Protecting people who participate in research

CITI Training Study Guide

Informed Consent

Informed Consent – the Process

- **Begins with recruitment and screening**
- **Continues throughout subject's involvement in the research**

Informed Consent – the Process

- **Provides specific information about the study in an understandable way**
- **Gives potential subjects time to consider their decision**
- **Result is voluntary agreement to enter the study – at any time during the research, subject may withdraw, decline to answer specific questions, or decline to complete specific tasks**

Informed Consent – Documentation

- Provides a record that the consent process took place
- Generally consists of a consent form read and signed by the subject or the subject's legal representative; can be oral and documented by an impartial witness (requires 2 forms)
- Documentation can occur by other means approved by the IRB, such as audio or video recording

Basic Required Elements of Informed Consent

- Statement that the study involves research, explanation of its purposes, expected duration of participation, description of procedures, identification of procedures that are experimental
- Description of reasonably foreseeable risks or discomforts to the subject
- Description of reasonably expected benefits to the subject or to others
- Disclosure of alternative courses of treatment that may be advantageous to the subject

Basic Required Elements of Informed Consent (continued)

- Description of records confidentiality
- Explanation of any compensation
- Explanation of available treatment if injury or distress occurs as a result of participation
- Whom to contact with questions about the research or participants' rights, or in the event of injury or distress
- Reminder that participation is voluntary and may be discontinued at any time – refusal to participate involves no penalty or loss of benefits

Additional Elements of Informed Consent – depend on nature of research and risks involved

- Description of costs that might be incurred
- Circumstances under which participation can be terminated by researcher
- Consequences of the subject withdrawing (e.g. for compensation), and procedures
- Statement that significant new findings that may affect participant will be disclosed to participant
- Approximate number of participants in study

Informed Consent – Begins with Recruitment

- All forms of recruitment must be reviewed & approved by IRB
  - Fliers
  - Email messages
  - Newspaper ads
  - Phone calls
  - Etc.

Informed Consent – Legal Rights

- Informed consent form may not ask subjects to waive legal rights or to release researcher, sponsor or institution from liability for negligence.
- May not even appear to ask this.
- Institutions may provide information about how liabilities would be covered.

Informed Consent –
Ensuring the Subjects' Comprehension of the Consent Form

- Reading level of the research description
- Language – IRB may require independent confirmation of the accuracy of the translation
- Culture – for example, a researcher may engage a community member to answer questions without researcher present
- Presentation – organization of content, images, use of questions, use of story telling

Informed Consent –
Avoid the possibility of coercion
(especially for vulnerable groups)

Examples of subjects feeling coerced or unduly influenced

- Adolescents whose parents or peers are in the room
- Parents asked by the school principal
- Athletes recruited by coach
- Employees recruited by employer
- Payments so high that subjects feel they can't afford to decline, or will misrepresent themselves in order to participate

Informed Consent –
Waiver of elements by the IRB

IRB may allow researcher to omit one or more informational elements if, and only if:

- Research involves no more than minimal risk to subjects
- Waiver will not adversely affect subjects' rights and welfare (e.g., subjects are not tricked into participating in a study they would object to)
- Research cannot practicably be carried out without the waiver
- When appropriate, subjects will receive additional pertinent information after participation

Informed Consent – Examples of Waivers

Deception:

- May be justified if essential to investigate a particular phenomenon, e.g., susceptibility to peer pressure
  - Subject may be told up front that the study is about something else.

Complete non-disclosure:

- When subjects may alter their behavior knowing they are being observed

Informed Consent – What Constitutes a Child's Assent?

It's up to each IRB to:

- define which elements must be included
- determine how to document the child's assent

Informed Consent – Waiver of Documentation

- Principal risk is breach of confidentiality concerning subject's participation, and consent form is the only record linking subject to study; OR
- Participation presents minimal risk of harm, AND
  - Procedures would not require consent if they weren't part of a research project
    - Example: telephone survey