Informed Consent Process for Research Coordinators

Lora Wilson, RN, BSN, OCN, Research Nurse and Research Liaison
Phyllis Carello, BS, CCRC, Research Study Coordinator Manager
Bridget Adams, MSHS, CCRA, Manager Investigator Support and Integration Services - OCTRI

Topics To Be Covered

• Elements of Informed Consent
• Common Consent Problems
• Writing Informed Consent Documents
  – Identifying the correct consent templates
  – HIPAA authorization forms
  – Waivers of Authorization
• Obtaining Informed Consent
  – Adults
    • Decisionally Impaired Adults
    • Adults with limited English proficiency
  – Assent from Children
• Documenting Consent

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

• Statement that study involves research
  – Purpose
  – Duration of participation
  – Procedures (screening, protocol, follow-up)
  – Experimental components
• Description of reasonable foreseeable risks or discomforts

Elements of Informed Consent cont.

• Potential benefits to subject or others
• Alternative treatments/options
• Confidentiality of research records
• Compensation and/or medical treatment available if injury occurs
  – Statement must be included for > minimal risk studies

Elements of Informed Consent, Cont.

• Whom to Contact
  – In case of injury
  – With questions regarding research subject’s rights
  – For answers to questions about the research
• Participation is VOLUNTARY
  – No penalty or loss of benefits if subject refuses to participate or withdraws
Additional Elements of Informed Consent

- Risk for pregnant subject & embryo/fetus
- Circumstances for termination of participation
- Additional costs to subject
- Consequences of subject withdrawal and procedures for orderly termination
- If new findings affect willingness to participate
- Approximate number of subjects to be included

Common 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 describe treatment alternatives
- Exculpatory language in consent documents
- Failure to obtain IRB/IEC approval before use
- Failure to document Informed Consent
Lay Language

• Per 46 CFR 116 consent must be given in a language that is understandable to the subject or representative
  – 8th grade reading level
  – Don’t rely exclusively on Microsoft Word readability stats
  – Use short sentences
  – Use simple declarative statements when possible
  – List procedures in chronological order

Lay Language, Cont.

• Written in native language or orally translated if subject isn’t fluent in English
  – Short Form
  – Translated consent document
• Formatting, grammar, and spelling are important for readability and understanding

Exculpatory Language

• Per 45 CFR 46.116 consents cannot include language that waives or appears 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
  – Don’t use terms like:
    • “I understand”
    • “The study has been fully explained to me”
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 OCI templates
  - Non-Medical Intervention, Education, Health Promotion Research – use low risk template
  - Studies with clinical procedures – use barcoded consent and HIPAA authorization forms
  - Study involves genetics – use genetic consent templates
  - Investigator intends to use photos, recordings for teaching, publications, advertising – use a media consent form
- [http://www.ohsu.edu/xd/about/services/integrity/policies/research.cfm](http://www.ohsu.edu/xd/about/services/integrity/policies/research.cfm) for complete list of templates

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 HIPAA Research Guidelines at: [http://www.ohsu.edu/xd/research/about/integrity/irb/hipaa_research_policy.cfm](http://www.ohsu.edu/xd/research/about/integrity/irb/hipaa_research_policy.cfm)
  - 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 and HIPAA authorization forms do I need?

- Not always easy to tell
- Use a combined Consent and HIPAA authorization
  - When no sample/data banking
- Use a separate consent and HIPAA authorization
  - When study involves optional banking
- OHSU IRB Guideline for Developing Consent Forms and HIPAA Authorizations
  - [http://www.ohsu.edu/xd/research/about/integrity/irb/upload/Consent-HIPAA-Forms-Flowsheet-03-31-09-v1.pdf](http://www.ohsu.edu/xd/research/about/integrity/irb/upload/Consent-HIPAA-Forms-Flowsheet-03-31-09-v1.pdf)
How Many Consents/Authorizations Do I Need?

• A Clinical Trial that includes a genetic test to determine inclusion/exclusion criteria.
• There is no banking involved.
How Many Consent/Authorizations Do I Need?

- A Clinical Trial that includes banking blood samples for future genetic testing
- The study also has an optional PK visit

How many consent and HIPAA authorization forms do I need?

- Sub-study consent vs. tiered consent?
  - No hard and fast rule
  - 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 be screened for the study only
  - Still requires a detailed consent for the entire study that is presented to prospective subjects that meet the inclusion exclusion criteria
  - 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 and subjects may decide not to participate when they receive the full consent form

- 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 under certain circumstances, such as with decisionally impaired participants, [http://www.ohsu.edu/research/rda/irb/policies.shtml](http://www.ohsu.edu/research/rda/irb/policies.shtml)
  - No template is available and it is usually incorporated into the consent form as a separate signature line

Confidentiality and HIPAA

- Confidentiality and Privacy of your protected Health Information
  - Not use name or identity for publication or publicity purposes
  - Will be assigned a study code number, if applicable
  - List who can review and or copy research records
  - Remember to refer to the HIPAA decision tree to when deciding whether or not you can use a combined consent/HIPAA authorization
Confidentiality and HIPAA

• Table of health information to be used or disclosed
  – Be sure to indicate everything you may be using: medical records for recruitment, lab reports if sample analysis is done, all procedures

• Purposes for using/disclosing PHI
  – A. To learn more about the disease
  – B. To facilitate treatment, payment, operations
  – C. To comply with federal or government regulations
  – D. For Teaching Purposes
  – E. To place in a repository or “bank” – only list if you plan to bank samples for future use. Saving samples to be assayed in batch form or to be re-assayed in case of error is not “banking”

Confidentiality and HIPAA

• PHI with additional regulatory protections
  – AIDS/HIV, Drug/alcohol, Mental health, Genetics
  – Must have subjects initial these items on the form in addition to the usual signing if you wish to use this data

• How long will you continue to use and disclose PHI?
  – The study is completed – be sure to say “after all data analysis is complete”
  – Indefinitely – the safest response
Confidentiality and HIPAA

- This form authorizes the investigator to use the data they’ve collected
- Persons authorized to use and disclose protected health information (PHI)
  - People within OHSU who will have access to study data
- Persons authorized to receive PHI
  - People outside OHSU who will receive study data

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, subjects would need to be reconsented at a later date for use of their samples
- The commercial development boilerplate language can be found in the genetic consent template
  http://www.ohsu.edu/xd/research/about/integrity/irb/

Consent Language Negotiations for Industry Sponsored Research

- Consents must be approved by the sponsor before they are submitted to the IRB
- 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/oc/ohrt/irbs/informedconsent.html#model
- If you have difficulties, you can ask the IRB for assistance in your discussions with the sponsor.
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
  – The requirement to document informed consent may be waived
  – Some required elements 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

Waivers of Authorization

• The IRB may approve a Waiver of Authorization to 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
• Data requested must be necessary to conduct the research
• See HIPAA Activities Preparatory to Research (http://www.ohsu.edu/xd/about/services/integrity/policies/upload/HIPAA-Prep-To-Research-Regulatory-Short.pdf)

Waivers of Authorization

• To approve a waiver, the investigator must establish:
  • The research involves no more than minimal risk to the subjects;
  • Waiver will not adversely affect the rights and welfare of the subjects;
  • The research could not practically be conducted without the waiver;
  • The research could not practically 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 at the earliest opportunity;
    – Adequate written assurances that the PHI will not be reused or re-disclosed to any other person or entity,
Consent Form Review Checklist

- Correct and Current consent/HIPAA template(s) used
- HIPAA form either embedded or attached, correct entities listed
- Spell check done
- Grammar/Sentence structure check done
- 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

Consent Form Review

• Remember that OHSU has some language that must be used. Always check the instructions for Consent & Authorization form for latest boiler plate language

OBTAINING CONSENT
Informed Consent Is an Educational Process

- Before a subject may be enrolled in a clinical trial he/she must
  - be provided with information regarding the trial
  - have the opportunity to consider this information and ask questions
  - subsequently agree to participate in the trial

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/research/rda/irb/policies.shtml](http://www.ohsu.edu/research/rda/irb/policies.shtml)
Consenting subjects with Limited English Proficiency (LEP)

- Two options
  - Option 1
    - Written Consent translated into language that the subject understands
      - Must be approved by IRB and bear the IRB approval stamp
      - If person obtaining consent does not speak the subject’s language interpreter must facilitate informed consent
      - Subject, investigator (person obtaining consent), witness (interpreter) sign the informed consent
  - Option 2
    - Oral presentation by interpreter of the informed consent information
      - In conjunction with translated short form
      - IRB approved written summary of what is presented orally (OHSU IRB requires full consent to be translated)
      - Required by IRB when study targets population in which there is high or certain likelihood of encountering non-English speakers.

Consenting subjects with Limited English Proficiency (LEP)

- Using a Short Form
  - Subject reads IRB approved/stamped short form
  - Interpreter reads standard informed consent in subjects 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 summary
Consenting subjects with Limited English Proficiency (LEP)

- Short consent form templates are available in several languages and a HIPAA authorization form is available in Spanish on the IRB website
  - Targeting non-English speakers vs. enrolling them incidentally, [http://www.ohsu.edu/research/rda/irb/docs/procedures/lep.pdf](http://www.ohsu.edu/research/rda/irb/docs/procedures/lep.pdf)
  - If you are not targeting non-English speaking participants, the IRB will let you submit without a short form if you say up front that you will submit one upon identifying a potential participant

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 capable of assent and the IRB requires
  - Assent be obtained before the child can participate in the research
  - if the child dissents from participating in research, even if his or her parents or guardian have granted permission, the child’s decision prevails.
- 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
  - 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 parents or guardian is also required before the child can be enrolled in the research.
- OHSU has a policy regarding when minors can consent for themselves. [http://www.ohsu.edu/research/rda/irb/docs/policies/minorconsentpolicy.pdf](http://www.ohsu.edu/research/rda/irb/docs/policies/minorconsentpolicy.pdf)

Informed Consent Video

The Informed Consent Zone

PAUSE
Talking too fast

PAUSE

PAUSE
Alternatives to participation

PAUSE

Lay Language
Cost benefit ratio

PAUSE

PAUSE
Time to consider

Who to call if questions

PAUSE
Presentation of Informed 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

Informed Consent Practicum

Demonstration

Your Turn!
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!!!!!!
  – 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
  – Copy doesn’t have to be signed by regulation but you need to follow what you told the IRB
  – If there are any OHSU clinical procedures, you must send a copy to medical records
    • [Link]

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
• Good Practice to write a progress note

Documenting Informed Consent

• Check the consent document closely!!!!!
• Did the person obtaining consent:
  • Provide the correct versions of the consent/HIPAA to the subject?
  • Date their signature with the correct date?
• Did the subject:
  – Sign all of the appropriate consent documents (consent, HIPAA authorizations)
  – 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
  – Date their signature with the correct date?