Informed Consent

Part Three:
Good Practice
Informed Consent: Good Practice

- Process of Informed Consent
- Drafting the Informed Consent Document
- Obtaining and Documenting Informed Consent
- Ongoing Consent Issues after IRB Approval
Informed Consent

• A *process* of information exchange that takes place between the prospective subject and the investigator, before, during and sometimes after the study

  ➢ Not just a signature on a form
  ➢ Document = written source of information & place to document that the subject has provided consent

*(FDA Guide to Informed Consent, 2014; OHRP Informed Consent FAQs; OHSP Policy 701, 2014)*
Informed Consent Process

• Not only reviewing/signing document but also:
  – Recruitment materials
  – Oral instructions/explanations
  – Q & A period
  – Assessing subject understanding
  – Providing time for subject review form & consider participation
  – Providing new findings, study updates
  – Periodic re-affirmation or re-consent

Informed Consent Process

• IRB Review: Is the process adequate given the nature of the study?

• When developing process consider:
  – Setting
    • Is it a private? Can others overhear you? Is it chaotic?
  – Timing
    • Seek consent in advance of any study procedures
  – Minimizing undue influence
    • Remove “intimidation factor”
    • Delegate consent responsibilities?
Informed Consent Process

• Additionally…
  – Use of additional aides (brochures, videos, etc.)
  – Seek consent in presence of “personal advisors”
  – Ask open-ended questions to assess understand. “In your own words, tell me…”
    • What the study is about
    • What will happen if you participate
    • What risks might you experience
    • What other options you have

(OHSP Guideline for Informed Consent, 2014)
Drafting the Consent Document

Consent Document

- Foundation of information exchange
- Enough info to make informed decision
- Clear & Understandable

→ Use RSRB templates & sample language

Drafting Consent Documents

• Information must be consistent with study protocol & IRB application
• Aim for a 6th-8th grade reading level
• Write as if you were talking to the subject
  – “You will be asked to…”
• Don’t use “I understand that…”
• Use “subject”, not “participant” or “patient”
• Use “study doctor” or “study investigator”, not “principal investigator”
Drafting Consent Documents

• Use lay terms (e.g., bronchodilator = drug that helps you breathe easier)
• Use subheadings and white space
• Use pictures, tables, charts, bullets and lists to show complex schedules/design/procedures

Drafting Consent Documents

• Check to make sure items are in a logical order

• Use consistent terminology (drug names, abbreviations)

• Use appropriate font size

• Keep words to 3 syllables or less

• Keep sentences/paragraphs short & direct

• Provide “quick reference guide”

(OHSP Guideline for Informed Consent, 2014)
Drafting Consent Documents

• Combine consent & permission documents as appropriate
  – In heading…“If you are the parent of a child or the authorized representative of an adult subject who may be enrolled in this study, the word ‘you’ in this form refers to the subject.”

• HINT: Work off previously approved consent for similar study
  – **Review for cut/paste errors & to ensure everything is consistent with application and protocol
IRB Review & Approval

- RSRB Expectations: Outlined in all RSRB approval letters

- Expectations the same regardless of risk
RSRB Expectations for Obtaining Consent

• RSRB Approval Letter States:
  
a) Consent must be obtained/documentated in the manner approved by RSRB (i.e., comply with protocol). For example:

  - If decisionally impaired are not eligible... subject must consent for themselves
  
  - If protocol states that the PI will obtain consent... PI must have discussion & sign as the person obtaining consent
b) Consent/Recruitment materials must bear RSRB watermark
   - Watermarked consents = only valid consent
   - Watermarked with each amendment & re-approval
   - Each page is watermarked
RSRB Expectations for Obtaining Consent

c) Only most recently approved version may be used;
d) Must be printed on letterhead;
e) PI responsible for:
   - Submitting any changes to the RSRB for review
   - Maintaining all approved pages of signed consents for at least 3 years (6 years if HIPAA included; maybe longer due to contract)
   - Maintaining copies of all approved documents in the study file.
Documenting Informed Consent

• Make sure the using the correct document
  – Consent or Permission; Written Assent or Verbal Assent
  – Control/Experimental Consent

• Signature & date from both the subject and the person obtaining consent required
  – Generally, dates should be the same. If not, document why

• Submit documents on electronic department letterhead
Documenting Informed Consent

• Make sure any checkboxes are completed
• DON’T sign/date the consent for the subject
• DON’T use a signature stamp
• DON’T white out, cross out of otherwise change any part of the approved consent form → Any revisions must submitted & approved prior to implementation
Documenting Informed Consent

• Ensure that anyone obtaining consent is listed on the RSRB application as study personnel
  – Sections 1.5-1.7 or 85.1 of the application

• Make sure to provide a signed copy of the entire consent to the subject

• Make sure any witness signature blocks are completed
  – Should be someone unaffiliated with the research
Documenting Informed Consent

• Document the process (relevant sequence of actions) in the progress note/case history
  – Who? What? Where?
    • Review of study/procedures;
    • Questions raised & answers provided;
    • Time to review document;
    • Subject understanding;
    • Agreement to participate

Document Informed Consent

– Example:

• 1/1/2012: Mr. Jones presented to the clinic today for his routine check-up. Study #1234 was presented to him as, per his routine lab work, he is eligible for participation. He has no history of diabetes, high blood pressure or cancer. The study was explained to him and the consent form provided to him for his review. The study coordinator will follow-up with him in one week.

  – Dr. Smith

• 1/15/2012, 1:00pm: Mr. Jones and his wife returned to the clinic today. The study was further discussed and the consent form reviewed. All of Mr. & Mrs. Jones’ questions were answered. Mr. Jones and I signed the study consent form and a copy of the entire signed document was provided to Mr. Jones for his records.

  – Nurse Harris
Ongoing Consent Issues after IRB Approval

- Storage of Informed Consent Documents
- Amending Consent Documents
- Re-Consenting Subjects
- Ongoing Review by the RSRB
- Errors in Obtaining/Documenting Informed Consent
- Preventative Action Measures
Consent Storage

Signed Consents:
- Maintain for at least 3 years after complete (longer if HIPAA or required by sponsor/regulatory body)
- Custody of PI’s Department
- Designate a specific area for all original copies of signed consents for a study
- Store in chronological order
- Maintain a link b/n consent document & subject ID

Approved Consents:
- Maintain a blank copy of all approved, watermarked consent documents in study file
Amending Consent Documents

→ Any changes to the form must be approved by the IRB prior to implementation

• Submit 2 versions:
  1. Tracked version showing proposed changes
  2. Clean, unmarked version with tracked changes accepted
Amending Consent Documents

• Notification to Subjects Required?
  – No: minor & do not affect subject participation
  – Yes: substantial changes or new information that may affect a subject’s willingness to continue participation

• If yes…
  – Orally…document in subject’s study file
  – Written via information letter, revised consent form or consent addendum

→ Method of communication depends on nature of change

→ Additional instructions for completing amendments in ROSS are available on the RSRB Website.
Re-Consenting Subjects

• When?
  – Minor subject turns 18
  – Subject originally enrolled with permission of authorized rep regains capacity
  – Subject that originally provides consents loses capacity
  – Incident of non-compliance
  – Substantial changes
  – New information

Re-Consenting Subjects

• How?
  – Current approved, IRB watermarked consent document
  – Current date (don’t back or use the date consent was originally obtained)
  – Person who originally obtained consent does not need to be the one to re-consent
Ongoing Review

- At time of Continuing Review submit a copy of the *entire* consent signed by the last subject enrolled

- If >1 approved consent, submit a copy of the *entire* last signed consent form for *each* type of approved consent
Ongoing Review

- Block out the name & signature of the subject to maintain confidentiality but not the date of consent or the name/signature of the person obtaining consent

Subject Consent
I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

[Signature of Subject]

Person Obtaining Consent
I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject’s satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

Jane Doe, CRC
Name and Title (Print)

[Signature of Person Obtaining Consent]

[Date: 1/2/2012]
Ongoing Review

• RSRB will review:
  – Signatures & dates provided
  – Person obtaining consent is approved by the RSRB
  – Entire, correct version used
  – Each page has current watermark
  – First page is on letterhead

(OHSP Guideline for Informed Consent, 2014)
Errors in Obtaining/Documenting Informed Consent

• Most Common Findings:
  – Using the incorrect form (outdated version or wrong document for population)
  – No letterhead, no watermark
  – Consent obtained by staff w/o research training or who have not been approved by the IRB
  – Cross outs/Additions to document
  – Study procedures prior to consent

(OHSP Guideline for Informed Consent, 2014)
Errors in Obtaining/Documenting Informed Consent

• How to Report it?
  – Type 8 (Non-Compliance) Reportable Event in ROSS
  OR
  – Question 5.8 on Progress Report (Did any problems occur in the process of obtaining and documenting informed consent?)
  – Not sure?…call your RSRB Specialist

(OHSP Guideline for Informed Consent, 2014)
Errors in Obtaining/Documenting Informed Consent

• How to Fix it?
  – Oral/Written notification to subject(s)
  – Re-consent subject(s)
  – Note to File
  – De-identify data
  – Exclude data

• Provide additional information/clarification
• Explain discrepancies or missing/incomplete data
• To be effective:
  ✓ Explain discrepancy
  ✓ Action taken to correct
  ✓ Preventative action adopted

(Guideline for Writing Notes to the Study File; OHSP Guideline for Informed Consent, 2014)
Invalid Consent Forms

• Failure to adhere to federal regulations and/or University policy = failure to obtain legally effective informed consent

• May be considered serious or continuing non-compliance under federal regulations

→ Reported to federal agencies

Preventative Action Measures

• Incorporate electronic letterhead on consent forms submitted to IRB
• Name only PI on consent heading
• Leave out subject initials on each page & witness signature blocks

Witness Signature Blocks:
• Only required by regulations when using a short form consent
• For all other studies that include witness signature → protocol should address whether they are optional or mandatory; if optional should clarify circumstance

Preventative Action Measures

• Develop a process for:
  – Maintaining the current approved consent
    • store on shared network drive
    • keep a current file in the clinic
    • designate a consent “gatekeeper”
  – Destroying outdated copies of consent forms
  – Ensuring the signature page is completed at the time of consent
  – Providing subjects with a signed copy

(OHSP Guideline for Informed Consent, 2014)
Questions?

Call RSRB @ 275-2398 & ask to speak to your RSRB Specialist.

Additional Resources

- OHSP Website:  http://www.rochester.edu/ohsp
References


