

Informed Consent: All the Things You Need to Know!

Presented by:

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Today's Agenda

- What is Informed Consent?
- Basic Elements of Informed Consent
- Types of Consent
- Documentation of Consent
- Common Rule Changes
- Consenting Tips and Tricks
- Brief Video
- Q&A

What is informed consent?

- Informed Consent is a voluntary agreement to participate in research
- Obtaining consent is process that begins before enrollment and is ongoing throughout the participation of the study



Basic Elements of Informed Consent



- *Purpose* of the research
- *Procedures* involved in the research
- *Alternatives* to participation
- *All foreseeable risks and discomforts* to the participant
- *Benefits* of the research
- *Length of time* of participation
- *Contact info* for answers to questions or in the event of a research-related injury or emergency
- Statement indicating that participation is voluntary
- Statement regarding the participant's right to confidentiality and right to withdraw

Types of Consent

- Written long form consent
 - Written short form consent
 - Waiver of documentation of consent (verbal consent)
 - Online consent
 - Parental permission
 - Child assent
 - Waiver of consent
 - Foreign language consent
1. Utilized for non-English speaking participants
 2. Utilized for participants under the age of majority
 3. Most common type utilized for a face-to-face consent process
 4. Utilized for minimal risk research involving surveys sent through the mail or conducted over the internet, telephone interviews, or the collection of sensitive information without a written record that could identify participant
 5. Utilized when the research is conducted without obtaining consent (medical chart reviews, analysis of existing data)
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Documentation of Consent

- Documenting informed consent occurs **after** explaining the research and assessing participant comprehension, this could be after the potential participant has had an opportunity to make a decision about the research, sometimes going home and discussing with family and/or friends, asking questions, etc.
- At minimum, it involves obtaining the signature of the participant as well as the person obtaining consent (if required by the IRB). The person obtaining consent indicates he/she has explained the research to the participant, ensured that the participant understands the research, and that the participant freely consents to participate.

But how do I document the written consent process?

- Create a Documentation of Consent Process form
- Utilize a spreadsheet
- Notes in the participant file
- Documentation in the medical record
(used on occasion depending on study type and complexity)

Study Title: _____
 PI: _____
 IRB #: _____

DOCUMENTATION OF CONSENT PROCESS

Subject Name/ID #: _____

Person obtaining consent initial each completed step in the process:

- ___ Informed consent was discussed with subject for the above referenced study. Copy of the consent form was provided for subject and/or authorized subject representative review.
- ___ Subject and/or authorized subject representative was given adequate time to read the consent form and discuss the study with study investigators and/or family members.
- ___ All questions were answered. Subject and/or authorized subject representative was given time to discuss.
- ___ Subject and/or authorized subject representative signed and dated the informed consent.
- ___ A copy of the consent form was provided to the subject and/or authorized subject representative upon conclusion of the consent process.
- ___ During informed consent process, the following questions were asked by the subject and/or authorized representative and were answered by study personnel:

- ___ Consent has been signed prior to any study procedures being performed.

Consent process documented by: _____
 Print Name

 Signature

 Date

Waiver of Documentation of Consent

- If a study contains a waiver of documentation of consent, the consent form does not have to be signed by the participant or representative. HOWEVER, as best practices, documentation may exist that confirms that participant was consented adequately and enrolled
 - This can be done via any of the methods described in the previous slide

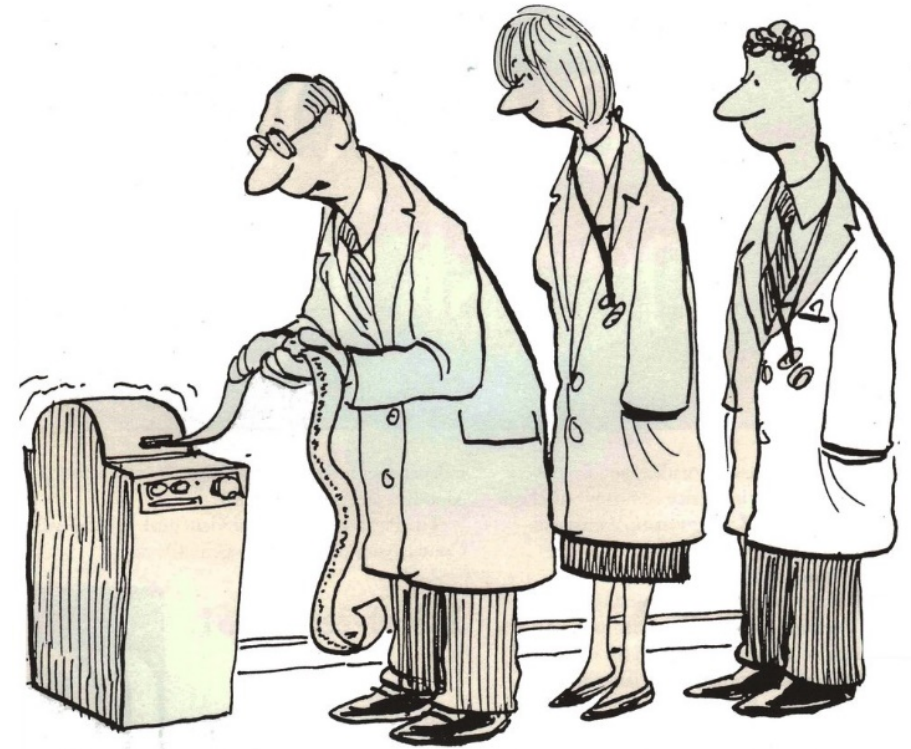
Common Rule changes

Common Rule provisions for federally supported studies that are first IRB approved on or after January 21, 2019 (*the NU IRB implemented this beginning December 2017/January 2018*)

New Requirement — Begin with a Concise Summary

The main change is to require that informed consent:

"...begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research."



“Stand by, new healthcare legislation coming in.”

Common Rule changes

New Requirements — Additional Elements of Informed Consent

The Revised Common Rule also adds four new elements to the consent process:

- For research that collects identifiable private information or identifiable biospecimens:
 - State whether identifiers might be removed from information and/or specimens, and
 - If so, state whether or not de-identified information and/or specimens could be shared with other researchers and used for future research without additional informed consent.
- For research involving biospecimens:
 - State whether biospecimens may be used for commercial profit
 - State whether or not subjects will share in that profit.
- For research that may generate clinically relevant results (whether aggregate or individual):
 - State whether or not clinically relevant results will be disclosed to subjects
 - If results will be disclosed, describe conditions of such disclosure
- For research that will or might include use of biospecimens for whole genome sequencing, include a statement to that effect.

Consenting Tips & Tricks



Ok, what part of antiaromatase neoadjuvant therapy for adenocarcinoma of the sigmoid colon demonstrating the EGFR receptor mutation don't you understand?

- The consenting process should be a **conversation**
 - Allow time for questions and comprehension checks
 - If the consent form is long, take frequent breaks ensuring the participant is still engaged
- Communication is key (both verbal and non-verbal)
- Consider sending the consent form to the potential participants prior to the visit or sending the “Key Information” section of the consent form
- Be prepared – know what you are talking about
- Don't read the entire form word-for-word
- KIS! Keep It Simple – use understandable language

Paging Dr. Peter



<https://www.youtube.com/watch?v=RoMtDC0ILow>

Scenario #1

- A patient awaiting surgery in the pre-op holding area, was approached to participate in a research study. The coordinator, asked if the patient would like to donate some of the specimens that would otherwise be discarded, and after a very brief discussion, without any explanation of what testing would occur on the specimens, the patient was asked to sign an informed consent form.

What went wrong or right in this scenario?

Scenario #2

- Protocol XYZ requires a pre-screening consent in addition to a main consent. Patient 0100 signed the pre-screening consent on October 31 and was scheduled to consent to the main study and complete screening procedures on November 4. After the visit was completed on November 4, it was discovered that the main consent was not signed as required.

What went wrong or right in this scenario and what should happen next?

Scenario #3

- Dr. Jones has a waiver of documentation of consent to conduct focus group interviews on nursing staff within the hospital. Dr. Jones obtained verbal consent from the participants but prematurely destroyed the records of who provided verbal consent prior to study closure. No record existed of who was consented into the study.

What went wrong or right in this scenario?

Scenario #4

- Mrs. Adams and her 8 year old daughter are at the doctor's office discussing a new clinical trial for Stacey's peanut allergy. Mrs. Adams signs the parent permission form but notices that there is another signature line for the second spouse. Mrs. Adams knows that Mr. Adams is in a meeting and will not be able to come down to the clinic to sign the form. Therefore Mrs. Adams signs on Mr. Adams behalf.

What went wrong or right in this scenario?

Scenario #5

- Kelly, the study coordinator for the project, called Mr. Smith into the clinic room to consent him for a cancer study. After going through the consent form thoroughly, Mr. Smith signed and dated the consent form. As he was signing, his wife called and Mr. Smith stepped out of the room to take the call. Upon his return, Kelly began the screening procedures. After the visit was completed, Kelly collected all of the consent forms from the day and signed and dated them. She noticed that Mr. Smith forgot to print his name on the form, so she printed it for him.

What went wrong or right in this scenario?

