Coordinating the Consent Process

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Objectives

- Identify the methods used to obtain informed consent using Good Clinical Practice (GCP)
- Recognize the informed consent as an ongoing interactive process between the patients and the clinician
What does it mean to be informed?

The active process of information sharing between the PI and subject
Who Can Consent?

- Only those designated on the IRB’s Authorized Personnel List (APL)
- A study coordinator may assist in the process by providing information, but cannot fully consent the research subject for interventional studies.
- Only the PI or designated medical professional can disseminate medical information related to the study
Why do we need a consent?

- Protection of rights and welfare of research subjects
- Informs the research subject of the nature of study
- Confirmation of participation
Ensuring Patient Rights

- Assessment of level of understanding
- Instruction and discussion tailored to the subject
- Short form
Barriers to Consenting

- Fear
- Mistrust
- Perception of coercion
- Vulnerable populations
- Language barriers
- Cultural differences
Eight Elements of Informed Consent

- Purpose of the study
- Risks
- Benefits
- Who may benefit?
- Alternative treatments
- Confidentiality of medical information
- Compensation
- Study-related injury
How do we know the subject really understands the consent and study?

- General demeanor
- Engaged in the discussion?
- Ability to re-state the process in own words
Purpose of Study

- Describes the nature of the research
  - Advancing new science
  - Building on existing standards
Risks and Benefits

- Balancing Ratio
  - Risk vs. Benefit
  - Safety and Efficacy
Who benefits from participation?

- What’s in it for me?
- Will someone else benefit?
- Participation is voluntary
Alternative treatments

- What happens if I become ineligible?
- Is there something else for me?
Confidentiality

- Who will be looking at my records?
- Where does this information go?
Compensation

- Will I be paid for this study?
- Will subjects be compensated for parking and/or transportation?
Study related injury

- Whom do I call?
- Who pays for my injury?
Provide an Optimal Environment

- Allow ample time to read the consent
- Allow time for questions
- Can the patient take the consent home?
- Encourage notes
- Copy the consent
- Provide IRB-approved educational handouts
Re-consent

- Whenever the study protocol has been amended and the changes directly affect the patient’s course of treatment.
Can I change my mind?

The research subject can change his/her mind at any time and withdraw consent.
Subject Advocacy

- Listen to the patient
- Offer concise information
- Provide on-going support
Resources

- Manager, team members
- Principal Investigator
- Web Information
- IRB
Coordination of Care

- Study coordinator
- Registered Nurse
- Medical Doctor
Thank you!
COORDINATING THE CONSENT PROCESS:

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Coordinating the Consent Process

What do you do when your potential study subject is not able to consent for themselves?
Consent and the LAR

- Objectives:
  - Identify laws that impact the consenting process
  - Who can be designated as LAR
  - How to obtain consent from the LAR
Consent and the LAR

What is a LAR?

L Legal
A Authorized
R Representative
Federal Law- DHHS and FDA regulations define a LAR as 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 CFR 46.102(c); 21 CFR 50.3(l)]
"Surrogate decision maker" means an adult individual or individuals who (i) have decisional capacity, (ii) are available upon reasonable inquiry, (iii) are willing to make medical treatment decisions on behalf of a patient who lacks decisional capacity, and (iv) are identified by the attending physician in accordance with the provisions of this Act as the person or persons who are to make those decisions in accordance with the provisions of this Act.

(Source: P.A. 95-331, eff. 8-21-07.)
Consent and the LAR

- Local-Institution
  - Advance directives
  - IRB policy (NWU-page 29)
When do you need a LAR?

- When experimental treatment is being provided to an adult patient who does not have capacity to make their own medical decisions.
Who can be the LAR?

- Health Care Surrogate: Individual named by person while competent to act (Durable Power of Attorney)
- Guardian: Individual appointed by the court
- Surrogate under the Healthcare Surrogate Act:
  - Spouse
  - Adult child
  - Parent
  - Adult sibling
  - Adult grandchild
Now that you know who, how?

- Type of study
  - minimal risk
  - Greater than minimal risk
Consent and the LAR

- Direct
Consent and the LAR

- Telephone: may be option for minimal risk studies
Consent and the LAR

- Facsimile/email
Re-consent process

- Once subject is able to make decisions and the LAR has initially authorized consent you must remember to try and obtain consent from subject for continued participation
Scenario

- 78 year old female admitted to CCU with a diagnosis of non ST elevated myocardial infarction (NSTEMI). Developed recurrent chest pain and has received morphine and nitroglycerin. She is candidate for experimental angioplasty catheter. Husband is 84 years old with dementia. She has 56 year old son in Florida and 50 year old daughter present. No durable power of attorney designated.
Who do you consent?
Scenario -

55 year old male subject was in a motor vehicle accident and is on a breathing machine and has developed septic shock. Subject is a candidate for an experimental therapy aimed to prevent further organ damage. Subject is divorced. Ex wife and girl friend are at the bedside. Both parents are deceased and there is no durable power of attorney designated. Subject has an 18 year old daughter off at college and 16 year old son.
What do you do?
Scenario

- Study coordinator was notified by primary team about a potential study subject for CVVH study. Patient was alert and oriented and making medical decisions. Had a POA designated as the eldest daughter.
Who do you consent?
Summary
- Be familiar with your applicable laws and policies
- Identify the proper individual designated as LAR
- When/if able, re-consent the study subject for continued participation
Thank you