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:
- At the end of this training session you will know Who, What, When, Why, and How to carry out the informed consent process.
What is Informed Consent?

• Investigators must educate potential subjects to ensure that they can reach a truly informed decision about whether or not 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 Subject Protection, Good Clinical Practice and with sufficient knowledge about the specific study.

  ✓ This may include the Principal Investigator (PI)
  ✓ sub-investigators
  ✓ research coordinators
  ✓ other 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.
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.
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 subject or others, that are reasonably expected.

4. **Alternative** - procedures or treatments available, if any.

5. **Confidentiality** - of records identifying subject, 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, subject’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 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.
4. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
5. Any additional costs to the subject that may result from participation in the research.
6. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
7. 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.
2019 Required New Section on the Consent Form – Key Information

• “The informed consent must 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.

• This part of the informed consent must be organized and presented in a way that facilitates comprehension.”

Revised Common Rule: Federal Register Volume 82, Number 12 (issued, January 19, 2017)
Four New Required Elements

1. De-identified data or biospecimens may be shared for future research (or not) HIPAA implications as well

   If applicable:

   2. Biospecimens may be used for commercial profit (and whether the subject will share in that profit)

   3. Clinically relevant results will be returned (or not)

   4. Research will involve whole genome sequencing
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.
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.

- It should never occur under duress, such as:
  ✓ While the subject is in pain
  ✓ After the subject has received medication that may alter their ability to give valid consent
  ✓ On the OR table
Subject 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
- Signatures
- Time
How Do Researcher’s Document the Consent Process?

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

- **03/30/2019 @ 3:30pm:** Ppt seen in GI clinic today. 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. Ppt was given time to review the consent form and ask questions prior to signing.

- All questions were answered.

- Ppt signed/dated consent form and was given a copy for her records. She will start research procedures on 04/05/2019. -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 subject.

- 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.
Special Circumstances Require More Documentation

- Legally Authorized Representative
- Subject physically unable to sign consent (i.e. bandaged hands, tremor, stroke)
- Subject 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 subject 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.

“A copy of the consent document must be provided to the subject and the original signed consent document should be retained in the study records.”

“Note that the FDA regulations do not require the subject’s copy to be a signed copy, although a photocopy with signature(s) is preferred.”

How can we Improve the Consent Process for Research Subjects?

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-subjects 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 subject 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 Subjects 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
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 subject
- 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 subject received a copy of the consent form
Informed Consent Problems

- Incorrect version date
- No source documentation of consent process
- No source documentation the subject was provided a copy of the consent
- Consent not dated by the subject
- Check boxes left blank; pages not initialed by subject
- 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!
Statement of Consent
You have been given and have read or have had read to you a summary of this research study. Should you have any further questions about the research, you may contact the person conducting the study at the address and telephone number given below. Your participation is voluntary and you may refuse to participate or withdraw at any time without penalty or prejudice to your present and/or future care.

You agree to participate in this study and you understand that you will receive a signed copy of this form.

Signature of Subject _________________________________ Date 5/21/19

Name of Subject Printed _________________________________

Signature of Principal Investigator or Study Designee _________________________________ Date 5/21/19

Name of PI or Study Designee Printed _________________________________

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May 13, 2019

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Procurement Services Department for purposes of reimbursing you for participation in this study. If you are not a US Citizen or Permanent Resident Alien you will be required to complete additional paperwork for payment.

Contact Information
You may contact [Name], the Investigator in charge of this study, at (802) 646-6544, for more information about this study. You may also contact [Name] at (802) 656-1341. If you have any questions about your rights as a participant in a research project or for more information on how to proceed should you believe that you have been harmed as a result of your participation in this study you should contact the Director of the Research Protections Office at the University of Vermont at 802-656-5040.

Statement of Consent
You have been given and have read or have had read to you a summary of this research study. Should you have any further questions about the research, you may contact the person conducting the study at the address and telephone number given below. Your participation is voluntary and you may refuse to participate or withdraw at any time without penalty or prejudice.

You agree to participate in this study and you understand that you will receive a signed copy of this form.

Signature of Subject

Name of Subject Printed

Signature of Principal Investigator or Designee

Name of Principal Investigator or Designee Printed

Address: Votec Hall, 33 Colchester Ave, Burlington, VT 05405
Telephone Number: (802) 646-6644

March 6, 2018
Parent's have not indicated if they wish to have their child enroll or not.
The master list of participant names will be kept separately from the research data in Dr. [Redacted] laboratory or office at UVM. The research data will be kept in locked filing cabinets in a locked room in [Redacted] laboratory. The electronic data (coded with identification number only) will be kept on a secure network, with password access. The results of this study may eventually be published and information may be exchanged between researchers; however, you and your child's confidentiality will be maintained. We do not plan to share any of the data with anyone outside of the research team unless we are required by law to do so. However, upon request, representatives from the Institutional Review Board and regulatory authorities will be granted direct access to your research record for verification of research procedures and/or data. There is a risk that confidential information might accidentally be disclosed. Professional standards for protecting confidential information will be used to minimize this risk.

Contact Information
You may contact Professor [Redacted], the Investigator in charge of this study, at 802-656-4773 for more information about this study. If you have any questions about your rights or your child's rights as a participant in a research study or for more information on how to proceed should you believe that you or your child has been injured as a result of participating in this study, you should contact the Director of the Research Protections Office at the University of Vermont at 802-656-5040.

Statement of Consent
You have been given and have read a summary of this research study. Should you have any further questions about the research, you may contact the person conducting the study at the address and telephone number given below. You and your child's participation is voluntary and you may refuse to participate or withdraw at any time without penalty. You agree to participate in this research study and you understand that you should sign both forms and keep one copy of the form for your records.

☐ Yes, I provide my informed consent for my child to participate in this research study.

☐ No, I do not provide consent for my child to participate in this research study.

Child's Name (please print)

Parent/Legal Guardian Name (please print)

Parent/Legal Guardian Signature Date

Parent/Legal Guardian Phone and Email

Name of Principal Investigator: [Redacted] Address: John Dewey Hall, Psychological Science, 2 Colchester Avenue, University of Vermont, Burlington, VT 05405 Telephone Number: (802) 656-4773 Email Address: [Redacted]
Case Studies

A researcher has approval from the IRB to conduct a drug study for which subjects must have a certain level of kidney function. As a screening procedure, the researcher draws blood to assess kidney function. After the researcher has determined which individuals are eligible for the study, she explains the study to these individuals and invites them to participate, using her IRB-approved consent process.

• Question: Did the researcher obtain appropriate consent from her participant?

• NO - The researcher should have obtained subject consent before any research procedures were done. The research protocol inclusion criteria required confirmation of adequate kidney function. The subject should have been consented as the blood draw procedure was necessitated by the research protocol.
Case Study

• You have submitted a protocol for a minimal risk study. The IRB approves your protocol. In your submission the informed consent process will involve documenting subjects’ consent using the IRB approved consent form. You are in the field and are speaking to a subject eligible for enrollment into your study. You discover you do not have the consent documents with you. You have described all the study procedures to the subject and allowed ample time for the subject to consider whether to participate. The subject indicates he does not need anything in writing and agrees to participate.

• Question: Is it OK to continue with the research activities with this subject?

• NO. The IRB approved the protocol with the understanding that written informed consent would be obtained. Obtaining verbal consent does not satisfy this requirement. Changes in research procedures, the informed consent process, and/or the consent document cannot be initiated by the researcher without IRB review and approval. Any research procedures conducted that do not follow the IRB approved protocol are considered protocol deviations and should be reported to the IRB.
A PI is conducting a research study looking at MRI brain images of epileptic children. She needs a control group of children to image as a comparator. Lucky for her she has 2 little girls who are not epileptic. She brings her girls into the lab, explains the procedures and signs the consent form as the parent/PI, the girls also assent.

Question: Is it ethical to have a PI consent on behalf of her own children to participate in their research?

NO: The very nature of the relationship with the subject can create the appearance of coercion. Even subtle cues of compromise can place subjects in a position of involuntary participation in a research project. For this reason, researchers should be aware of the potential for coercion that exists when a research subject is also a family member student, employee, colleague, or subordinate of the researcher.
Questions??