Learning the Consent Process: How to Swim, Not Sink

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Learning the Consent Process: How to Swim, Not Sink

- Informed Consent & the Consent Process
- Resources for Learning the Process
- Process Example
- Documentation of Process
- Lesson Learned
Informed Consent

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

- Informative, Comprehensive & Voluntary
- Not just a signature on a form
- Document = written source of information & place to document that the subject has provided consent
Informed Consent Process

- May include:
  - Recruitment materials
  - Oral instructions/explanations
  - Additional aides (videos, cover sheets, etc.)
  - Q&A period
  - Assessing subject understanding
  - Providing time for subject to review form & consider participation
  - Providing new findings, study updates
  - Periodic re-affirmation or re-consent
Informed Consent Process

…but how do I actually obtain consent from someone?
Informed Consent Process

KEEP CALM AND DO YOUR HOMEWORK
Resources for Learning the Process

- **DHHS**
  - OHRP & FDA Regulations, Fact Sheets
  - You Tube Videos:
    1. [General Informed Consent Requirements](#) (OHRP)
    2. [Elements of a Successful Informed Consent Video](#) (NIH)

- **RSRB**
  - Guidance on Recruitment & Informed Consent
  - Informed Consent Presentation
Resources for Learning the Process

- CTSI
  - Research Subject Advocacy Program
  - Guideline for Obtaining Written Consent

- Professional Organizations & Journals
  - ACRP, SoCRA, PRIM&R

- Network, Find a Mentor & Observe (SCORE!)

- The Web – Google it!
The PAGIC Model

Informed Consent Process

Ok, I did my homework…

now what?
STOP and THINK!

Prior to initiating the study, thoughtfully consider:

- Study Design
- Study Population
- Logistics
- Access to Subjects

- Setting
- Timing
- Minimizing Undue Influence
- Subject Advocate
Coordinator Process Example

Study: Investigator-Initiated, Randomized, Placebo-Controlled Trial of an Investigational Drug (16 wks of study drug; additional study-related imaging/lab testing & clinic visits)

1. Notified of potential subject
2. Ensure you have the most recent RSRB approved, watermarked consent document
3. Consider your access to the subject & the setting
Coordinator Process Example

4. Introduce yourself
   - Is it a good time?

5. Provide a verbal explanation of the research
   - Purpose, procedures, risks, benefits, costs/payments, alternatives to participation, etc.
   - Allow ample opportunity to ask questions
Coordinator Process Example

7. Provide subject with a copy of the written consent form & any additional aides
8. Provide subject with your contact information, a follow-up timeframe…and leave them alone
   - Provide sufficient time to review written materials & consider participation
   - Document the process so far
Coordinator Process Example

9. Follow-up with subject... Do they have more questions? Do they want to participate?

10. If yes, assess subject comprehension

- Useful questions are open-ended and non-directive (“Just so I’m sure that you understand the study, can you tell me in your own words...”)
  - Why the study is being done?
  - What will happen if you participate?
  - What randomized and placebo mean?
  - What risks you might experience?
  - What alternatives there are for participating?

- Asking questions may prompt further discussion
Coordinator Process Example

11. All questions answered & agreement to participate → sign & date the consent form
   - Subject and person obtaining consent
   - Still using current, RSRB approved, watermarked consent?


13. Provide the subject a copy of the entire, signed consent document

14. Document the process
That Said…

Every study is different & every subject/family that you will consent within the same study is different.
About That Documentation…

- Requirement vs. Best Practice
  - Review of study/procedures
  - Questions raised & answers provided
  - Time to review document
  - Subject comprehension
  - Family/Friends present
  - Agreement to participation
  - Signed copy provide to subject
About That Documentation…

- Remember the 5C’s
About That Documentation…

- Make sure process documentation is consistent with other source documentation
- Be concise (include nature, discussion outcome)
- Document each interaction as soon as possible after they occur
- Continue documentation throughout course of study (re-consent/subject notification)
- Checklist vs. narrative documentation
- Be careful of your paperwork…
About That Documentation…
Lessons Learned

Know what standards you’re being held to:

- Federal Regulations
  - Elements, Subparts B, C & D
- RSRB Expectations
- Department SOPs
- Sponsor Expectations
- Protocol-Specific Criteria
Lessons Learned

Know your options:

- Written Consent
- Information Sheets & Verbal Consent (Waivers of Documentation of Consent)
- Mailing Consent
- Notification vs. Re-Consent
  - Consent Addendums, Information Letters
Lessons Learned

- Know when to call in reinforcements:
  - Is the study appropriate for you to obtain consent?
  - Are you able to adequately explain study procedures/risks and answer questions?
  - Recognize when you need the PI’s help
Lessons Learned

- Don’t be shy…

Call the RSRB/CTSI with questions, concerns, problems
Lessons Learned

- Finally...

Use common sense
&
common courtesy

Please and Thank You
ARE STILL MAGIC WORDS.
Questions?