative (LAR), the subject's legally authorized representative must then provide informed consent on the subject's behalf.

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

Whenever possible the investigators will obtain the assent for those 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.

Based on the level of risk involved in the research and the likelihood that participants will derive benefits from participation, the IRB may consider additional safeguards to protect participants, such as:

- Requiring the involvement of participant advocates
- Requiring independent monitoring
- Requiring waiting periods
- Appointing a monitor to supervise the informed consent process