2011

Challenges with consent

Jonathan Green
Washington University School of Medicine in St. Louis

Jeanne Velders
Washington University School of Medicine in St. Louis

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Jeanne Velders, JD
Washington University in St. Louis

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The process of consent

- The process should be tailored to the type of study and circumstances of the populations being recruited:
  - How much time will the individual have to consider participation?
  - Where will the consent process occur? The setting should be private.
  - Individuals involved in the consent process should have a good understanding of the study and be able to answer questions.
    - For treatment studies, we would expect there will be an overlap of clinical and research questions.
  - The overall consent process (timing, setting and presentation of the study) should occur under circumstances that avoid coercion or undue influence.

Who can obtain consent?

- This should be described in your IRB application.
- The IRB can require that certain individuals be involved in the consent process.
  - Example: The IRB could determine that based on the risk and complexity of the study only the PI may obtain consent.
- If the consent process is delegated by the PI to another individual they must be
  - fully trained
  - aware of all aspects of the study and;
  - the PI must still be available to answer questions

Residents obtaining consent

- There are Institutional requirements for Human Subject Research Training
- Satisfaction of this requirement is tracked in the myIRB application.
- IRB must be aware of and approve all individuals "engaged" in the research to ensure qualifications and define IRB oversight.
- Adding someone to the myIRB application-DEMO!!
- The PI is responsible for ensuring that these individuals have a good understanding of the study and can answer questions.

The Consent Document

- The consent document is the only written record we have that says exactly what it is that you will tell the subject.
- It must contain all information that a reasonable person needs to know to decide whether or not to participate in the study.
- Should be presented in a way that is understandable.
- It must contain information that addresses specific regulatory requirements.

Signing the Consent Document

- IRB policy:
  - Participant and person obtaining consent must sign and date the consent document
  - The participant (LAR, if applicable) must be provided with a signed copy of the consent document.

Signing the Consent Document

- Until the participant signs the consent document do not make assumptions based on earlier conversations
  - The participant could be in full agreement and the next day/hour/minute change their mind.
  - Once the participant signs, it will be the responsibility of the participant to let you know if they changed their mind.
- Person obtaining consent
  - Not advisable to sign prior to the participant…why?
    - See prior bullet point
    - A “meeting of the minds”, “a mutual agreement”
    - Can create questions about the validity of the consent process.
- Investigator acknowledgement
  - Not an IRB requirement

Signing the Consent Document

- The participant:
  - "Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study."
- Person obtaining consent:
  - "The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that he or she understands the risks, benefits, and procedures involved with participation in this research study."

Timing of Consent

- The amount of time required by a subject to make a decision will depend on the nature of the study, the degree of risk, potential benefits, alternatives, and desire to consult with family members or others.
- If a prolonged period of time elapses from the date of consent to the date of entry into the study even if there have been no changes in the study design or no new significant findings affecting the study it might be prudent to review the information contained in the consent form with the subject prior to initiating any research procedures with the subject.
- OHRP FAQs on consent

Decisionally impaired individuals

- Enrolling individuals that are decisionally impaired or that could become decisionally impaired over time requires IRB approval.
- Considered a vulnerable population
- IRB will want to know:
  - Why is it ethically appropriate to include this population?
  - In the alternative, consider if it is appropriate to exclude the population.
  - How will you assess competency?
  - Will you obtain assent from the participant?
  - How will you consent the LAR?
  - How will you ensure the LAR understands their role?

Use of the LAR

- Who can sign?
- If the participant has a legal guardian or attorney-in-fact this individual must sign as the LAR.
  - If there is no legal guardian or attorney-in-fact the individuals listed below may sign in order of priority.
    - (1) Spouse unless the participant has no spouse, or is separated, or the spouse is physically or mentally incapable of giving consent, or the spouse's whereabouts is unknown or the spouse is overseas;
    - (2) Adult child;
    - (3) Parent;
    - (4) Brother or sister;
    - (5) Relative by blood or marriage.

Use of the LAR

- How to use the priority list
  - Recognize that this process is different than in the clinical setting
  - There is no “reasonably available” exception when going down the priority list.
  - For example, if the participant does not have a spouse but has an adult child, that is the person that can provide consent. You cannot go to the parent if they are more conveniently available.

Use of LAR in minimal risk studies

- Possible policy change forthcoming
- For minimal risk studies where there is no legally appointed representative will allow other individuals listed on the priority list to give consent even if not first on the list.

Non-English Speakers

- Enrolling individuals that do not speak English requires prior IRB approval.
- Whenever possible, the consent document should be in a language understandable to the subject, and include all the elements necessary for legally effective informed consent. Subjects who do not speak English should be presented with a consent document written in a language understandable to them. Memo from OHRP

Short Form

- A “short form” includes an oral presentation of informed consent in conjunction with a short form document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally. A witness to the oral presentation is required, and the subject must be given copies of the short form document and the summary.
  - Oral presentation and short form should be in language understandable to the subject
  - The English version of the consent may serve as the summary
  - The witness should be fluent in both English and the language of the subject
  - Short form signed by participant, the summary signed by person obtaining consent, the short form and summary signed by the witness (the translator may be the witness)

Allowing use of the short form

- When would the IRB allow use of the short form in lieu of a fully translated consent?
  - The issue: Depending on the type of study the participant may need a reference document (the consent) or ongoing translational support to stay fully informed once they go home.
  - How complex is the study, what are the risks, what is the ongoing involvement of the participant?

Other unique challenges

- Physically unable to sign
- Visual impairments
- Unable to read or write
- “Making their Mark”

- We have guidance!!

Physically unable to sign

- The individual must be competent.
- The individual must be able to indicate their approval or disapproval
  - Verbal, raise hand, nod
  - “making their mark” is considered a valid signature
- Person obtaining consent should document the method used to communicate approval on the consent
- Impartial witness present during consent process
  - Below signature block have witness sign and indicate they witnessed the consent process and the individual agreed to participant by <insert method>.

Visual impairments/Cannot read or write

- The individual must be competent.
- The individual is able to indicate their approval or disapproval.
- There must be continuing support to relay information in the consent document such as: what is involved, risks, contact information for PI and WU IRB.
- Procedure:
  - document method of agreement, if not signing consent or "making mark"
  - impartial witness present during consent process
  - written attestation to consent process by witness

Take home points

- The consent process is a critical element of good human subjects research and a critical part of the IRB review process.
- The consent process will be driven by the circumstances of the study.
- The signatures should represent the flow of the consent process.
- When using LARs research is different than clinical care
- Tell the IRB what you are doing!!

Questions?