# Informed Consent Process for Research Coordinators

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## AGENDA

- Introductions
- Elements of Informed Consent
- Writing a Great Informed Consent
- Navigating the Authorization Options
- Confidentiality and HIPAA
- Obtaining Informed Consent
  - VIDEO
  - Motivational Interviewing
- Consent & Special Populations
- Documenting the Consent Process

## Regulatory Requirements: Elements of Informed Consent

- 45 CFR 46.116
  - Applies to all research conducted at OHSU
- 21 CFR 50.25
  - FDA regulated studies

## Elements of Informed Consent

- Purpose of the research study
- Risks and discomforts
- Reasonably expected benefits
- Appropriate alternative procedures/treatments
- Extent of confidentiality
- Costs/compensation – subject injury
- Whom to contact for questions about research, subject rights, and research related injury
- Participation is voluntary and will not affect the patient's rights or benefits to which they are entitled.

## Additional Elements of Consent Must be included, when appropriate

- Risks to embryo or fetus
- Circumstances when the investigator may terminate the subject's participation without their consent
- Additional costs to the subject
- Consequences of subjects decision to withdraw
- Approximate number of subjects
- Significant new findings will be shared with the subject

## Cost Language

- IRB has a document that has text for the 3 options
  - Subject pays for all study expenses
  - Subject pays for some of the expenses
  - Subject pays for none of the expenses

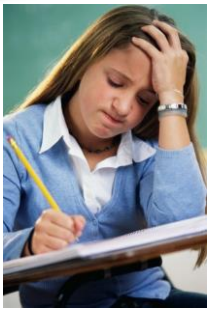
## Liability Language

- Liability not listed in the regulations but it does help explain the potential costs to subjects and consequences of participation
  - Template language cannot be altered without prior approval of the IRB chair

## Commercial Development

- Required if the investigators plan (may be in the distant future) or think there is a possibility they may develop commercial products based on collected samples
  - If you don't include this language in the consent, subjects would need to be reconsented at a later date for use of their samples

## WRITING A GREAT CONSENT FORM



## Consent Templates

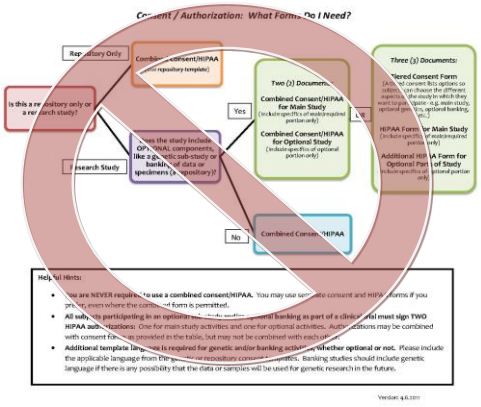
- Always use one of the OHSU IRB approved templates
- Select the template appropriate for your study and follow the instructions
  - Cancer studies – use Knight Cancer Institute templates
  - Shriners Consent and Authorization
  - Non-clinical Consent and Authorization – education, health promotion
  - Clinical Research Consent Template – studies that include clinical procedures
  - Repository Only Consent – use for data and samples
  - Information Sheet – minimal risk studies
  - Treatment Use for Drug or Device Consent Form

## Confidentiality and HIPAA

- Health Insurance Portability and Accountability Act (HIPAA) is federal law but the implementation is institution specific
- There are several types of HIPAA authorizations see the
  - Research authorization (approved by the IRB and signed by the research subject)
  - Waiver of Authorization (approved by the IRB)
  - Research Involving Only Decedents' Information (approved by the IRB)

## How Many Consent forms do I need?

- This varies depending on the study complexity
- The more optional procedures there are the more HIPAA authorizations you will need
- VA Consent if VA subjects will be enrolled
- The more special populations participating the more consent documents you will need
  - Limited English Proficiency (short forms)
  - Children (assent forms)




## How many consent and HIPAA authorization forms do I need?

- Sub-study consent vs. tiered consent?
  - Consider using a tiered consent
    - when a sub-study is simple and the purpose matches the overall study design (e.g. extra blood draws for a PK study)
  - Consider using a separate sub-study consent
    - if you are only asking a subgroup of study participants to take part
    - there are several additional procedures/risks or the purpose is different

## How many consent and HIPAA authorization forms do I need?

- Screening Consents
  - provide a brief description of the study – subject consents to screening procedures only
  - Requires a full consent for prospective subjects that meet the inclusion criteria before they continue in the study
  - Generally used when there are minimal risk screening procedures and the screen failure rate is expected to be high
  - Advantage – saves time
  - Disadvantages:
    - Additional documentation
    - Subjects may decide not to participate when they get the full protocol

## How many consent and HIPAA authorization forms do I need?

- Assent is required for children ages 7-17 when the children are able to understand
  - Assent template is available on the OHSU IRB website
  - List the same investigators as on the consent form
- Adult assent is also required for decisionally impaired adult participants, http://www.ohsu.edu/xd/about/services/integrity/policies/upload/di.pdf
  - No template is available and it is usually incorporated into the consent form as a separate signature line

## How Many Consent/Authorizations Do I Need? Scenario

An open label study of an investigational drug vs. SOC the PI expects to enroll 250 subjects

- Genetic test required to determine inclusion criteria (1 in 5 screen failure rate expected)
- Optional blood draws for PK study – only need 40 people for the PK study who are assigned to investigational agent
- Protocol states blood will be stored in the sponsor's repository. PI has permission from company to store some left over blood in the PI's repository
- PI has clinics at the VA and OHSU

## Consent Language Negotiations for Industry Sponsored Research

- The IRB of record is the final authority on the content of the consent documents that is presented to the prospective study subjects
  - http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm
- Consents must be approved by the sponsor before they are submitted to the IRB
  - Even pre-board or IRB requested changes

## Sponsor Negotiations

- Common sponsor language that isn't accepted by the IRB
  - Language that states the subjects must follow instructions for treatment related to AEs
  - Language from the sponsor that states the sponsor will cover costs not paid for by insurance
    - CRBO has white papers that explain OHSU's position

## Sponsor Negotiations

- Sponsor and OHSU don't always agree on what is standard of care (SOC)
  - SOC varies from institution to institution
  - If you PI doesn't order a test as part of his regular clinic practice then it is being done for research
  - You can get help from the CRBO if you are at an impasse with the sponsor.

## Sponsor Negotiations Tips

- Feel like you are wasting time with the CRO– ask if you can get a sponsor contact
- If the sponsor/CRO won't agree to the OHSU boilerplate language – submit to the IRB with a cover memo highlighting the sections that the sponsor required.
- If the sponsor has agreed to OHSU language in the past remind them of this and give an example
- If it looks like consent form language will prevent the study from moving forward you can ask the IRB for assistance in your discussions with the sponsor

## Before Consent

- What can I do before or without consent?
  - Activities preparatory to research
  - Activities covered by a waiver of authorization and/ waiver of consent
  - Nothing that the IRB hasn't approved

## Preparatory to Research Activities

- The IRB may approve the use and/or collect PHI for the following purposes:
  - preparing a research protocol;
  - developing a hypothesis;
  - writing a grant application; or
  - identifying subjects or records of subjects who may be recruited for the research.
- Data cannot be shared outside of OHSU
- **HIPAA Activities Preparatory to Research** http://www.ohsu.edu/xd/about/services/integrity/policies/upload/HIPAA-Prep-To-Research-Regulatory-Sheet.pdf

## Waivers of Authorization

- **To approve a waiver, the investigator must establish:**
- Study involves no more than minimal risk to the subjects;
- Waiver will not adversely affect the rights/welfare of the subjects;
- Research could not practicably be conducted without a waiver;
- The research could not practicably be conducted without access to and use of the PHI;
- The use or disclosure of the PHI involves no more than minimal risk to the privacy of the subjects as a result of:
  - Adequate plan to protect the PHI from improper use and disclosure;
  - Adequate plan to destroy any identifiers contained in the PHI
  - Adequate written assurances that the PHI will not be reused or re-disclosed to any other person or entity

## Prep to Research form vs. Waiver of Authorization

- Waivers are more encompassing so when in doubt submit a waiver
  - If you want to collect data for use in the research study, as for a waiver
- Prep to research can be submitted to the IRB at anytime
  - Use if you are assessing study feasibility
  - Prepping for research/ not conducting research

## Waiver of Consent

- With IRB approval the consent process may be altered in special circumstances (http://www.ohsu.edu/xd/about/services/integrity/policies/upload/Altered-Consent-Guidance.pdf)
- Minimal risk research
  - A short form may be signed to document an oral consent process
  - Consent elements (including documenting consent) may be altered or waived
  - The requirement to obtain consent may be totally waived
- More than minimal risk research
  - Waiver of requirement to document consent
  - Oral consent process with use of a short form to document consent.
  - Exception from informed consent requirements for emergency research

## Consent starts at the first contact

- Phone screens, advertisements, and flyers are part of the consent process
  - Must be IRB approved
  - Don't include anything in one of these documents that isn't in the consent
  - Don't collect PHI from subjects on the phone without an approved waiver of authorization

## Common Consent Audit Findings

- Failure to include required elements of consent
- Failure to include additional elements of consent when appropriate
- Language is too complex
- Failure to describe procedures completely
- Failure to adequately describe risks
- Failure to describe treatment alternatives
- Exculpatory language in consent documents
- Failure to obtain IRB/IEC approval before use
- Failure to document Informed Consent Process

## Consent Form Review Checklist

- ✓ Correct and Current consent/HIPAA template(s) used
- ✓ Submitted all the appropriate consents/waivers
- ✓ Spell check done
- ✓ IRB instructions deleted
- ✓ Grammar/Sentence structure check done
- ✓ 8th grade language used
- ✓ Information included is consistent with the protocol and other study documents
- ✓ Does it make sense? clearly written, understandable
- ✓ Charts/tables (if any) are clear, easy to read and match the protocol
- ✓ Risk section (for the drug) matches IB/protocol/package insert
- ✓ Cost section matches billing schedule/budget/contract
- ✓ Reviewed by PI
- ✓ Updated version/revision date in the footer

## OBTAINING CONSENT

**A properly conducted interview accomplishes more than a well written form**
**– Stanley Geyer**

## Obtaining Informed Consent

- Is a discussion, not a form.
- Required before any research procedure is performed.
- Must comply with 45 CFR 46.116 [basic elements of informed consent]

## Informed Consent Is…..

- "A process of sharing information and addressing questions or concerns."
  - World Health Organization
- Our legal and ethical obligation
  - Historical context
- Obtaining informed consent is one of the principal roles of a study coordinator.
  - Represents an ongoing conversation about participation, risk/benefit, and individual need.

## How do you obtain informed consent?

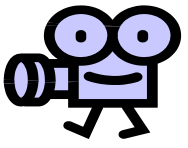
- Use the elements of informed consent as your guide –
  - Non-coercive (language - verbal & non-verbal)
  - Respect for autonomy (disclosure of risk/benefit, alternatives, confidentiality)
  - Transparency (Liability, sponsorship, staff)
  - Rights (legal, experimental procedures, liability of investigator or institution)
  - Equity (language, ability, special populations)

## How Do You Know If You Are Doing It Right?

- Are you complying with 45 CFR 46.116?
- Does it feel like a open and honest conversation?
- Did you begin obtaining consent from the moment you spoke with the participant?
- Does the participant demonstrate that they fully understand?
- Have you addressed the issues or concerns of your participant?
- Do you have a strong working knowledge of the protocol, visits, procedures, and privacy protection practices?

## Informed Consent Video

**The Informed Consent Zone**



## Presentation of Informed Consent

- Verify you have the correct version of the consent
- Consent subject in a room not in the hall or waiting area.
- Have participant read consent form if they have not done so previously.
- If possible have participant sit across from you with consent form facing them
- Point to each section and go over content
- Make good eye contact
- Speak slowly enunciate each word this will slow you down
- Verify participant understands what is going to happen to them and what side effects they could incur

# Special Considerations

## Definitions of Literacy

- **General Literacy:**
  "An individual's ability to read, write, and speak in English, and compute and solve problems at levels of proficiency necessary to function on the job and in society, to achieve one's goals, and develop one's knowledge and potential."
  - National Literacy Act of 1991
- **Health Literacy:**
  "The degree to which individuals have the capacity to obtain, process, understand, and act on basic health information and services needed to make appropriate health decisions."
  --Healthy People 2010
- *Estimated that ½ of US Population may be at risk for low health literacy.*

## National Adult Literacy Survey 1993,2003

- Most accurate portrait of literacy in the US, 2003 n= 26,000.
- 21% of American adults have inadequate literacy
  - Able to sign name, total bank deposit
  - Unable to use a bus schedule, comprehend "gist" of article, or fill out insurance form
- 27% of American adults have marginal literacy
  - Able to locate information in a newspaper article
  - Unable to read bar graphs/charts or understand insurance form

## Examples of health literacy tasks

| Level | Sample Tasks |
|---|---|
| Proficient | • Calculate an employee's share of health insurance costs for a year, using a table that shows how the employee's monthly costs varies.<br>• Find the information required to define a medical term. |
| Intermediate | • Find the age range during which children should receive a particular vaccine<br>• Determine healthy weight range, based on graph that relates height and weight to body mass index. |
| Inadequate | • Give two reasons why a person with no symptoms should be tested for a disease, based on information in a clearly written pamphlet.<br>• Read prescription bottle and communicate drug schedule for a week. |
| Marginal | • Circle the date of a medical appointment on a hospital appointment slip<br>• Identify what is permissible to drink before a medical test based on a short set of instructions. |

## Functional Health Literacy

- Can you say the following words: menopause, diabetes, colon polyp, carcinogen?
- What does it mean If the doctor says, "You have hypertension. You need to abstain from high-sodium foods, and partake in a rigorous exercise regimen"?
- Can you calculate your cholesterol level?

## Who is at risk?

- Populations most likely to experience low health literacy:
  - Older adults (>60 years old)
  - Racial & ethnic minorities
  - Less than high school education or GED
  - Low income
  - Non-native speakers of English
  - Compromised health status

## Patient Knowledge about their chronic condition

**Hypertension** Patients with hypertension who knew that exercise lower blood pressure

- Inadequate 38%
- Marginal 55%
- Adequate 73%

**Diabetes** Patients with diabetes who knew that they should eat some form of sugar if feeling shaky, sweaty, or hungry

- Inadequate 40%
- Marginal 45%
- Adequate 68%

## Low Health Literacy

- **Health Literacy Equals Problems with…**
  - Medications
  - Appointment slips
  - Informed consents
  - Discharge instructions
  - Health education materials
  - Insurance applications

***What does this mean for those involved in research?***

## Barriers to communication (Patient)

- The anxiety or intimidation within the medical interaction.
- Patient stress associated with seeking health care services
- Preconceived notions about doctors, health care, etc that make patients or doctors less likely to listen
- Cultural and linguistic differences between patients and physicians
- Physician/clinic time constraints
- Overuse of medical jargon

## Barriers to communication (Research)

- Time constraints
- Reliance on medical jargon
- Reliance on verbal communication
- Protocol, procedures, or process constraints
- Strength of communication skills
- Comfort or familiarity with protocol, procedures , or processes
- Cultural and linguistic differences

## How to improve the Informed Consent Process through Understanding Health Literacy

- Regulatory guidelines
  - GCP elements of informed consent
- Frequent checks for understanding
  - Verbal and non-verbal communication
- Tools
  - ICF checklist
  - Document process
- Limit barriers to communication
  - Make it a conversation
  - Build a relationship
  - Respect for subject
- Don't make assumptions about literacy
  - Understand risk factors
  - Understand study population and their unique characteristics

## Why Does It Matter

- Regulatory perspective
  - Are you following GCP guidelines
- Ethical considerations
  - Historical context
  - Current abuse
  - Research vs. Treatment
- Data Integrity
  - Compliance
  - Retention
- Professionalism
  - Custodians of the protocol
  - Diligence to safety and respect to research subjects

## Expanding Understanding of Consent Process

- Consent process goes beyond review of procedures, risks/benefits, etc.
  - Request for change (lifestyle, habit, treatment decision, etc.)
  - Non-coercive and voluntary
- Building retention from the first conversation
- Recognition that
  - Change is difficult
  - Subject's experience with the health care system, chronic or terminal medical issue
  - Socially complicated
  - Motivation to participate varies
  - Underserved populations with limited access to regular ca

## Tools for Expanding Understanding and Assessing Readiness

- Motivational Interviewing
  - Widely used technique in health psychology, public health, and in therapeutic situations
  - Focus is on exploring person's motivation to change behavior and resolving ambivalence
  - Supports change from the individual's own values
- Approach
  - It's a conversation….about change
  - Collaborative and person-centered
  - We are partner's in this process.
  - What motivates this participant? What are their concerns?

## How you can utilize MI to check for understanding and assess readiness

- ICF Checklist
  - Add MI-driven questions
- Use MI techniques in screening process
  - Recognize their values - "It sounds like giving back to the MS community is really important to you. I appreciate your willingness to give back through research."
  - Recognize their concerns – "It sounds like you are concerned about switching your medications. Would you like to talk with your doctor before proceeding with enrollment?"
  - Identify potential barriers - "Do you think you can make all 8 study appointments with your work schedule? Is there anything we can do to make it easier for you."
  - Understand there is always ambivalence – "I know Dr Doctor talked with you about our study, but it sounds like you might be giving it a second thought. Is it the study drug? Or is there something else about the study that is concerning you?"

## Motivational Interviewing Supports Ethical Research

- Was there ever time where you felt "uncomfortable" enrolling someone?
- Do you have experience with a subject whose motivation to participate was in an ethical "gray" area?
- How do you think motivational interviewing may assist you with being more ethical and patient-centered in your work?

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## MI Techniques & Difficult Consents

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## Informed Consent & Special Populations

## Decisionally Impaired Adults

- PI/MD investigator needs to make the Determination regarding the potential subjects ability to consent/assent
- There are differing levels of impairment
  - Fluctuating decisional impairment - e.g. mental illness
  - Progressive decisional impairment - e.g. early stages of Alzheimer's
  - Limited decisional impairment - e.g. limited capacity but still able to object or assent
  - Complete decisional impairment - e.g. later stages of Alzheimer's disease or unconsciousness due to trauma

## Decisionally Impaired Adults

- Need subject assent and Authorized Representative for Research (ARR) consent.
- The subject may designate an ARR when the subject has no decisional impairment or may be identified by the investigator in the same manner that he or she would determine a decision maker for health care treatment.
- http://www.ohsu.edu/xd/about/services/integrity/policies/upload/di.pdf

## Consenting subjects with Limited English Proficiency (LEP)

- Two options
  - Fully written translated consent
  - Short form + interpreter present

  **http://www.ohsu.edu/xd/about/services/integrity/policies/upload/lep.pdf**

## Consenting subjects with Limited English Proficiency (LEP)

- Written Consent translated into language that the subject understands
  - Must be approved and stamped by IRB
  - If person obtaining consent does not speak the subject's language an interpreter must facilitate informed consent
  - Subject, investigator (person obtaining consent), witness (interpreter) sign the informed consent
  - Pros
    - Subject has a document they can refer to later
    - They can take time to consider
    - If you are specifically targeting a non-English speaking group this is the approach you should use
  - Cons
    - Expensive

## Consenting subjects with Limited English Proficiency (LEP)

- Short Form plus oral presentation by interpreter of the full informed consent information
- Pros
  - Short form is available in 7 languages
  - You can get one approved quickly if you encounter a potential subject that speaks one of these languages
- Cons
  - Subject has nothing to refer to in their own language once they leave the clinic
  - Confusing regarding who signs what

## Consenting subjects with Limited English Proficiency (LEP)

- Using a Short Form
  - Subject reads IRB approved/stamped short form
  - Interpreter reads the IRB approved consent form aloud in the subject's native language.
  - Interpreter facilitates any of the subject's questions to investigator
  - Interpreter relay's investigator's overview of study
  - Subject signs the short form, investigator signs the standard consent form and the interpreter signs both the short form and the consent

## Consenting subjects with Limited English Proficiency (LEP)

- HIPAA authorization form is available in Spanish on the IRB website

## Child Assent

- Encouraging the child's involvement in decision-making is done out of respect for their rights as individuals and the desire to give them a sense of ownership in what happens during the trial.

## Child Assent

- If a child is between the ages of 7-18 and is capable of assent and the IRB requires Assent be obtained before the child can participate in the research
  - See OHSU IRB Help sheet – OHSU Guidance on Determining if Child Consent or Assent is Appropriate http://www.ohsu.edu/xd/about/services/integrity/policies/upload/IRB-SUPP_Help-Sheet-Child-Assent.pdf
- However, the regulations 45 CFR 46.408(a) state that the IRB may waive the assent requirements
  - If the intervention or procedure involved in the research holds out the prospect of direct benefit that is important to the health or well-being of the children **and**
  - If the intervention is available only in the context of research.

## Child Assent

- If a child assents to participate in research, and parental permission has not been waived by the IRB, the permission of the parent(s) or guardian is also required before the child can be enrolled in the research
  - Some studies only require one parents signature see 45 CFR 46.404 and 46.405
    - Research does not involve greater than minimal risk or
    - Involves greater than minimal risk but presents the prospect of direct benefit to the individual subject.
  - OHSU has a policy regarding when minors can consent for themselves http://www.ohsu.edu/xd/about/services/integrity/policies/upload/Children-in-Research-clean-2-9-11.pdf

## Documenting Informed Consent

- Consent process starts when subjects are initially contacted, so start documenting!
  - Advertising and Phone screening is considered part of the consent process
- IRB needs to be aware of who is consenting subjects – make sure the IRQ is up to date

## Documenting Informed Consent

- Use IRB approved/stamped consent form
- Signed & dated by subject and person obtaining informed consent at the time of consent
  - DO NOT date for the subject, witness, or PI!!!!!!
  - Some sponsors require PI sign all consents in addition to person obtaining consent
  - Both parents may be required to sign for pediatric studies
    - If research presents more than minimal risk and offers no prospect of direct benefit to child participants

## Documenting Informed Consent

- Provide a copy of consent(s) to subject
  - Document that a copy was provided
  - If the consent form includes the HIPAA authorization you must give the subject a signed copy
  - If there are any OHSU clinical procedures, you must send a copy to medical records
    - http://ozone.ohsu.edu/healthsystem/policy/display.cfm?id=729

## Documenting Informed Consent

- Witness signatures aren't required by OHSU IRB unless you are translating the consent
  - If you have a witness signature line you are required to have a witness sign
  - Per OHSU IRB the witness must be present for the entire consent process

## Documenting Informed Consent

- 21 CFR 312.62 and 812.140 specifically required to document that consent was obtained prior to study participation
- Progress note is required if consent obtained same day as study procedures and timing of consent isn't evident
  - Time on consent form isn't enough unless all study procedures are noted with the time
- Best Practice to write a progress note

## Sample Informed Consent Progress note

- During Ms X clinic visit 07/20/2011, I approached her about participating in Protocol ABC. After Ms X finished reading the consent form, we discussed study eligibility, study visits and procedures, the risks and benefits, alternative treatments, confidentiality, and her rights as a participant. All of her questions were answered. Ms X expressed understanding of the study information provided and agreed to participate in the study. She signed the consent and HIPAA authorization form prior to starting study procedures. A copy of the consent and a ***signed*** copy of the HIPAA authorization was provided to her.

## Documenting Informed Consent

- Check the consent document closely!
- Was the subject provided the current version of the consent?
- Does the date of the consent match the signature date for all (subject/person obtaining consent) if not why?
- Were all of the appropriate consent documents signed per IRB and Sponsor (if applicable) requirements
  - Initial every page (if required by sponsor)?
  - Initial the appropriate sections of a tiered consent
  - Initial the appropriate lines on the HIPAA authorization if study involves genetic, HIV status, drug/alcohol treatment

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# Other Consent Issues

## Other Consent Issues

- Re-consent –
  - Significant new information or changes that would impact willingness of participant to continue with study:
    - Risk, additional procedures, new use of subject data or specimens, alternate treatment and/or changes in study schedule.
    - There are exceptions to this rule (IRB policy)
  - The process and documentation is the same as the initial consent.

## Other Consent Issues

- Consented but…Ineligible, expired consent, forgot initial).
- Consenting vulnerable populations:
  - Understand historical and/or current socio-cultural context
  - Need to include spouse, friend, or family
  - Characteristics of study population
- Managing expectations (of subject, sponsor, PI, etc.)
- Navigating Exemption from Informed Consent