Informed Consent Training

University of Florida Institutional Review Boards Brown Bag Series

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Learning Objectives

- Informed Consent Form vs. Informed Consent Process
- Requirements
- Special Situations
- Survival Tips
Informed Consent as BOTH a Form and a Process

- Informed consent involves:
  - Information
  - Comprehension
  - Voluntariness
Basic Elements of Informed Consent

General Requirements for Informed Consent as Indicated in the Common Rule

- A statement that the study involves research
- An explanation of the purposes of the research
- The expected duration of the subject's participation
- A description of the procedures to be followed
- Identification of any procedures which are experimental
- A description of any reasonably foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others which may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled
Additional Elements of Informed Consent as Appropriate

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
- Any additional costs to the subject that may result from participation in the research
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
- The approximate number of subjects involved in the study
Informed Consent Form Tools

- UF Informed Consent templates: IRB-01 and IRB-02
  - Tip: The ICF must be consistent with the study protocol and myIRB SmartForms
- Standardized Text for Informed Consent Forms: IRB-01 and IRB-02
- All consent documents should be written at an 8th grade reading level. A Glossary of Lay Terms for Use in Informed Consent Forms is available.
- Informed Consent Checklists:
  - Office for Human Research Protections
  - IRB-01 Informed Consent Process Checklist
  - IRB-02 Informed Consent Document Checklist
Who Can Obtain Consent?

- Only IRB Approved, trained research personnel may obtain consent.
- **Approved Human Research Roles Guideline** describe the research roles for which individuals may be eligible
  - Consider feasibility.

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The Informed Consent Process

- Informed Consent must be obtained **before** the subject is involved in the research.
  - **NO FORM. NO DATA.**
- Use of an IRB approved ( stamped and dated) informed consent form
  - **Tip:** To get a stamped document (e.g. informed consent, flyers, phone scripts, etc.), go to myIRB rather than to your share drive or personal computer
- Review the informed consent form with the subject and/or Legally Authorized Representative (LAR).
- Discuss all elements of the informed consent including: purpose, procedures, risks, benefits, alternatives to participation, etc.
- You MUST allow the ample opportunity to ask questions. Following this explanation, the subject is provided a consent form and given sufficient time to consider whether or not to participate
- After allowing the subject to read the consent form, further discussion and opportunity to ask questions should be afforded. The Investigator is responsible for assessing for subject comprehension.
- Once an individual has had all of their questions answered and has agreed to participate in the study, the subject should sign and date the consent form.
- The Investigator who has reviewed and consented the subject also must sign and date the consent form.
  - The Investigator's signature cannot pre-date the subject's signature.
- The subject should always be provided with a copy of the consent form to use as continual reference for items such as scheduling of procedures and for emergency contact information.
- **Note to File or Documentation of Consent Process**
Informed Consent Process is Ongoing

- Discussions regarding the research must be had with the subject before, during, and after signing Informed Consent Form.
- Subjects must be made aware of any changes in the research.
  - Re-consent?
Survival Tips

- Be consistent across all study documents including but not limited to the study protocol, ICF, and myIRB smartforms
- Write a flexible protocol
  - Provide broad ranges and few limits
  - Anticipate difficulties with conduct of the study and accommodate for them in the Protocol
- Keep organized
  - Keep original Informed Consent Forms separate from the research records
  - All records related to individual studies should be kept together, in a labeled file folder
- Use an Enrollment Log
  - Track the number of enrolled participants and dates of enrollment as this helps with version control
Obtaining Consent: Special Situations

- IRB-01 Guidelines for obtaining consent in special situations
- IRB-02 Special Population Requirements
Obtaining Consent: Special Situations

- **Assent of Children**
  - Assent is not recommended in children less than 7 years old, irrespective of risk or benefit;
  - Assent is recommended, but not required for children between the ages of 7 and 14, irrespective of the risk or benefit;
  - Assent is required* for children over the age of 14, irrespective of the risk or benefit.
    - a. Unless there is an incapacity
    - b. If there is potential for direct benefit, and there is a conflict between the subject and LAR, then an Ethics Committee review is required*.

*Required: this is the preferred recommendation. However, the IRB can opt not to require assent depending on the project or situation.
Obtaining Consent: Special Situations

- When a subject can not read or write English
  - Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak or Read English Guideline
  - If it is likely that the research population will include non-English speaking participants, the IRB approved informed consent must be translated into the native language of the subject population, with a back-translation of the document, if appropriate. Translations must be performed by a qualified third party, and must be submitted for IRB review following approval of the final version of the English consent document.

- If your study does not specifically target subjects who cannot speak or read English, regulations permit the use of a “Short Form” to be used along with
  - (a) an approved Informed Consent form and
  - (b) a translator (or third party outside the research team who reads the English version to the potential subject).

If your study targets English speaking subjects and you happen to have a subject who cannot read or speak English; have a translator read the short form to the subject and obtain appropriate signatures. The translator must also translate your “full sized” normal consent(s), and if the subject agrees to participate obtain signatures as usual. Per our Investigator Guideline, the translator should sign the full Informed Consent form.
Waivers or Modifications of Consent

- **Waiver of Documentation of Informed Consent** - The researcher will still inform the potential subject about the research and seek to obtain consent, sometimes by including an IRB approved written statement that includes the mandatory elements of consent. However, consent of the subject is not documented by having the subject sign an Informed Consent form.
  - **Waiver of Documentation of Informed Consent Sample Letter**

- **Modification of Informed Consent** - Written Informed Consent is obtained in a non-standard way (e.g. delaying written informed consent or **Telephonic Consent**)

- **Full Waiver of Informed Consent** - Subjects will not be informed nor will consent be sought or obtained prior to their involvement in the research (including collection of data from identifiable records or tissue). The study **must meet specific criteria** to obtain a full waiver of informed consent and you are **required to describe and justify** why the research could not practicably be carried out without the waiver.
Questions?