

Obtaining and Documenting Written Informed Consent for Research

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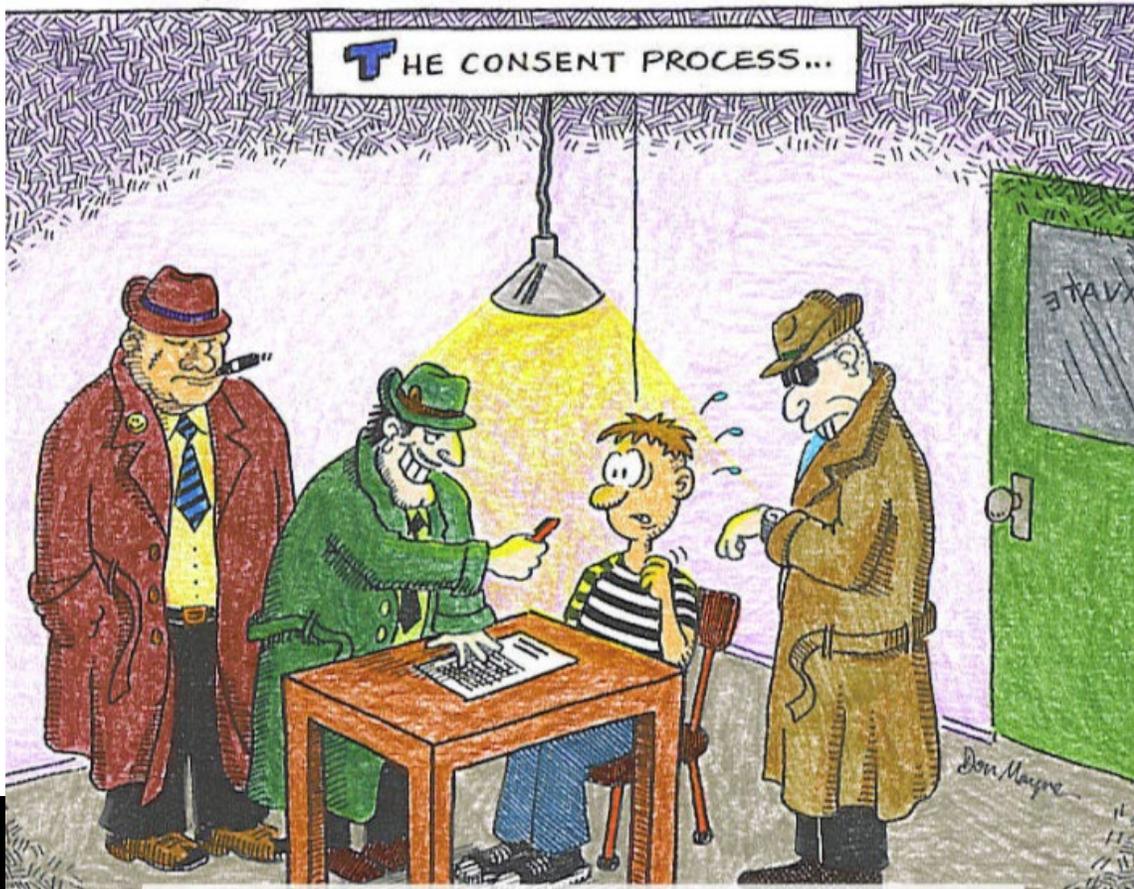
Training Goal:

- All research team members are knowledgeable about the process of obtaining and documenting written informed consent for study participation.
- Written informed consent is obtained in compliance with OHRP, FDA, IRB, and guidelines for Good Clinical Practice.

Performance Objectives:

- Who, What, When, Why, and How to carry out the informed consent process.

What is Informed Consent?



- Investigators must educate potential participants to ensure that they can reach a truly informed decision about whether to participate in the research.
- Informed consent must be given freely, without coercion, and must be based on a clear understanding of what participation involves
- Interactive discussion
- More than a signature on a consent form!

Who is Responsible for Obtaining Consent?

Qualified research team members *trained* in Human participant Protection, Good Clinical Practice and with sufficient knowledge about the specific study.

This may include the Principal Investigator (PI)

sub-investigators

research coordinators

another research team member approved by the IRB.



Though the PI may delegate obtaining consent to other team members, proper oversight and execution is *always* the PI's responsibility.

The logo for the Office for Human Research Protections (OHRP) features the letters "OHRP" in a large, bold, blue sans-serif font.

Office for Human
Research Protections

When is Informed Consent required?

- Documentation of informed consent is to be obtained unless alternate procedures are approved by the IRB, in accordance with [45 CFR 46.117](#) and [21 CFR 50.27](#).
- The IRB and RPO staff review all informed consent documents to assure the adequacy of the information contained in the consent document.
- The IRB and RPO staff ensures adherence to federal regulations regarding the required elements of informed consent.



U.S. Department of Health & Human Services



U.S. FOOD & DRUG
ADMINISTRATION

8 Required Elements of Consent

1. **Research** – statement that study involves research, its purpose, duration, procedures, & identification of experimental procedures.
2. **Risks** - or discomforts, that are reasonably foreseeable.
3. **Benefits** – to participant or others, that are reasonably expected.
4. **Alternative** - procedures or treatments available, if any.
5. **Confidentiality** - of records identifying participant, though may be inspected by authorized entities (*i.e.*, FDA, IRB, UCD/UCH, Sponsor).
6. **Research-Related Injury** – available treatment & compensation (if study is greater than minimal risk).
7. **Contact** – person for questions regarding the study, participant's rights, or research-related injury.
8. **Voluntary** – no penalty or loss of benefits for choosing not to participate & may discontinue at any time.

[FDA 21 CFR 50.25](#) & [45 CFR 46.116](#)

Additional Elements of Consent required by UVM's IRB

1. The name, address, and telephone number of the principal investigator(s) or contact person(s).
2. The amount of compensation, if any, for participation.
3. A statement that the treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable.
4. Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent.
5. Any additional costs to the participant that may result from participation in the research.
6. The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant.
7. A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant.

Who initiates the informed consent discussion & answers questions?

- The Principal Investigator (PI) may be the best person to initiate informed consent and answer all questions and concerns potential research participants may have, especially for interventional/therapeutic protocols.
- The PI may *delegate* the consent process to different members of the research team.
- The complexity of the protocol and level of risk must be considered when delegating the responsibility of obtaining legally effective informed consent.

Delegated persons must:

be key personnel on IRB list for the specific study

complete the required IRB human protections training

understand the research protocol

Where Should Informed Consent Take Place?

Depending on the type of study and the risk associated with it, participants should have adequate time to review the consent form, ask questions about the research, and consult with family, friends or others (if desired) before signing the consent form.



The consent process should not be a rushed process.



Consent should be conducted in a private area that allows a research participant to feel comfortable to ask any and all questions.

When
Should
Informed
Consent
Take Place?

Prior to conducting any study related tests, procedures, treatments, or questionnaires.

Ample time must be given for questions and a thorough discussion

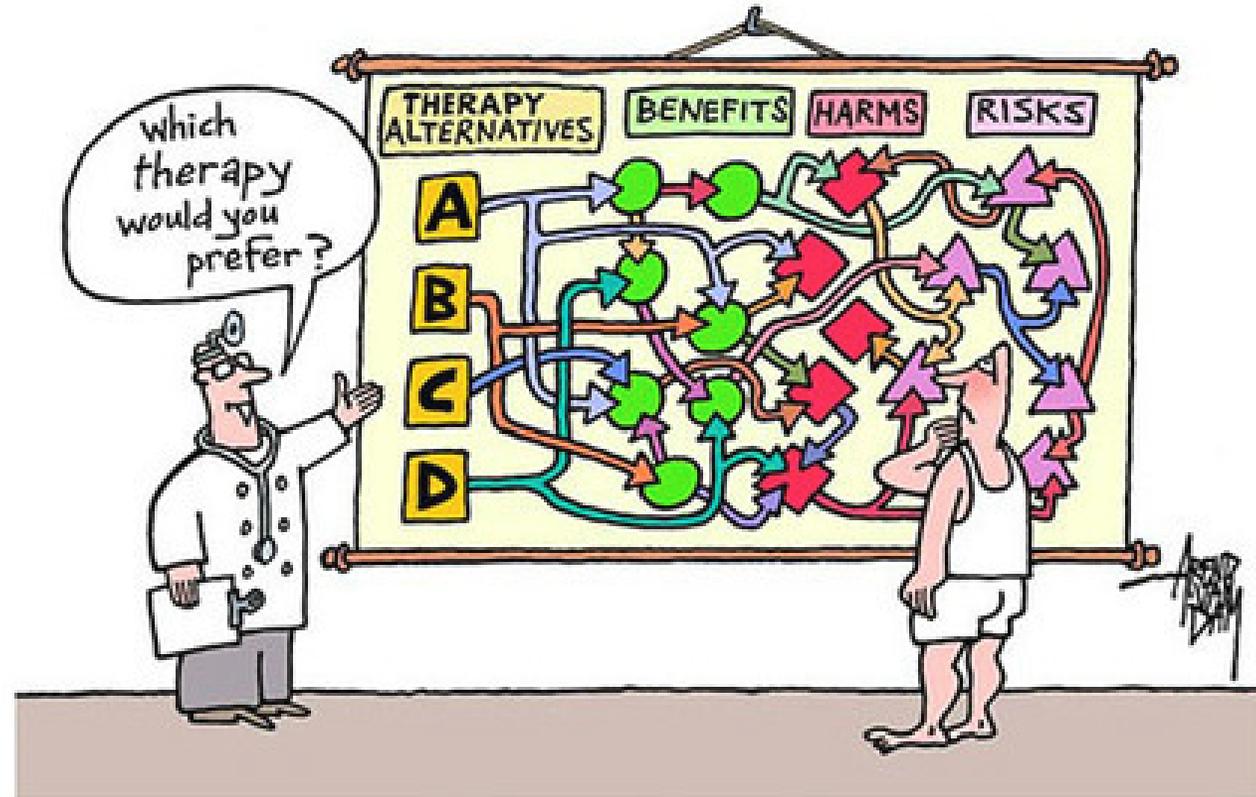
Best to conduct the discussion in person

After eligibility has been determined

When should a participant not be consented?

The consent process should never occur under duress:

- ✓ While the participant is in pain
- ✓ In a waiting room or lobby
- ✓ After the participant has received medication that may alter their ability to give valid consent
- ✓ On the operating room table



informed consent



Participant Comprehension - open-ended questions are best

- "Just so that I'm sure you understand what is expected of you, would you please explain to me what you think we're asking you to do?"
- "Describe in your own words the purpose of the study."
- "What more would you like to know?"
- "What is the possible benefit to you of participating in this study? What are the possible risks?"
- "Can you describe what the alternatives to participation in this study are?"

Informed Consent Process

Discussion

Review

Conversation

Time

Signatures

How Do Researcher's Document the Consent Process?

Example of a note to the research file or Smartphase in EHR documenting the informed consent process:

- *03/30/2022 @ 3:30pm: Mrs. Jones was seen in GI clinic today. After reviewing her labs, she was found to meet all eligibility criteria. Reviewed the consent form; specifically explained the purpose of the study, risks and benefits, expected duration of participation, the number of visits per year, weekly diaries, confidentiality, right to withdraw at any time and emergency contact information. She was given time to review the consent form and asked questions prior to signing.*
- *All questions were answered.*
- *Mrs. Jones signed/dated the consent form and was given a copy for her records. She will begin research procedures on 04/05/2022. -Judith Smith, MD*

How Do Researcher's Document the Consent Process?

- This crucial step is to document the consent discussion and process with the potential study participant.
- The form can be utilized at the beginning of the research and throughout the clinical study, when updates and revisions to the consent form(s) are required
- The Research Protections Website has three different templates researchers can modify and use. These can be found through the [forms library](#).

Study Name:
Study IRB #:

Study PI:

Documentation of Informed Consent

Participant:	
Version of consent used:	
Consent obtained by:	
Date of consent:	

Check all that apply (provide necessary *details* in the notes space below):

- The study was explained and the consent form was reviewed with the participant.
- All of the participant's questions were answered and all the consent elements, such as purpose, procedures, and risks were reviewed.
- The participant was given sufficient time to consider participation.
- The participant agreed to participate in the study and personally signed and dated the consent form.
- The consent form was signed and dated by the researcher.
- The participant was given a copy of the signed informed consent form.
- The consent process was completed *prior to the start of research procedures*.

If Applicable:

- The consent process was witnessed by an impartial witness.
- Verbal consent/assent was obtained (as approved by the IRB)
- Participant agreed to audio or videotaping

Notes about the consent process (i.e. who was involved in consent process, what questions ~~did~~ the participant have, translator number, whether a teach-back process was used, was debriefing was completed, etc.):

Signature/Date of person completing this form: _____

Special Circumstances Require *More* Documentation

- Legally Authorized Representative
- Participant physically unable to sign consent (i.e., bandaged hands, tremor, stroke)
- Participant not able to read a consent form (i.e., illiteracy, vision-impairment)

Signature illegible

Screen failure

Cognitively impaired

Ward of the state

Non-English speaking consent process

Source Documentation

- Informed Consent Form + Source Documentation of Consent Process
- = No Audit Findings
- Remember to include in the research and/or medical record a concurrent note describing consent process and statement that participant received a copy of the signed consent.



Copy of Consent



It is a federal requirement that the patient be given a copy of the consent form.



FDA IRB Information Sheets – “A Guide to Informed Consent”

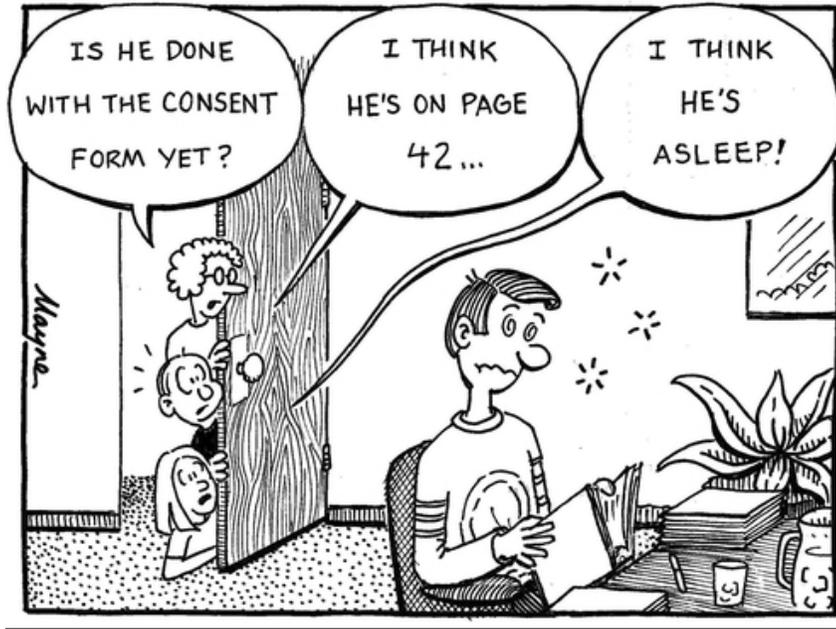
- “A copy of the consent document must be provided to the participant and the original signed consent document should be retained in the study records.”
- “Note that the FDA regulations do not require the participant's copy to be a signed copy, although a photocopy with signature(s) is preferred.”

Additional Points to Consider When Creating an Informed Consent Process

- Will participants be given a copy of consent form to read ahead of time?
- Time interval between presenting study information and the actual signing
- How will participant comprehension be assessed?
- Who from the study team will be authorized to sign the consent form?

How Can We Improve the Consent Process for Research Participants?

After signing a consent form, many patients still do not understand the risks and benefits of their proposed treatment options.



Participants don't always understand what they are consenting to.

A study of 287 adult cancer patients participating in clinical trials revealed that 70% of patient-participants did not recognize the unproven nature of the study drug. NEJM. 2003;348:721–726.

18 months after the end of a clinical trial, 43 participants received a questionnaire, which focused on the quality of the information given to them before entering the trial.

Neither researchers nor participants were aware in advance that the trial would become the participant of this follow up investigation. BMJ.1991 Sep 14;303(6803):610-3.

1. All but one of the participants had been aware that they were taking part in a research project.
2. Five women stated that they had not been aware that a second laparoscopy was performed only for research reasons.
3. Seven women reported that they had not been aware of the meaning of participating in the project
4. 17 that they had had no information about the possibility of withdrawing from the study whenever they wanted.

Why are Participants Confused About Research?

- **Patient Factors:**
 - ✓ Low health literacy
 - ✓ Limited English proficiency
 - ✓ Cognitive impairments
 - ✓ Confusion about the purpose of consent process
 - ✓ Feeling of intimidation, and stress or time pressure

How Can We Improve the Consent Process For Researchers?

Provider Factors:

- Lack of time for up-front patient education
- Overly complex or overly broad written materials
- Lack of support with interpreters
- Wrong assumptions about patient comprehension

Ongoing discussions regarding the study is imperative in assessing a participant's willingness to continue study participation.

Every interaction a researcher has with a participant is an opportunity to continue the informed consent process.

Ongoing discussions improve participant comprehension and compliance with the protocol.



Ongoing discussions should include restating:

- Purpose of the study
- Research Procedures versus Standard of Care
- Risks and Benefits
- Alternatives
- Confidentiality Protections
- Withdrawal Procedures

Ongoing Consent

Ongoing Consent Process: Sharing New Information

Over the course of a study new information may become available that may impact a participant's willingness to continue in a study.

The Principal Investigator must consider the following questions:

1. How will new findings be communicated?
2. How will you determine if the participant is willing to continue study participation?
3. How will ongoing consent be documented?



Options for Sharing New Information

Verbal Exchange

- Information should only be shared in this way if it does not affect risk to participant.
- Conducted during a routine study visit or by phone.
- Document discussion in the research record.

Informational Sheet

- Information shared in this way typically does not substantially affect risk to participant.
- Does not require a participant signature, but investigator needs to document that information was provided to the participant in a research record.
- IRB review/approval is required prior to distributing to participants.

Options for Sharing New Information

Informed Consent Addendum

- Typically used when there is a substantive change to the risk/benefit profile or new procedure.
- Only includes information that is new/different from the originally signed document, reducing the potential for participant confusion.
- Requires IRB review/approval and IRB approval stamp prior to use. Reviewed, signed and dated by the participant and the researcher in the same manner as the original consent document.
- The participant's signature indicates their willingness to continue participation in the study.

Full Consent

- IRB policy is that a consent addendum be used instead of requesting the participant sign a fully revised consent, as this may cause potential confusion for the participant. Changes to this policy will be reviewed on a case-by-case basis.

Common Consent Problems

- An IRB approved consent form has been altered
- Non-IRB approved (no IRB stamp on the signature page)
- Incorrect version of the consent form has been given to the participant
- Missing signatures and dates
- Pre-signing the consent form
- Consent forms signed by personnel not listed as participating in the study



Informed Consent Problems

- Lost consent forms
- Keeping only the signature page of the consent – what did the other pages say?
- Unsecured consent forms – possible breach of confidentiality
- No verification that a participant received a copy of the consent form



Informed Consent Problems

Incorrect version date

No source documentation of consent process

No source documentation the participant was provided a copy of the consent

Consent not dated by the participant

Check boxes left blank; pages not initialed by participant

Original consent missing

Not re-consented when required

*Be Advised: The IRB
Committee may
determine that data
obtained without
legally effective consent
sometimes may not be
used!*

Informed Consent Problems

- **Do not** use one consent form for multiple participants, only one consent per participant
- **Do not** have someone other than the participant sign or date the consent form
- **Do not** pre-sign consent forms, the PI or designee may sign and date after the participant and prior to research procedures but should never sign and date before the participant is allowed to read, ask questions and sign
- **Do not** hand write any additional information on the consent form that you have a participant sign, all changes to the consent form must have prior IRB approval

Click [HERE](#) to take the Informed Consent Module quiz and record your training

Informed Consent Module Registration