These slides contain summaries of regulations (mainly 45 CRF 46) and OHR Policies. Please follow the full regulations and policies.
Objectives

• Identify the basic regulatory requirements for the informed consent process and documentation of informed consent (45 CFR 46.116 and 117).
• Assess whether or not consent form language appropriately addresses the elements of informed consent (45 CFR 46.116).
• Differentiate between acceptable and coercive language in a consent form.
• Determine if a study meets the requirement for a waiver or alteration of consent (45 CFR 46.116 and 117).
• Evaluate consent scenarios and select which consent documents and signatories are required.
• Based on a change to a protocol, design a plan for re-consenting subjects.
Please Note

• For answers to the questions in these slides, please refer to the notes found on the bottom of the screen in “Normal View”.
Topics

- Consent Regulations
- Consent Requirements for:
  - ‘Standard’ Consent
  - Assent - Children/Developmentally Disabled Adults
  - Surrogate Consent - Temporarily Impaired Adults
  - Subjects Physically Unable to Sign
    - Witnesses
  - Non-English Speaking Subjects
    - Full Translated Consent Form
    - Short Form Consent
    - Translations
  - Consent Amendments and Re-Consent
Consent Regulations
Common Rule - 45 CFR 46.116 and 117
Consent - What You Must Do:

• Obtain consent
• Give the subject the opportunity to read the consent form
• Give the subject time to consider participation
• Consent form must be signed and dated
• Give the subject a copy of the consent
Note:

It should be documented that the subject received a copy of the signed and dated consent form using:

- Consent note in EPIC (eMR)
- Checkbox on consent form
- Consent checklist is recommended (see sample on Essential Documentation page of OHR website)
Consent Regulations
Common Rule - 45 CFR 46.116 and 117

Consent - What You Can’t Do:

• Use Coercion - Pressure the subject to participate (more later)
• Make the subject waive their rights
• Release PI/Sponsor/Institution from negligence
Consent Regulations
Common Rule - 45 CFR 46.116 and 117

“The Big 3”

• “informed consent shall be documented by the use of a written consent form approved by the IRB”

• “The information that is given to the subject or the representative shall be in language understandable to the subject”

• The consent form must be “signed by the subject”
Consent Regulations
Common Rule - 45 CFR 46.116

The 8 (13) Basic Elements that Must be in a Consent Form

- Explain that the study involves research
- Purpose of the study
- Duration of the subject’s participation
- Procedures that will be done
- Experimental procedures
- Risks
- Possible benefits
Consent Regulations
Common Rule - 45 CFR 46.116
The 8 (13) Basic Elements that Must be in a Consent Form

• Alternatives to participating in the study
• Confidentiality (HIPAA)
• Compensation/Treatment in case of injury
• Contact info (study, injury, rights as a research subject)
• That participation is voluntary
• Subject may chose not to participate or to withdraw without penalty
Consent Regulations
Common Rule - 45 CFR 46.116

The 6 Additional Elements that Frequently Apply and should also be in the Consent Form

- Unforeseeable risks to subject, unborn child
- The possibility of ending the study without the subject’s consent
- What will happen if the subject leaves the study early
- Any cost to the subject
- That significant new findings will be provided to the subject
- Number of subjects in the study
Does this consent text fully address the element of consent?

Element: Study involves research

Consent Text: This study involves research.
Does this consent text fully address the element of consent?

Element: Study involves research

Consent Text: This is a research study. The procedures in this study are different than those you would normally have. Also, the drug used in this study is not approved for use. The purpose of this study is to see if the drug works for people with your condition.
Should this element of consent (purpose of the study) be worded differently?

Element: The purpose of the research

Consent Text: The objective of this study is to determine if X-1Z is efficacious following surgical resection of an esophageal malignancy.
Does this consent text fully address the element of consent?

Element: The purpose of the research

Consent Text: This study is being done to see if an experimental drug will help kill the remaining cancer cells after throat surgery.
Coercion, or pressuring the subject to participate, can be subtle:

A Print Advertisement

- A+ Pharmaceuticals has selected Ivyleague University to offer an invitation to people with X needed for a clinical study.
Coercion

A Print Advertisement - Note the word choice.

• A+ Pharmaceuticals has selected Ivyleague University to offer an invitation to people with X needed for a clinical study.
A Print Advertisement - The only information needed.

- A+ Pharmaceuticals has selected Ivyleague University to offer an invitation to People with X needed for a clinical study.
Make sure the consent form is not over-selling the benefits of participation.
Discussing these elements provides the opportunity to avoid coercion:

- Study Involves Research
- Purpose
- Risks
- Benefits
- Alternatives
- Voluntary Participation
- Consent is a presentation of the facts.
Role of the IRB - Consent

- To make sure the consent process is appropriate for the study.
- To approve the consent form and amendments.
- To approve plans for re-consent.
Waivers - 45 CFR 46.116

• The IRB may approve an alteration or waiver of consent if:
  • There is no more than minimal risk
  • The rights and welfare of the subjects will not be adversely affected
  • The study couldn’t be done without the alteration or waiver, and
  • When possible, the subjects will be given information after participation
Waivers - 45 CFR 46.117

• The IRB may specifically waive the requirement to obtain a signed consent form if either apply (verbal consent may be required):
  • The consent would be the only record linking subject to a sensitive study, or
  • There is no more than minimal risks and consent is not usually required for any of the procedures
Role of the IRB - Consent

• Describe the plan for consent in your IRB submission (OHR-2) and the IRB will evaluate.

• You must follow the consent process approved by the IRB.
Topics

The following slides describe the requirements for the different types of consent:

- ‘Standard’ Consent
- Assent - Children/Developmentally Disabled Adults
- Surrogate Consent - Temporarily Impaired Adults
- Subjects Physically Unable to Sign
  - Witnesses
- Non-English Speaking Subjects
  - Full Translated Consent Form
  - Short Form Consent
  - Translations
- Consent Amendments and Re-Consent
General Notes:

• If the investigator is the person obtaining consent, the signature of another person obtaining consent is not required (but note this on consent form).
• Printed names do not have to be dated.
The Investigator is the Person Conducting the Consent Interview

John Smith, MD
Name of Person Conducting Consent Interview

John Smith
Signature of Person Conducting Consent Interview

3/7/17
Date

Name of Investigator or Co-Investigator

Signature of Investigator or Co-Investigator

Date
The Investigator is the Person Conducting the Consent Interview

John Smith, MD
Name of Person Conducting Consent Interview

John Smith
Signature of Person Conducting Consent Interview

3/7/17
Date

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Name of Person Conducting Consent Interview
Same
Name of Investigator or Co-Investigator

John Smith
Signature of Person Conducting Consent Interview

3/7/17
Date

Signature of Investigator or Co-Investigator
Date
The Investigator is the Person Conducting the Consent Interview

Name of Person Conducting Consent Interview

John Smith, MD

Signature of Person Conducting Consent Interview

John Smith

Date

3/7/17

Name of Investigator or Co-Investigator

John Smith, MD

Signature of Investigator or Co-Investigator

John Smith

Date

3/7/17
‘Standard’ Consent

- English Speaking Adults
- English Consent
- 3 Signatures
  - Subject
  - Person Conducting Consent Interview
  - Investigator
Assent

- Assent is simplified consent.
- Children/Developmentally Disabled Adults.
  (Adults who are not capable of consent due to a developmental disability, but who should be given the opportunity to assent).
- Assent can never stand alone. Assent must always occur with consent.
- Children 7 - 17 should be given the opportunity to assent (OHR Policy SC 506).
- Younger children should use an approved assent form (OHR-8C).
- Older children can assent using the consent form.
Surrogate Consent

• Adults who cannot consent for themselves due to a medical condition that is temporary or of unknown duration.
• The full consent form is used, but the Surrogate Consent Form (OHR-8B) replaces the regular signature page.
• The OHR-8B gives the priority of the surrogates.
• If able, the patient can initially assent to participate.
• If the patient later becomes able, assent or consent should be obtained.
Physically Unable to Sign

- Patient is physically unable to sign, e.g. paralyzed (not mentally unable to sign)
- The patient’s name and date of signature may be written by someone else.
- Include the following note on the signature page: The subject is physically unable to sign the consent form. All pages of the consent form were reviewed with the subject, who voluntarily consented to participate in this study.
Physically Unable to Sign Consent

Signatures:

Patrick Herbison  
Your Name (please print or type)  

X

(Date)

Your Signature

Lola Herbison

(Date)

Witness Signature  
(Only required if subject understands and speaks English, but cannot read English, or if subject is blind or cannot physically sign the consent form—delete if inapplicable)

Marnie Piper

Name of Person Conducting Consent Interview

(Date)

Marnie Piper

Signature of Person Conducting Consent Interview

11/12/13

Greg Gregson

Signature of Principal Investigator or Co-Investigator

11/12/13

The subject is physically unable to sign the consent form. All pages of the consent form were reviewed with the subject, who voluntarily consented to participate in this study.
Impartial Witness

In general, a witness is required if the patient:
- Is illiterate
- Is blind
- Cannot physically sign the consent form
- OR if the short form process will be used (more later)

The witness must be:
- An adult
- Impartial, cannot be study personnel
- Present for the entire consent discussion
- Available throughout the study

Regulation and policy do not prohibit family members and non-study staff from acting as witnesses.
Non-English Speaking Subjects

Remember “The Big 3”

• “informed consent shall be documented by the use of a written consent form approved by the IRB”

• “The information that is given to the subject or the representative shall be in language understandable to the subject”

• The consent form must be “signed by the subject”
Non-English Speaking Subject

Expected

Not Expected

Short Form Process

Full Translated Consent Form

Summary (Full English Consent)

Short Form (OHR-8S)
Non-English Speaking Subjects - Expected

- A full, translated consent form is used.
- The translated consent form is approved by the IRB.
- Translated documents need documentation of accuracy:
  - For an individual translator, submit translator’s name and qualifications to the IRB.
  - Translation agencies will provide documentation of accuracy.
Non-English Speaking Subjects - Not Expected

Short Form Process

• There are OHR-8S forms in several languages on the OHR website.

• The completed OHR-8S must be approved by the IRB (expedited).
Non-English Speaking Subjects - Not Expected

Short Form Process

- The study is explained to the subject by the translator using the summary, which is usually the full, English consent form.

- The short form is in the patient’s language and states that consent has been explained verbally.
Non-English Speaking Subjects - Not Expected Short Form Process

- The patient is given copies of both signed documents.
- After a patient is consented using the short form process, the full consent form should be translated and approved by the IRB. The subject is then provided with the translation (which should be documented).
Expected and Unexpected - Translator

- In both cases, a translator is needed for the consent discussion.
- The translator should be an adult.
- The translator can be a professional translator, study personnel, other non-study staff, or a family member.
- Must be fluent in both languages and familiar with medical terms.
- If the translator is impartial (not study personnel), that person may act as the witness as well.
- Present for the entire consent discussion
- Available throughout the study
Note: Short Form Process - Translator

- For the short form process: If an investigator or study team member is bilingual, you still need a bilingual witness.

- The short form process requires an impartial witness (45 CFR 46.117).
- The witness has to be bilingual to confirm the study information was presented correctly.
Consent Signatories Guidance

- The Consent Signatories Guidance document is on the OHR website.
- It shows what documents need to be signed and who has to sign them for most consent scenarios.
<table>
<thead>
<tr>
<th>CONSENT SIGNATORIES</th>
<th>Regular Consent</th>
<th>Surrogate Consent (Use OHR-8B as signature page)</th>
<th>Assent (Always used with parent / guardian consent)</th>
<th>Parent / Guardian Consent (Used with assent)</th>
<th>Subject is Physically Unable to Sign</th>
<th>Subject is Illiterate (Full consent form is presented verbally)</th>
<th>Subject is Blind (Must use braille consent or reading device)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X (Makes Mark if Possible)</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Person Conducting Consent Interview (May be the Investigator)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Investigator</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Impartial Witness (May not be study personnel)</td>
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<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
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<tr>
<td>Parent / Guardian / Legal Representative / Surrogate</td>
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<td>X</td>
<td>X</td>
</tr>
<tr>
<td>CONSENT SIGNATORIES</td>
<td>Translations - Full Consent Form</td>
<td>Translations - Short Form Process - Investigator / Study Personnel Does Not Speak Other Language</td>
<td>Translations - Short Form Process - Investigator / Study Personnel Speaks Both Languages and Acts as the Translator</td>
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<tr>
<td>Investigator / Study Personnel does not speak other language</td>
<td>Investigator / Study Personnel speaks both languages and acts as the translator</td>
<td>Short Form</td>
<td>Summary</td>
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<tr>
<td>Subject</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Person Conducting Consent Interview (May be the Investigator)</td>
<td>X</td>
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<tr>
<td>Investigator</td>
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</tr>
<tr>
<td>Impartial, Bilingual Witness (May not be study personnel)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Translator</td>
<td>X</td>
<td>A translator is needed but doesn’t sign unless also acting as the impartial witness.</td>
<td>X</td>
<td>A translator is needed but doesn’t sign unless also acting as the impartial witness.</td>
<td>A translator is needed but doesn’t sign unless also acting as the impartial witness.</td>
<td></td>
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</tr>
</tbody>
</table>
Short Form Consent Process

Short Form Process = 2 forms + 5 signatures including a Witness
vs.
Regular Consent = 1 form + 3 Signatures

• The short form process is more complicated than the regular consent process
• Only use it for unexpected, non-English speaking subjects
• If you need a shorter consent form for a less complex study, use the OHR-8A - Consent Form for Blood Draw
• Contact the IRB before using the short form process for English speaking subjects
Consent Amendments

• From 45 CFR 46.116: The subject will be informed of any change that may affect the subject’s willingness to continue participation (changes to any of the elements of consent).

• Who can ask for changes to the consent and re-consent:
  • Sponsor
  • PI
  • Study Personnel
  • IRB
  • Other
Re-Consent

• The study team describes the amendment and makes the recommendation for re-consent on the OHR-12
• The IRB agrees or modifies and includes the re-consent requirement on the approval page.
Re-Consenting Process

• Same as consenting process including documentation.
• You must discuss the changes to the study and consent form.
• You should review any important information previously discussed.
Re-Consent: Non-English Speaking Subjects

• For re-consent, any non-English speaking subjects are now EXPECTED.
• The short form process should not be used.
• Use 1 of the following 2 options:
Re-Consent: Non-English Speaking Subjects

• Option 1
• Submit to the IRB:

  • 1. The full English consent form
  • 2. The full translated consent form
  • 3. The documentation of accuracy of the translation
Re-Consent: Non-English Speaking Subjects

- Option 2
- Submit to the IRB:
  
  1. The full English consent form
  2. An English addendum, just stating the changes to the consent form
  3. A translation of the addendum
  4. The documentation of accuracy of the translation
Re-Consent: Non-English Speaking Subjects

• Option 2 (addendum) is more cost effective, but presents more of a maintenance issue in terms of having both a full consent and an addendum to keep track of, and going forward if you have any more amendments.

• For re-consent, all of the signatures discussed previously for initial consent are required.
General Consent Recommendations

• Have a method in place to ensure most current, IRB approved consent is used.
• Document the consent process. This is done with a consent note in EPIC (eMR). A separate checklist is also recommended.
Consent Observations

- You will be observed consenting a patient.
- A low-key way to get some feedback on your technique.
Consent Observations

• Patient (at the start of the consent process): “Where do I sign?”
• Coordinator: “Before you decide, we have to review the consent form together.”
• Patient: “Just hit the highlights.”
• Coordinator: “I want to give you enough information so you can make an informed decision whether or not you want to be in the study.”
• Patient: “OK, sounds good.”
Questions?

Always available for assistance:

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