FLORIDA STATE UNIVERSITY

Study Coordinator Bootcamp Session II

Informed Consent Boot Camp

Presented By

The Office for Clinical Research Advancement (OCRA)

FSU Office for Human Subjects Protection (OHSP)

Learning Objectives

Informed consent is one of the primary legal and ethical requirements underpinning human research, reflecting the **basic principle of respect for persons;** informed consent is an **ongoing process**, not only a form, script or a moment in time. Informed **consent helps to ensure** that prospective, active and previously participating human subjects understand the nature of the research and that their **participation is voluntarily**.

Presenters:

- Julie Haltiwanger , CIP, CHRC, CCRP
  - OHSP Assistant Director
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  - OCRA Clinical Research Program Director

This session will be recorded via ZOOM and published on the Lunch and Learn Series Website for future reference. For our ZOOM participation, please post questions in the CHAT.

Definitions and Key Terminology

- **The informed consent process** involves three key features: (1) disclosing to potential research subjects information needed to make an informed decision; (2) facilitating the understanding of what has been disclosed; and (3) promoting the voluntariness of the decision about whether or not to participate in the research. Informed consent must be legally effective and prospectively obtained. HHS regulations at 45 CFR 46.116 and 45 CFR 46.117 describe the informed consent requirements.

- **Not just a document**

  It is -the critical communication link between the prospective human subject and an investigator, beginning with the initial approach of an investigator to the potential subject (e.g., through a flyer, brochure, or any advertisement regarding the research study) and continuing until the completion of the research study.

- The **consent form** is intended, in part, to provide information for the potential subject's current and future reference and to document the interaction between the subject and the investigator. However, even if a signed consent form is required, it alone does not constitute an adequate consent process**.**
  - **See** HRP-502 Template Consent Document in the RAMP IRB Library

Additional Definitions at the link below:
https://myrampirb.research.fsu.edu/IRB/sd/Doc/0/FUC26GOCNFO458JE1OBERD0H79/HRP-001%20-%20SOP%20-%20Definitions.pdf

https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html

Basic Elements of Informed Consent:

HHS regulations at 45 CFR 46.116

FDA 21 CFR 50 Subpart B

A statement that the study involves research
An explanation of the purposes of the research
The expected duration of the subject's participation
A description of the procedures to be followed
Identification of any procedures which are experimental
A description of any reasonably foreseeable risks or discomforts to the subject
A description of any benefits to the subject or to others which may reasonably be expected from the research
A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
Research, Rights or Injury: An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled

Minimizing Coercion and Undue Influence

<8th Grade Reading Level

- Use of images/pictures
- Avoid complex medical terms and legal jargon
  - Example: a sample of your blood will be collected by a trained nurse using a needle in your arm or hand. The amount of blood is about a teaspoon.
    - Rather than: Standard venipuncture techniques will be followed for the collection of 5mL of whole blood.

- Allow for ample time to review, ask questions and discuss participation (Family, Friends, Trusted others)
- Alternatives to participation
- Possible Benefits
- Known Risks
- The expected experience of the participant

The statement regarding voluntary participation and the right to withdraw at any time can be taken almost verbatim from the regulations (45 CFR 46.116 [a][8]). It is important not to overlook the need to point out that no penalty or loss of benefits will occur as a result of both not participating or withdrawing at any time. It is equally important to alert potential subjects to any foreseeable consequences to them should they unilaterally withdraw while dependent on some intervention to maintain normal function.

How does FSU IRB evaluate the Consent process

Using HRP-314 - CHECKLIST - Criteria for Approval sections 5, 6, 7, 8.

Complete remaining items when applicable	
5	**Consent Process** (Check if **"Yes"**. All must be checked)
☐	The investigator will obtain the legally effective informed consent of the subject or the subject's legally authorized representative (LAR).
☐	The circumstances of consent provide the prospective subject or LAR sufficient opportunity to consider whether or not to participate.
☐	The circumstances of consent minimize the possibility of coercion or undue influence.
☐	Information to be given to the subject or LAR will be in language understandable to the subject or LAR.
☐	The prospective subject or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. (**N/A if research is subject to Pre-2018 Requirements) N/A:** ☐
☐	Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR 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. (**N/A if research is subject to Pre-2018 Requirements) N/A:** ☐
☐	Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate. (**N/A if research is subject to Pre-2018 Requirements) N/A:** ☐
☐	There is no exculpatory language through which the subject or LAR is made to waive or appear to waive the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability from negligence.
☐	Consent will disclose the elements in **Section 7: Elements of Consent Disclosure**

6	**Long (Standard) Form of Consent Documentation** (Check if **"Yes"** or **"N/A"**. All must be checked)
☐	The written consent document is accurate, complete, and consistent with the protocol.
☐	The written consent document embodies the elements in **Section 7: Elements of Consent Disclosure**
☐	The investigator will give either the subject or LAR adequate opportunity to read the consent document before it is signed.
☐	The subject or LAR will sign and date the consent document.
☐	The person obtaining consent will sign and date the consent document.
☐	A copy of the signed and dated consent document will be given to the person signing the document.
☐	If there is a LAR or parent signature line, the IRB has approved inclusion of adults unable to consent or children. **("N/A" if no signature line) N/A:** ☐
☐	When a subject or LAR is unable to read: An impartial witness will be present during the entire consent discussion and the consent document notes that the witness attests that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject or LAR, and that consent was freely given. **("N/A" if all subjects are able to read) N/A:** ☐

When should I consent?

- Consent in Advance: HHS/FDA does not specify how far in advance of study entry a subject can provide consent. The amount of time required by a subject to make a decision would presumably depend on the nature of the study, taking into account, among other factors, the degree of risk, potential benefits, alternatives, and desire to consult with family members or others.
- However, if a prolonged period of time elapses from the date of consent to the date of entry into the study even if there have been no changes in the study design or no new significant findings affecting the study, it might be prudent to review the information contained in the consent form with the subject prior to initiating any research procedures with the subject.

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Special considerations of consent process based on study population

What if an adult cannot consent for themselves?

- Unless the IRB has waived the requirement to obtain consent, when research involves adults unable to consent, permission must be obtained from a Legally Authorized Representative (LAR).
  - Who can be a LAR
    - An attorney in fact under a durable power of attorney. Florida Statute §765.204
    - A designated Health Care Surrogate as defined in Florida Statute §765.202.
    - In the absence of a Health Care Surrogate, the following individuals in the following order of priority:
      - The judicially appointed guardian of the subject or the guardian advocate of the person having a developmental disability as defined in s. 393.063, who has been authorized to consent to medical treatment;
      - The subject's spouse;
      - An adult child of the subject, or if the subject has more than one adult child, a majority of the adult children who are reasonably available for consultation;
      - A parent of the subject;
      - The adult sibling of the subject or, if the subject has more than one sibling, a majority of the adult siblings who are reasonably available for consultation;

  See SOP: LARs, Children, and Guardians

If the subject/representative cannot speak English:

- The IRB must have specifically approved the protocol to allow the enrollment of subjects able to speak language that the subject understands.
- Verify that you are using the most current IRB-approved version of the study-specific consent form and that the consent form is in language understandable to the subject/representative.
- If the subject/representative cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the subject/representative. The interpreter may be a member of the research team, a family member, or friend of the subject/representative.

What if the subject cannot read?

If the subject/representative cannot read obtain an impartial witness to be present during the entire consent discussion to attest that the information in the consent form and any other information provided was accurately explained to, and apparently understood by, the subject/representative, and that consent was freely given. The witness may be a family member or friend. The witness may not be a person involved in the design, conduct, or reporting of the research study.

See SOP: Informed Consent Process for Research

What if the person is a minor?

- The IRB must have specifically approved the protocol to allow the enrollment of children.
- Permission is obtained from both parents unless:
- One parent is deceased, unknown, incompetent, or not reasonably available;
- Only one parent has legal responsibility for the care and custody of the child or
- The IRB has specifically approved the protocol to allow the permission of one parent regardless of the status of a second parent.
- In the absence of a parent, permission may be obtained from an individual authorized to consent under applicable law on behalf of a child to general medical care.

- See SOP: Informed Consent Process for Research

Documenting of Informed Consent:

- **Informed consent shall be documented by** the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative.
  - A copy shall be offered/given to the person signing the form.
    - A copy should ALWAYS be made available to the participant upon request
- **What if being done electronically**
  - the subjects would electronically affix their signatures and date, as well as print/sign/scan the consent form and return the signed and dated consent to the study team; the study team will subsequently counter-sign, return the counter-signed copy to the subject for subjects' records
- **Done Orally- only if approved in advance**
  - A **short form written consent** document, stating that the elements of informed consent required by §46.116 have been presented **orally** to the subject or the subject's legally authorized representative. When this method is used, there shall be a **witness** to the oral presentation. Also, the IRB shall approve a **written summary** of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

See SOP: Written Documentation of Consent

How to apply what I learned last session as it applies to consent

Ensure proper training is completed:

- **Study Specific Training** (an ongoing process, not stagnant)
    - Protocol regarding sections 22 and 23
    - Consenting hold mock sessions

What about the consent process is going the regulatory binder?

- In the authority log document, which study team members are approved and trained to participate in the consent process
- Copies of all versions of the approved ICFs and approval letter
- ICF training records on all versions

A.L.C.O.A-C

Attributable

- Who did what? From documentation to events, all items should be traceable to a person, visit, date, and time.

Legible

- Easy to read and identifiable
- Single Line Cross-out any changes
  - Initial and Date the cross-out

Contemporaneous

- Document as it occurs
- “Late Entry” is acceptable if it is defined and justified

Original

- Original Source Documents MUST be maintained (maybe a sticky note)

Accurate

- Real and Consistent Representation of the Facts

Complete

https://www.fda.gov/media/85183/download

https://www.research.fsu.edu/research-offices/ohsp/investigator-resources/research-information-security/

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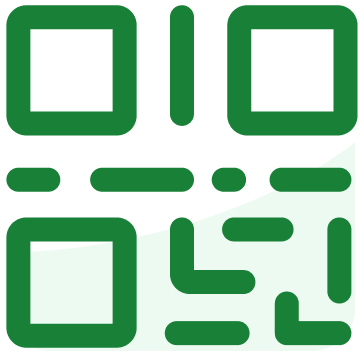

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What do you think was missed/ or done incorrectly?

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Got a lot on your mind?
HAVING A TOUGH TIME? NEED TO TALK?

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What do you think was missed/ or done incorrectly?

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What if my consent Changes?

Submit to the IRB for review DO NOT USE the “new version” for consenting subjects until it is IRB Approved.

Once a “new version” is approved DO NOT USE any Previous Versions for consenting subjects.

Remember: ALL IRB Approved Versions of the Consent MUST be available in your investigator binder. It is Best Practice to file items in REVERSE Chronological Order (Newest in the front).

<u>When Will I need to Reconsent subjects</u>

- Reconsenting may be appropriate certain cases

Ex: A pediatric subjects reaches adulthood while the study AND will still be a participant

- If you are instructed to Reconsent Subject by the IRB

Resnik DB. Re-consenting human subjects: ethical, legal and practical issues. J Med Ethics. 2009 Nov;35(11):656-7. doi: 10.1136/jme.2009.030338. PMID: 19880699; PMCID: PMC3971530.

What is a Waiver consents?

- Waiver of Documentation
  - For some research projects, the IRB may approve a request to waive the documentation of informed consent. This means that the study team must provide a subject with the required consent information, but the study team is not required to obtain the subject's signature on the informed consent document
    - See Waiver of Documentation of Informed Consent
- Waiver of Consent /Elements of Consent
  - The federal regulations authorize the IRB, under strict and very limited circumstances, to approve a consent procedure for which a researcher proposes not to obtain informed consent, or to alter some or all of the required elements of informed consent. In order to approve of a waiver of consent or an alteration of a required element of consent, the IRB must first, based upon sufficient rationale and information provided by a researcher, unambiguously find and documents that:
    - the research involves no more than minimal risks to subjects;
    - the waiver or alteration will not adversely affect the rights and welfare of the subjects;
    - the research could not practicably be carried out without the waiver or alteration; and,
    - whenever appropriate, the subjects will be provided with additional pertinent information after participation.
      - See Waiver of Informed Consent

Aside from the above, federal regulations also provide for the waiver of consent in certain emergency research. The regulations are applicable to only a narrow class of research activities. [**external DHHS link**] [**external FDA link**]

When to request waivers?

- Waiver of Documentation- only minimal risk research
  - the administration of online/electronic or mailed surveys, telephone interviews, or when anonymous sensitive information is collected, and you do not want any written documentation that links the participants to the research study.
  - The signature on the informed consent document would be the only record linking the subject to the research, and the principal risk of harm to the subject would be a breach of confidentiality.
  - Involves no procedures for which written consent is normally required outside the research context.

See Checklist - Waiver of Written Documentation of Consent

- Waiver of Informed Consent
  - Retrospective Chart reviews
  - The project meets four criteria necessary for a waiver of informed consent: (1) the research will not expose subjects to more than minimal risk, (2) the waiver will not adversely affect the participants, and (3) the research would not be feasible to carry out without the waiver. (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation,

See CHECKLIST: Waiver or Alteration of Consent Process

- Parental Permission. Some exceptions to the general requirement for parental permission may apply for research involving children; refer to this **Waiver of Parental Permission** algorithm.

Revoking or Withdrawal of Consent (HHS):

Revoking ALL Consent: the investigator must discontinue all of the following research activities involving that subject's participation in that study (45 CFR 46.116(a)(8)):

Interacting or intervening with the subject in order to obtain data about him or her for the research study

Obtaining additional identifiable private information about the subject for the research study by collecting or receiving such information from any source

Obtaining additional identifiable private information about the subject for the research study by observing or recording private behavior without interacting or intervening with the subject

Partial With drawl:

OHRP recommends that when a subject decides to withdraw from a clinical trial, the investigator conducting the clinical trial ask the subject to clarify whether the subject wishes to withdraw from all components of the trial or only from the primary interventional component of the trial. If the latter, research activities involving other components of the clinical trial, such as follow-up data collection activities, for which the subject previously gave consent may continue

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Where should I store my signed informed consent? do you think was missed/ or done incorrectly?

ⓘ Start presenting to display the poll results on this slide.

How long do I Need to keep my informed consent

There are several different regulations, each of which has different requirements. As a result, researchers must comply with the longest applicable standard that applies.

- **OHRP Requirements:** 45 CFR 46 requires research records to be retained for at least 3 years after the completion of the research.
- **HIPAA Requirements:** Any research that involved collecting identifiable health information is subject to HIPAA requirements. As a result records must be retained for a minimum of 6 years after each subject signed an authorization.
- **FDA Requirements:** Any research that involved drugs, devices, or biologics being tested in humans must have records retained for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.

The documents cannot merely be recycled or simply thrown away as the information would then continue to be viewable and available. Destroying the records can be achieved in a number of ways, including shredding, burning, etc.

Do's and Don't of an IRB Approved Consent Form

- Do not utilize an UNAPPROVED version of a consent (If you do this is a Protocol Deviation aka RNI)
  - An Approved Version will display the FSU IRB Approval Stamp in the TOP Right Corner of EVERY PAGE ONLY the STAMPED VERSION of the consent should be utilized
- Copies (or printouts) may be front and back to save paper
- If your IRB Submission includes a signature, you MUST get a signature
- If the signature is "wet" it cannot be substituted as digital without IRB Approval
  - If the signature is a "wet" version it MUST be in PEN (no pencils)
- An IRB Approved Informed Consent is the ENTIRE CONSENT: do not remove a single page (ie: the signature page)
- All pages should be numbered in the formatted Page ___of____ (IE: Page 1 of 4)

Questions

Contact Us

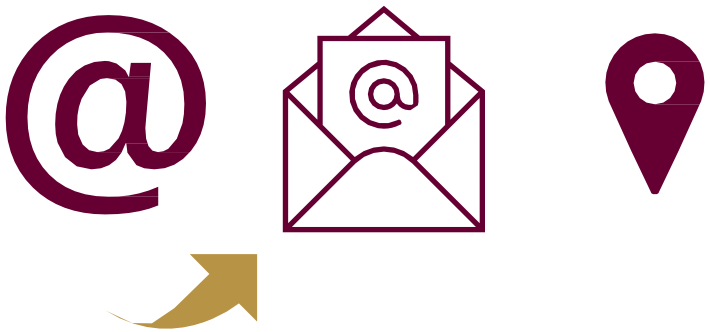
OHSP

Click an icon above to contact or find OHSP.

Or

Virtual IRB office hours, every Wednesday between 10-11 AM ET

OCRA



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For questions about this slide deck:

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