Obtaining Informed Consent

Duke Translational Nursing Institute
Objectives

To learn:

• Why have a consent?
• What are ethical foundation and federal regulations of a consent?
• What are basic elements of informed consent?
• What is informed consent and when, why and how must it be obtained?
• What are types of consent?
Why Have a Consent?

• For the protection of human subjects
• Disclosing to potential research subjects information needed to make an informed decision
• Facilitating the understanding of what has been disclosed
• Promoting the voluntariness of the decision about whether or not to participate in the research
What Are Ethical Foundation and Federal Regulations?

- **Belmont Report** is the basis for the US Dept. of Health and Human Services human subject protection regulations and includes:
  - Respect for Persons
  - Beneficence
  - Justice
What is: Respect for Persons?

- People are autonomous
- Those with diminished capacity should be protected
What is: Beneficence?

- Respect for participant decisions
- Protection from harm
- In the Belmont Report, beneficence is an obligation, not just an act of kindness. Thus, the following are required:
  - Do not harm
  - Maximize benefits & minimize potential harm
What is: Justice?

1. To each person an equal share.
2. To each according to individual need.
3. To each person according to individual effort.
4. To each person according to societal contribution.
5. To each person according to merit.
Application of Belmont Report to Research

1. Informed Consent
2. Assessment of Risks & Benefits
3. Selection of Subjects
Belmont Report & Informed Consent

• **Respect for Persons**
  – Freedom to choose based on:
    • Information about the study
    • Comprehension
    • Voluntary
Regulatory Oversight for Human Subjects Research

• Government agency:
  – Department of Health and Human Services

• Document that governs details of human subjects research:
  – Code of Federal Regulations (CFR)
Federal Regulation 45CFR 46.116: Informed Consent

“…no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative.”
45 CFR 46.116: Informed Consent

“An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.”
45CFR 46.116: Informed Consent

“No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.”
What Are Basic Elements of Informed Consent (45CFR 46.1)?

1. Statement that the study involves research
2. Explanation of the purpose of the research
3. Expected duration of subject participation
4. Description of procedures to be followed
5. Identification of any procedures that are experimental and, if applicable, statement that drug is investigational and not approved by FDA
Basic Elements of Informed Consent (continued)

6. Description of any foreseeable risks or discomforts

7. Description of benefits to the subject or others that may result from the research

8. A statement describing the extent, if any, to which confidentiality of records identifying the subjects will be maintained
Basic Elements of Informed Consent (continued)

9. An explanation that participation is voluntary and that the subject may discontinue at any time.

10. An explanation about what will be done with the responses they have already provided if subjects decide to discontinue participation.

11. Terms of payment and conditions under which subjects will receive partial or no payment.
Basic Elements of Informed Consent (continued)

12. For studies that are greater than minimal risk:
   – Statement whether any compensation is offered
   – Statement if medical treatment is available if injured
Basic Elements of Informed Consent (continued)

13. Participation is voluntary:

--Can refuse to participate without prejudice, loss of services or benefits

--Can withdraw at anytime without prejudice, loss of services or benefits.
Basic Elements of Informed Consent (continued)

14. Name and phone # of contacts for subjects to call with questions about:

--The research study
--Their rights as subjects
--In the event of research-related injury
Basic Elements of Informed Consent (continued)

15. Risks to fetus if subject were to become pregnant.

16. Situations where the researcher could terminate the subject’s participation in the study.

17. Any other costs to the subject that could result from participation in the study.
Basic Elements of Informed Consent (continued)

18. Consequences of early withdrawal from the study and process for withdrawal.

19. Statement that subjects will be notified of new findings that could affect their willingness to continue in the study will be provided.

20. Approximate number of subjects in the study.
Informed Consent vs. Consent Form

• Informed consent = process
• Consent form = document
  – Consent form templates available
    http://irb.duhs.duke.edu/modules/irb_forms/index.php?id=1
  – Most common eIRB submission errors related to consent form:
    • Misuse of “informed consent” as a document
    • Not adhering to standard consent form language. More than 50% of modifications requested relate to use of updated standard language
      http://irb.duhs.duke.edu/modules/irb_stdlng/index.php?id=1
Required Components of a Consent Form

- Research purpose and rationale of study
- Study procedure or methodology
- Benefits of participating
- Risks or possible discomfort incurred due to participation
- Alternative treatments, therapies or options if one does not participate
- Procedures to ensure confidentiality/HIPAA language
- Research related injury clause (i.e. responsibility for, and course of action in the event of)
- Statement guaranteeing voluntary participation
- Consent for participation
Use of Short Form Consent at DUHS is largely limited to:

- When English is not understandable to a potential research subject and the investigator does not have an IRB approved consent document translated into a language understandable to potential subject
  OR
- When the window of opportunity for subject to benefit from research participation is brief and IRB finds that the use of the Short Form provides sufficient opportunity for the subject to make an informed decision about study participation
Oral and Short Form Consent

• Must have a short form written consent stating that the required elements (per 46.116) were:
  – Presented orally
  – Witnessed during the oral presentation
  – Summarized during the oral presentation

• IRB approval of oral consent procedures, study summary and short form
Waiver of Signed Consent 45 CFR 46.117c

• IRB may waive requirement for signed consent if:
  – Consent is only documentation of subject’s participation and the primary risk would be potential harm due to breach of confidentiality
  OR
  – Research presents no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context

• IRB can require subjects be given a written summary about the research.
Waiver or Alter of Some Elements of Consent-
-45 CFR 46.116(c)

IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of consent or waive the requirement to obtain informed consent provided the IRB finds and documents that:

- C1: Research designed to study certain aspects of public benefit or service programs;
- C2: Research could not practicably be carried out without the waiver
45 CFR 46 Subpart D: Permission of Parents/Guardians 46.408

• Permission of one parent is sufficient if research does not involve greater than minimal risk or involves greater than minimal risk but has potential for direct benefit

• Otherwise, permission of both parents are necessary, unless one parent is:
  • deceased
  • unknown
  • incompetent
  • not reasonably available
  • one parent has legal responsibility for child
Subpart D 46.408(d) Waiver of Parental Consent if:

- Subject population of research is such that consent is not a reasonable requirement to protect the subjects (abused or neglected children)
Assent vs. Consent – What’s the Difference?

• For a child to participate in research, permission of one or both parents is required, and in most cases, **assent** of the child is also needed.

• Consent form is a legal document obtaining a subject’s voluntary agreement, based upon an adequate knowledge and understanding of relevant information, to participate in research.

• **Assent** is an affirmative willingness to participate in research. Mere failure to object, absent affirmative willingness, should not be construed as assent.
  
  • For subjects who are not able to give consent, **assent** provides the opportunity to agree to participate through the assent process (e.g. minors, adults with diminished capacity /cognitive impairment).
45 CFR 46 Subpart D: Assent of Children 46.408

- Verbal assent required of those over 6
- Signed assent required of those over 12
- Assent can be waived:
  - limited capability
  - prospect of direct benefit that is only available via the research
- If there is a chance that subject will turn 18 yrs. old while on study, there must be a plan to re-consent these subjects as adults
Foreign Language Consents

• “in language understandable to the subject”

• If subjects are non-English speakers and require a translator and translated consent material
Foreign Language Consents

45 CFR 46.116 and 45 CFR 46.117

There are two methods for obtaining and documenting informed consent for research subjects who do not read, speak, or understand English:

– Written consent in the subject’s language
– Oral consent

• The preferred method is to provide consent forms written in the subject's language. Duke requires forward and backward translations by different translators
Foreign Language Consents
Alternative Short Form

Oral consent plus short form can be used when:

– Accompanied by a written summary of oral presentation. English version of IRB approved consent can serve as summary.

– Must be witnessed. Witness can be translator.

– Ethical Consideration – Equitable protection of subjects taking into account content of consent form.
Criteria for IRB Approval of Research
45 CFR 46.111

• Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

• Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

• Selection of subjects is equitable
Criteria for IRB Approval of Research
45 CFR 46.111(continued)

• Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 46.116.
• Informed consent will be appropriately documented, in accordance with, and to the extent required by 46.117.
• Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
• Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
• When some or all subjects are members of vulnerable populations, additional safeguards have been included in the study and in the IRB review process.
Duke IRB Standards

• MO345 Form to be used for consents so it will be suitable for inclusion in subject’s medical record

• Where appropriate consent document includes HIPAA authorization information

• Standard Language available on IRB website: http://irb.duhs.duke.edu/
Duke IRB Standards

• For every IRB approved protocol, the investigator must
  – Use an IRB approved consent process
  OR
  – Have received IRB approval for waiver of consent/authorization

• Informed Consent and Its Documentation policy is available on the IRB website: http://irb.duhs.duke.edu/wysiwyg/downloads/Informed_Consent_and_its_Documentation_4-22-2008_jw.pdf
Additional Considerations

• Follow your consent process plan

• PI may delegate obtaining consent to **qualified** and **trained** research team members.
  – Responsibilities delegated must be documented on the signed delegation of authority log
  – These individuals should be identified as key personnel in eIRB

• Training is documented

• Cross-training (Is there a back up plan?)

• Important for study team members to know what each person’s role on the team is and who is able to answer study questions for the participant

• Resources identified for staff associated with the subject’s care when they have to field questions?
Conclusions

Why, when and how of valid consent?

• WHY: Ethical foundation of respect for person, beneficence and justice with Federal Regulations as guidance

• WHEN: Prior to participating in any study procedures, allowing sufficient time for subject to consider whether to enroll in study

• HOW: Informed consent as a process to allow potential subjects to consider risk, benefits and alternatives of participation.
Frequent Errors Found with Consents

- Missing
- Name and MRN not on each page of consent
- Not signed (by either patient or witness)
- Not initialed
- Not dated
- Incorrect Protocol Number
- Use of draft, incorrect or expired consent version
- Not re-consenting when appropriate
Where to Find The Latest Approved & Watermarked Consent

ALWAYS retrieve it from eIRB to ensure you have the latest version
Do NOT use DRAFT consent form

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Approved Consent

Signature of Subject ___________________________ Date __________

Signature of Person Obtaining Consent ___________________________ Date __________

Check the date on the APPROVED & WATERMARKED consent

Protocol ID: Pro00019792
Continuing Review Before: 9/24/2011
Reference Date: 9/13/2010
How About This One?

• Do not use this:

Protocol ID: «IRBNo»
Continuing Review Before: «ExpireDate»
Reference Date: «Version»
Strategies For Success

• Follow the HRP policies for Informed Consent
• Use consent form templates and tools
• Use standard language for consent sections
• Enlist the help of expert
Enlist the Help of Expert

• DTNI: email dtni@mc.duke.edu
  919-668-2344

• DUSON ORA:  
  919-684-5376

• DUHS Research Nurse Scientist:  
  919-613 6406
Special Thanks

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