

UC DAVIS OFFICE OF RESEARCH

AAHRPP Preparation

UC Davis Human Research

Part V – The Consent Process and Waivers

Cindy Gates
IRB Administration

Informed Consent

1. What are the general regulatory requirements for consent?
2. May an IRB waive the requirement for a signature on a form?
3. May an IRB waive the requirement for consent?
4. What are the requirements when the research changes?

The requirement for consent comes from the principle of "Respect for Persons" found in the Belmont Report.

Informed consent for research includes both a document and a process. The IRB should ensure that informed consent is obtained in compliance with:

- IRB requirements
- The protocol
- The ethical principles of the Belmont Report
- ICH (when applicable)
- Regulations



Belmont Report

Respect for Persons

- Information
- Comprehension
- Voluntariness

Except as provided elsewhere in this policy [in Sec. 50.23 if under FDA jurisdiction) no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the **legally effective informed consent** of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative **sufficient opportunity** to consider whether or not to participate and that **minimize the possibility of coercion or undue influence**. The information that is given to the subject or the representative shall be in language **understandable** to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Federal regulations 45 CFR 46 and 21 CFR 50.20



- Legally effective
- Sufficient time
- Avoiding undue influence
- Avoiding coercion
- Understandable
- No waivers of liability

Legally effective:

Person providing consent

- has authority
- has all required information

...and the person obtaining consent documents this information





Procedure for obtaining legally effect informed consent should include:

- Requiring evaluation of consent document to ensure that the document includes all required information
- Requirement for assessing whether individual giving consent has authority to consent



An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate...



Time to Consider

1. Take consent form home?
2. Obtain consent before the day of surgery, if research involves elective surgery
3. Consider timing of consent for research conducted in an urgent or emergent situation





An investigator shall seek such consent only under circumstances that ... minimize the possibility of coercion or undue influence.



Minimizing Coercion

1. Consider using someone who is not a "authority figure" to conduct consent discussion.
2. Assure individual that he or she will not be penalized or harmed if he or she decides not to enroll or decides to withdraw from study.
3. Conduct the consent process in a safe, comfortable location.



Minimizing Undue Influence

1. Language should not be overly reassuring.
2. Do not underemphasize risks or overemphasize the potential benefits
3. Amount of compensation should not unduly influence participants to participate without carefully considering risks and responsibilities associated with participation
4. Compensation should not be contingent upon completing the study

The information that is given to the subject or the representative shall be in a language understandable to the subject or the representative.



Assessing understanding - Ask questions

- Are we offering you your usual medical care or are we asking you to be in a research study?
- Do you have to take part in this study or is it okay to say "no?"
- What is the purpose of the study?
- Tell me what will happen to you in this study.
- Tell me about the risks you will face if you join this study.
- Tell me about any benefits you could receive if you join this study.
- Suppose you want to drop out of the study - when can you drop out?

No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.



ICH E-6

If the individual cannot read the consent document -

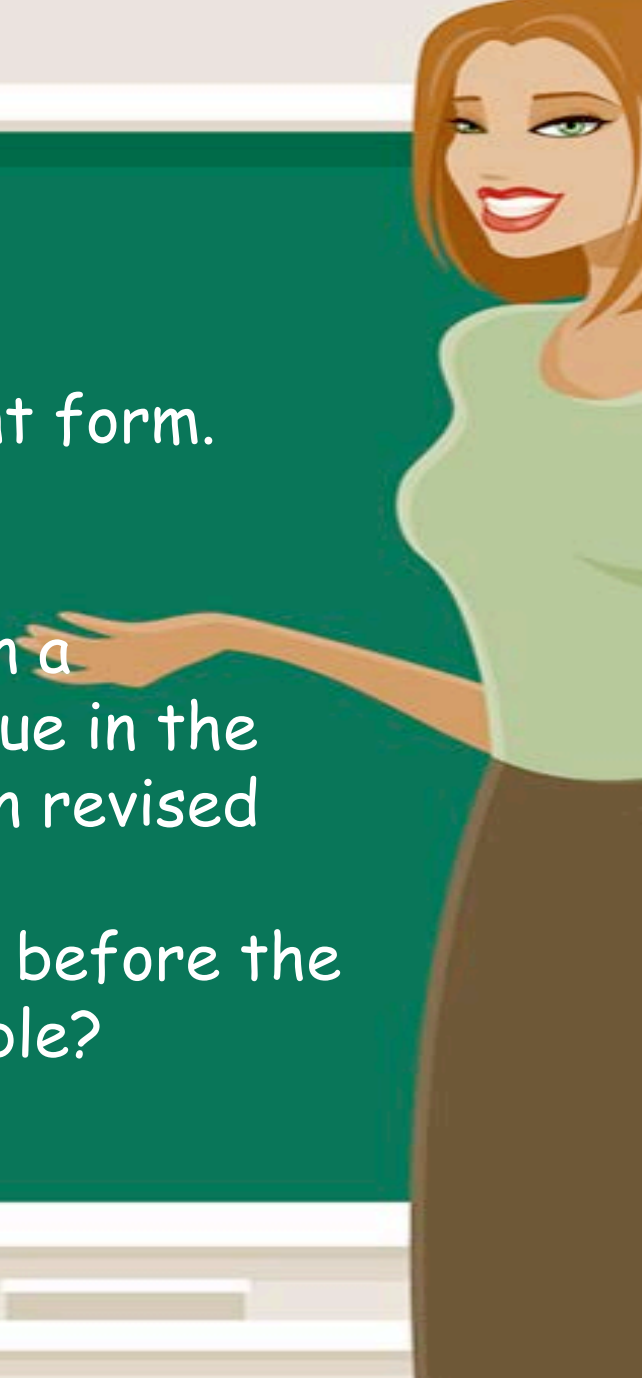
Investigators must ensure the consent discussion is witnessed by an impartial witness.

The impartial witness must sign the consent form attesting that the information in the document was accurately presented to the individual and apparently understood by the individual and the individual consented freely.



Changes to Research

- Compare revised protocol to consent form.
- Are there new procedures?
- Are there new risks?
- Would the new information result in a participant's unwillingness to continue in the research? (Should participants sign revised form?)
- What about participants who enroll before the new, revised consent form is available?



Waiver of Documentation of Consent Permitted by Common Rule and FDA regulations if:

- The research involves no more than minimal risk
- The research includes no procedures for which written consent is normally required outside of the research context.

The IRB may require the investigator to provide to the subject written information about the research.





Common Rule Waiver of Documentation of Consent

- (1) Only record linking the subject and the research would be the signed consent form; and
- (2) The principal risk of the research is breach of confidentiality.

Subjects must be asked if they want documentation linking them to the research and the investigator must comply with the subjects' decisions.



Waiver of Consent

1. Minimal Risk
2. Waiver would not adversely affect participant's rights
3. Consent could not practicably be conducted without waiver

Could research be done without the waiver?

- Scientific validity (ex. Must include data from all eligible individuals)
- Unable to obtain consent (ex. cannot locate participants to obtain consent)



Whenever appropriate, the subjects will be provided with additional pertinent information after participation.





Waiving Consent for Research on Public Benefit Programs

- (1) The research must be conducted by or subject to the approval of state or local government officials; and
- (2) The research must be designed to study, evaluate or examine:
 - A public benefit or service programs
 - Procedures for obtaining benefits or services for the program
 - Changes in or alternatives to the program or procedure
- (3) The research cannot be practicably carried out without the waiver.

Thank you – Don't miss Part VI of this continuing series!

