Informed Consent

UWCC

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Informed Consent: Definition

A **PROCESS** by which a research participant voluntarily confirms his or her willingness to participate in a particular research study, after having been informed of all aspects of the study that are relevant to their decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.

Ethical Basis for Informed Consent

- Humans are autonomous and have the right to make important decisions in their life.
- Participation in research is not an obligation.
- Research participants often face additional risks beyond standard medical care, and do so for the good of other people.

Ethical Basis for Informed Consent

The basic function of informed consent is to provide research volunteers with the information they need in order to make their own voluntary choice about whether or not to participate in the research.

This allows volunteers to exercise their autonomy when considering research participation.

Ethical Basis for Informed Consent

Informed consent alone does not make a study ethical.

There must also be:

- minimization of risk
- appropriate risk/benefit ratio
- fair selection of subjects
- safety monitoring
- protection of confidentiality
- consideration of additional safeguards for vulnerable populations

Purpose of Informed Consent

- To provide potential subjects with adequate information about the study and their rights, so that they may make an informed decision about being in a research study
- To facilitate understanding
- To provide documentation of agreement to participate in a study
- To provide continuing information to a subject about a research study

Principles of Informed Consent

Informed Consent must:

- Be approved by IRB
- Be obtained prospectively (before research begins)
- Provide sufficient opportunity/time to:
  - Consider options, participation and ask questions
  - Ensure subject comprehends information
- Minimize possibility of coercion or undue influence
- Be in language understandable to subject/representative
- Contain basic elements + additional elements as required
- NOT contain exculpatory language that
  - Waives or appears to waive subject's legal rights
  - Releases investigator, sponsor, or institution from liability for negligence
- Be documented

Who Can be Involved?

Human Subject

Principal Investigator

Study Staff / Consent Designee

IRB/ Research Subject Advocate

Family / Friends

Legally Authorized Representative

Witness

Who: Special Consent Situations

Non/Limited-English Proficiency

Literacy Challenges

Cultural Differences

Sight and Hearing Impaired

Capacity to consent

Who: Non/Limited-English Proficiency Subjects

The consent must be in language understandable to the subject and/or representative

Translated version must be:

- Certified
- IRB approved

Translator to facilitate questions and answers

More information:

- http://www.hhs.gov/ohrp/humansubjects/guidance/ic-non-e.htm
- http://irb.jhmi.edu/Guidelines/nonenglishconsent.html

Who: Literacy Challenges

1993 survey of > 90 million Americans

48% of American Adults have low literacy skills

SoCRA SOURCE May 2004

Document the challenge and what you did to obtain consent in the situation.

Capacity to Consent

- Participants must fully understand what they are agreeing to do and this must be documented.
- New procedures for Exam 7, first introduced in MESA Mind.

- More on capacity in a few minutes!

Who: Other

Cultural Differences: Consider consulting with someone that has knowledge of the culture.

Sight and Hearing Impaired: Must be IRB approved. Provide alternate methods of communication.

Who Signs and Dates the Consent Document?

Person who obtained consent

The subject **must** sign **and** date the consent form. Unless….

- Subject unable to consent
  - LAR gives consent, participant signs assent

Witness (if used)

Anyone else, as required by the IRB

Written Informed Consent

Provides a Summary of Study

Discusses Rights as a Subject

Starting Point for Necessary Exchange of Information

Written containing all required elements

When to Consent

After

- IRB approval
- Subject has been given adequate time to:
  - Review consent form
  - Ask questions
  - Consult family/friends

Before

- Any study procedures are performed

Where Should Consenting Take Place?

The consenting process should take place in a private, neutral setting.

Where Should Consents be Stored?

Signed consents should be stored:

- Original – study/medical record
    - Electronic record – document consent
- Copies – secure location

Consents should be copied for use as needed

How to Document Informed Consent

Use IRB approved consent form

Must be signed and dated by subject (legally authorized representative when appropriate) before participation

Must be signed and dated by person obtaining consent at the time subject signs.

Must give copy to participant (signed is better!)

Must place original in study/medical record

Tips for Improving Understanding

- Know your target audience
- Use visual aids, charts or pictures to relay complicated or detailed procedures
- Use interactive techniques such as leaving a space for questions
- Test the consent form before use

Remember…

Informed Consent is a **process**, not just a form

The document is a **teaching tool**

The document should **describe** the overall experience that will be encountered

Why Do All of This?

To protect human subjects while trying to discover new and improved ways to understand and treat conditions or diseases

Potential Consent Documentation Deficiencies

Date discrepancies

Missing dates

Missing signatures

Improper correction technique used

Most recent IRB-approved consent is not used

Expired consent forms

Hand written changes to a consent form

Non-IRB approved consenters

Practical tips to overcome/Ongoing Dilemmas

- Time, time, time and more time.
- Whenever possible, provide the form to the volunteer prior to the consent discussion.
- Use short words, speak slowly and clearly
- Stop and address questions as you go along.
- Engage the volunteer in conversation about the material
- Assess comprehension systematically. List of specific questions, written questionnaire.
- Re-iterate information during the course of the study.

Capacity to Consent

Procedure is new to MESA

For Participants WITHOUT a known history of dementia:

MESA-Mind introduced the UBACC, a well validated instrument to assess capacity to consent.

A tool to help identify whether participants understand what is being asked of them, and therefore if they are able to provide consent.

All participants without a known history of dementia (or who were not flagged as a result of MESA Mind Visit A) will be asked three questions. Participants must respond to all three questions correctly.

If any of the three questions is incorrect, proceed with administering the entire UBACC.

Participants have three "tries" to get entire UBACC correct.

Participants must get a perfect score.

If the participant is unable to consent as determined by UBACC administration, a LAR (Legally Authorized Representative) is needed to give consent on behalf of the participant, and the participant must also give **assent**.

Capacity to Consent

Procedure is new to MESA

Consent for Participants with known cognitive impairment:

If participant is deemed unable to give consent, a LAR (Legally Authorized Representative) is needed to give consent on behalf of the participant, and the participant must also give **assent**.

Participants with a known cognitive impairment must bring an LAR to the MESA clinic visit. These participants will review and sign the MESA Assent Form and their LAR will review and sign the MESA Exam 7 Consent Form. Do not administer the UBACC questions to these participants.

Lack of capacity to consent is defined as:

1) Had to have an LAR at MESA Mind Visit A
2) Were adjudicated with probable dementia at Visit A (2-3% of cohort)
3) Have a clinical diagnosis of dementia

This information will be provided in the Contact History Report on the MESA website and in the Participant Information Form in the MESA Exam 7 REDCap program.

Capacity to Consent - LAR

Procedure is new to MESA

An LAR (Legally Authorized Representative) is someone who can give consent on behalf of a prospective research study participant, according to applicable state **and** local law.

The legal criteria for selecting an LAR may differ by state and local IRB

***Ensure you know your site IRB's requirements for:

1. Capacity to consent
2. LAR criteria

For LAR consent:

Go section by section reviewing the entire consent.

Ask questions to ensure the LAR understands what was discussed and ask them to return the information (to confirm they understand)

Encourage the LAR to ask any and as many questions as they have about the study and process.