Proxy Consent
What Now??

Theresa Colecchia, JD
University Legal Counsel

Richard Guido, MD
IRB Chair
Today’s Topics

• **Review of Proxy Consent Process**
  – Legal Considerations
  – Regulatory Considerations

• **IRB Review**
  – Assessing decisional capacity
  – Documentation

• **Case Studies for discussion**
Basic Consent Considerations

- As a general rule, all adults, regardless of their diagnosis or condition, should be presumed competent to consent to participation in research unless there is evidence of serious disability that would impair reasoning or judgment
  - Diminished capacity to understand the risks and benefits for participation in research and to autonomously provide informed consent
  - Decisional impairment may result from a psychiatric, organic, developmental or other disorder that affects cognitive or emotional functions, or may result from the effect of drugs or alcohol
  - The impairment may be temporary, permanent or may fluctuate
IRB Considerations

- Common Rule Requirements
- Permitted Categories
- Subject Selection
- Consent/Assent
- Documentation
Regulatory Requirement

• When some or all of the subjects are likely to be vulnerable to coercion or undue influence, including those with cognitive limitations, the IRB must be sure that additional safeguards have been included in the study to protect the rights and welfare of these subjects (45 CFR 46.111 and 21 CFR 56.111)
Permitted Research Categories

The research bears a **direct relationship** to the decisionally impaired **subject’s condition or circumstance**;

The research also meets **one** of the following criteria:

1) presenting **no greater than minimal risk** to the involved subjects;

2) presents an increase over minimal risk to involved subjects, but which offers the **potential for direct individual benefit** to the subject;

3) presents a minor increase over minimal risk to involved subjects and which does not have the potential for direct individual benefit; provided that the knowledge sought has **direct relevance for understanding or eventually alleviating the subjects' disorder or condition**.
Subject Selection

• Research should have a direct relationship to the subject’s condition or circumstances
  – Does the research involve the study or treatment of the condition that has produced their decisional impairment, or is otherwise related to the subject’s condition?

• Subjects should be recruited from among non-institutionalized populations whenever possible
Additional Safeguards

The IRB can request that additional safeguards be implemented depending on the nature of the study:

- Independent party (independent of the study investigator with appropriate expertise) to assess the capacity of the potential subject;
- Standardized assessment of cognition and/or decisional capacity;
- Informational or educational techniques;
- Independent person to monitor the consent process;
- Waiting periods to allow for additional time to consider information about the research study.
Consent/Assent Considerations

- Mental illness, cognitive impairment or other disability alone should not disqualify a person from consenting to participate in research.
- Verbal or non-verbal objection raised by an adult with decisional impairment should be binding.
- Use assent in addition to proxy consent in order to respect the autonomy of individuals with decisional impairment.
Documenting Assent

The following information must be documented in the research record:

- whether the subject demonstrated the ability to understand the nature of the research procedures, the potential risks and benefits, the voluntary nature of the participation and to make a personal judgment about participation;

- use of any supplemental methods to enhance or evaluate decisional capacity;

- a summary of the matters discussed with the subject’s legally authorized representative
Who Can Consent When the Participant Cannot?

- The Common Rule requires written consent from the participant or the participant’s “legally authorized representative.”
  45 C.F.R. § 46.116

- Who is a “legally authorized representative” is determined by state laws?
Legally Authorized Representative

• An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research (45 CFR46.102)

• Pennsylvania State law
  – Pennsylvania is a battery state for medical consent
  – Pennsylvania state law creates a hierarchy of surrogate decision-makers for medical consent
  – Only one statute specifically addresses research consent
Court-Appointed Guardian

- Persons who have been adjudicated under Pennsylvania law as “incapacitated” can be enrolled in research by their court-appointed guardian only if:
  - the court order appointing the guardian specifically states that the guardian has authority to consent to the enrollment of the person in “any experimental biomedical or behavioral medical procedure or participation in any biomedical or behavioral experiment.”

- A copy of the court order must be maintained with study documentation.
Pennsylvania law allows for an advance health care directive, under which a patient may appoint a proxy to make medical decisions in the event that the patient becomes incapacitated in the future.

Where a potential research participant has executed such a directive, that document should be consulted to confirm the correct holder of the proxy and to determine if the holder of the health care proxy can consent to the enrollment of the patient in the procedures contemplated in the protocol.
When There Is No Written Proxy Or Order, Who Decides?

- If no guardian or health care proxy use the following order:
  - Spouse
  - Natural or adoptive parent
  - Adult child
  - Adult brother or sister
  - Other adult relative through blood or marriage known to have made health-care decisions
What Is the Proxy’s Role?

"Since the right of self-determination can only be exercised by a person competent to evaluate her condition, a patient lacking this capacity forfeits her right of self-determination unless the surrogate decision-maker, standing in the place of the incompetent, asserts the patient's preference. . . . [citation omitted]" In re Fiori, 438 Pa. Super. 610, 651, 652 A.2d 1350, 1370-71 (1995) (en banc) (Popovich, J., concurring and dissenting) (emphasis added), alloc. granted, 540 Pa. 600, 655 A.2d 989 (1989)."
Whose Law do you Follow?

- For the consent to be legally valid, it must comply with the state law where the procedures are carried out.
- Many states do have specific laws regarding research proxy consent (e.g., Virginia, Oklahoma) and their requirements may be different.
After Proxy Consent

- Regulations do not explicitly describe all of the circumstances that might require repeating or supplementing the informed consent process
  - Intermittent or temporary impairment, include a mechanism for obtaining the subject’s subsequent direct informed consent to participate in the research
- If a subject regains decision making capacity and declines to continue in the research, the decision must be respected
Consent is an On-Going Process

- Assessing and enhancing comprehension at each stage may be essential
- Single sheet summaries of important information about key elements of the studies
- Encourage study participants and their families to ask questions regularly
- Use of videos demonstrating study interventions or use of post-tests to document comprehension
If the Participant Regains Capacity to Consent

- Obtain the direct consent of the individual for the remaining part of the study
- Disclose all research procedures performed to date and allow the individual an opportunity to continue in or withdraw from the study
- Participant should sign the consent document
- Research record should document what research procedures were already performed or remain to be performed
Resources

• HRPO website
  – Policies and Procedures
    • Chapter 14; Research Involving Decisionally Impaired Individuals

• Secretary’s Advisory Committee on Human Research Protections (SACHRP)
  – Recommendations from the Subcommittee for the Inclusion of Individuals with Impaired Decision Making in Research (SIIIDR)
    – http://www.hhs.gov/ohrp/sachrp/20090715letterattach.html#
CASE STUDIES
Case #1

I am conducting a drug and behavioral intervention study and have proxy consent approved. My population is individuals with schizophrenia who, depending on their current mental status, may be able to provide consent.

Since most of my participants were enrolled by proxy, am I required to re-evaluate the capacity for consent at each study visit?
Case #2

I am conducting a drug trial and all of my subjects will be intubated and therefore sedated at the time of enrollment. The IRB has approved proxy consent but I am not sure at what time point I must assess the capacity to provide consent. They may still be critical but have lucid periods.

- Obtain consent at time when they are alert/oriented?
- Wait until they are off the respirator?
- Wait until no sedatives/narcotics?
- Get independent opinion on ability to provide consent?
Case #3

We are conducting a study of traumatic brain injured subjects who were unconscious or lack the ability to consent at the time of admission. The IRB has approved proxy consent.

Most of the research interventions are completed within the 48 hours of admission leaving only a questionnaire to be completed at 28 days post injury.

Am I required to consent subjects just for the last activity?
Case #4

Study is the progression of disease for individuals with early Alzheimer's disease who will be followed for seven years. Procedures include blood draws and cognitive testing.

The IRB approved proxy consent for the study.

- Re-evaluate consent at each visit?
- Demonstrate the subject is competent to continue?
- Reassess competency at each visit?
- If combative, continue to perform research blood draws and cognitive testing?
- What if the family obtains a guardianship at some point?