Impaired Consent Capacity in Adults: a new broad based policy

A fundamental principle of this forthcoming policy calls for investigators to pause and think about their potential subject population relative to consent capacity.

Consider these concepts:

- Impaired consent capacity is not limited to specific disorders but occurs in a wide range of conditions and disease states
- An individual's consent capacity is not simply absent or present– but best understood as occurring along a continuum
- Consent capacity is task specific and study specific
- Capacity may improve, fluctuate over time, or worsen

The new policy provides a unique multidimensional tool to aid investigators in developing a systematic consent capacity assessment that is tailored to the study population and research protocol. Suggested assessments range from informal verbal checks to validated instruments depending on the risk of the study, likelihood of capacity limitations, and potential for capacity fluctuations over time.

The policy also offers additional safeguards to protect the rights and welfare of these adult subjects and presents tools to enhance the consent process, enabling individuals to make competent decisions regarding study participation.

Learn more about new directions in assessing consent capacity at the March Clinical Research Update sponsored by the Clinical Research Development & Operations Center (CR-DOC). Your feedback is instrumental in shaping and implementing this policy. We will also solicit volunteers to pilot test the policy, forms and procedures.

New LAR Pamphlet Available

Legally Authorized Representatives (LAR) provide consent on behalf of a potential research participant. A new pamphlet entitled, Legally Authorized Representatives (LAR) of Adult Participants, is now available to help an LAR understand his/her special role in the consent process. The information presents considerations for making a decision on behalf of the potential participant as well as potential impact on caregivers.

Copies appropriate for Medical and Non-medical research are available to download from the ORI Research Participants webpage.

Special recognition goes to Robert Walker, Assistant Professor of Behavioral Science and IRB member for developing this educational tool. Thanks also to Allison Mateyoke-Scrivner, Center on Drug & Alcohol Research, for creating the pamphlets.