Informed Consent Process
Kathleen O’Malley RN, BSN, CCRP
Manager of Education and Training
Jefferson Clinical Research Institute
Learning Objectives:

• Provide rationale for the reason informed consent should be considered a process
• Describe appropriate settings for informed consent
• Provide examples of what can be done in advance to improve the informed consent process
• Give two methods of assessing subject comprehension
• Outline the information that should be included when documenting the informed consent process
• Identify two measures to avoid undue influence during the informed consent process
Why is it so important?

Why is it referred to as a process?

Who, what, where, when, why and how of Informed Consent process?

What are your responsibilities?
“The single biggest problem in communication is the illusion that it has taken place.”

George Bernard Shaw
Why is it informed consent so important?

- **Ethical requirement** and the **LAW**!
- Protects the rights, safety and wellbeing of subjects
  - Ensures the subject is fully and accurately informed
  - Comprehends the information
  - Decision is voluntary
Why is it referred to as a process?

- **Ongoing interaction** between the subject and research personnel
- Begins with the first contact and exchange of information
- Continues beyond study termination

Each contact is an opportunity to reiterate information and ensure that participation continues to be fully informed and voluntary
The informed consent **document** is a teaching tool:

- **Describes:****
  - requirements of the protocol
  - responsibilities of the subject
  - risks/benefits of participation

- Documentation of consent is **only the first step**
  - Documents voluntary and informed consent, prior to any study procedures
WHO:

Who should present and obtain the informed consent?

• Principal Investigator
• Study personnel designated and trained by the PI*
  • Sub-investigator, CRC, key personnel
  • Appropriately qualified (CITI trained)
  • Appropriately trained and intimately familiar with protocol
• Adequate medical knowledge and understanding of potential adverse effects
• Ability to communicate effectively
Delegation of Authority (DOA) (Log):

The assignment of responsibility to another person to carry out specific activities

- Authority may be delegated, but **ultimate responsibility still rests with PI**

The Investigator has the authority to delegate any study-related task and responsibility to any member of the study team who has been **properly trained** to carry out the designated function.

**TJU Policy: GA 125, 3.3.1**
WHO:

Who should present and obtain the informed consent?

The ultimate responsibility for ensuring informed consent is obtained, and that the consent interview is conducted in such a way that all questions and concerns are answered, rests with the PI.

If the consent interview is conducted by key personnel other than the PI, the PI or Co-I must be reachable by phone, if the subject has questions that cannot be answered by the person conducting the interview.

TJU OHR Policy IC 701, 4.4
Primary physician vs. Study physician?

- Recruiting a patient is not the same as recruiting a subject
- If PI is also the primary physician:
  - Roles may become blurred
  - Imbalance of power between patient and doctor
  - Patient may feel they don’t want to disappoint Doctor
  - Patient may confuse research with clinical care
Therapeutic Misconception:
The belief held by a research subject that the purpose of the research is to provide therapeutic benefit.

Therapeutic Misestimation:
When subjects overestimate the benefits that a study can provide them or when they underestimate the potential risks associated with a study.

Both are detrimental to a subject’s understanding of a study, which is crucial for an autonomous decision.
Who can give informed consent?

• The subject or the subject’s legally authorized representative (LAR)
• Adults (over the age of 18) or “the person has married, has been pregnant, or has been graduated from high school may give effective consent and the consent of no other person shall be necessary”

** see TJU OHR Policy IC 704, 4.0 for applicable definitions

WHO:

Special Circumstances
(AKA: Vulnerable Populations):

- Children (parents give consent - child gives assent)
- Persons illiterate in English (understands, but does not read)
- Persons that do not understand or speak English
- Hearing or vision impaired
  - Ask about glasses +/- or hearing aids!
- Individuals physically unable to sign
- Prisoners, Students
- Cognitively impaired, mental disorders
- Economically or Educationally disadvantaged
Special Circumstances:

**PLANNING = SUCCESS!**

- Consider safety beyond the time of consent
- Need adequate *time!*
- Low literacy can prevent understanding
- See Institutional Policies and Procedures for guidance
WHO:

Non-English speakers:

• Appropriately translated consent forms and/or foreign language versions of short form consent documents must be approved by the IRB prior to enrolling subjects

• CAUTION- Family members as translators
  • Inadequate understanding of medical terms and research
  • May not translate verbatim
  • Not unbiased
  • May not share all information (both directions)
  • May be culturally/socially inappropriate
Non-English speakers:

**Note: If a translator and/or translated consent is used, a “translator should also be available during the full course of the non-English speaker’s participation in the study, so that the subject can always communicate reliably with the research team, which is a right of any research subject.”

TJU OHR Policy IC 705, 4.5
The informed consent document is a teaching tool:

- Must include comprehensive study information
- In language that is understandable to subject
- Contain all elements required by applicable regulations

With increasingly complex studies, this is a challenge!

Unfortunately, most are very long, poorly written and organized, and complicated.
Wait, what?

informed consent
Informed consent as a teaching tool

- As simple and short as possible!
- Avoid medical terms/technical jargon = Lay language
- Short sentences
- Large font, organized layout
- Balance text with white space
- 5th-7th grade reading level (10-12yrs old)
- Use supplemental strategies (visual aids, pamphlets, video/computer presentations)
WHERE:

Best Practices:

• Comfortable setting
• Private
• Neutral
• With or without family/friends
• (Adequate time!)

*Need to be flexible and adaptable within the confines of the clinical setting. Try to optimize above.
WHERE:
Where should consents be stored?

Signed consents:
- Original: study record
- Copies: Subject, eMR

Original, unsigned, IRB approved consents:
- Regulatory binder

CAUTION: copies should be printed on an as needed basis ONLY!

- One of the most common mistakes is using the wrong version.
Preparing to discuss informed consent document:

- Subject understand English?
- Level of education/comprehension ability?
- **Vulnerable subject/special circumstances?**
- Maximize location and availability of time?
- Involvement of others (parent, LAR, family, etc.)?

In some instances, provide a copy of consent in advance of first meeting
- must be part of IRB approved plan
WHEN:

BEFORE:

- Any study procedures are performed!!

AFTER:

- IRB approval
- Review of consent form
- Questions, concerns answered
- Discussion with family, friends, other providers
- Adequate time for consideration
Late at night, and without permission, Reuben would often enter the nursery and conduct experiments in static electricity.
WHEN:

When is informed consent not needed?

• If you have obtained an IRB approved waiver of informed consent

TJU OHR Policy IC 706

When do you need to re-consent a subject?

• If new information is learned, during the course of the study that may affect the subject’s willingness to participate
• New information that affects risks or benefits*
  • *IRB will determine if current subjects must re-consented
Remember:
Every subject contact is an opportunity to reiterate information and ensure that participation continues to be fully informed and voluntary.
HOW:

Presenting the informed consent - Best Practices:

• Know your target audience - adapt appropriately
• Use tools: visual aids, videos, tablets, demonstrations
• **Practice** presenting the consent before use
• Repetition of key words, points, phrases
  • Ask subject to repeat words, points phrases
• Speak clearly and slowly
HOW:

Presenting the informed consent - Best Practices:

• Send consent form in advance
• Place teach back moments throughout, to assess comprehension as you move forward
• Consider a “post-test”
• Keep it conversational
• Watch your subject
• Adequate TIME!

Provide non-judgmental, safe and welcoming environment
HOW:

How to assess comprehension:

Teach-back, or “Tell me in your own words”:

• How would you describe this study to your friends/family?
• What will happen to you in this study?
• What will you gain by participating?
• What are the potential risks/adverse effects that may happen?
• What are the alternatives treatments to being in the study?
Avoid undue influence/coercion:

**Coercion:** an overt or implicit threat of harm is presented to obtain compliance

Ex. PI tells prospective subject that s/he will lose access to needed health services if they don’t participate

**Undue influence:** excessive or inappropriate reward offered to obtain compliance

Ex. PI offers his/her students extra credit if they participate in a research study (and it is the only way they can earn the credit)
HOW:

Avoid undue influence/coercion:

• Should feel free to decline participation without fear of repercussion (or disappointing provider)
• Reassure potential subject that declining participation will not influence the care he/she would otherwise receive
• May withdraw from study at any time
• Provide sufficient time for consideration
• Avoid leading or overly reassuring statements
  • Just the facts

Important to be aware of any personal objectives!
Primary physician vs. Study physician?

- Recruiting a patient is not the same as recruiting a subject

- If PI is also the primary physician:
  - Roles may become blurred
  - Imbalance of power between patient and doctor
  - Patient may feel they don’t want to disappoint Doctor
  - Patient may confuse research with clinical care
Documenting the informed consent:

- Informed consent shall be documented by the use of a written consent form approved by the IRB.
- Signed and dated by the subject or the subject's LAR, at the time of consent.
- A copy shall be given to the person signing the form.

TJU OHR Policy IC 701, 4.4:

- The person conducting the consent interview will also sign and date.
- If the PI/CO-I is not present, s/he should sign and date the consent asap, so that a copy with all signatures can be given to the subject.

21CFR 50.27
WHERE:
Where should consents be stored?

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Documenting the informed consent:

When is it important to include the time with signature and date?

• If study procedures are due to occur on the same day of informed consent.
• Demonstrates consent was obtained prior to any study procedures.
Documenting the informed consent in the Medical Record:

- Identification of study and presenter’s role
- Date and time of discussion
- Individuals present for discussion
- Special circumstances or clarification of irregularities
- Questions/concerns answered
- Subject verbalized understanding
  - Appropriate questions
  - Correct “teach-back” responses
Documenting the informed consent in the Medical Record:

- Ample time given for consideration
- Subject voluntarily agreed to participate
- Consent obtained prior to any study procedures
- Confirmation that a copy of (signed) consent was provided to subject
- Copy of consent in MR
- Signature of person completing consent process
- Contact information
Best Practices:

• Checklists to ensure systematic, standardized and thorough process
• Practice/feedback
• Prepare for target audience

Caution!:

• Versions
• Check boxes in the body of consent form
• Missed signatures/dates
WHY:

“Interventions to improve research participants' understanding in informed consent for research: A systematic review”

• Available data suggest that prospective research participants frequently do not understand information disclosed to them in the informed consent process

• Efforts to improve understanding have had limited success

• Having a study team member or a neutral educator spend more time talking one-on-one to study participants appears to be the most effective way of improving research participants’ understanding

WHY:

“Factors That Most Inform and Educate Clinical Research Participants”:

- Study staff and health care professionals play an essential role in volunteer recruitment and retention
- These individuals are central to establishing trust, rapport and motivation to comply with participation requirements

Findings from CISCRP Focus Groups with study volunteers. The Center for Information and Study on Clinical Research Participation (CISCRP) http://www.ciscrp.org/
Clinical Research Coordinator plays a critical role:

- Often the primary contact person; “The face of the Study”
- Serve as a liaison between the PI and the subject
- Primary source of education and understanding of the study
- Assists subject to navigate study procedures and the institution
- Subject/patient advocate
Why is it so important?

- Ethical requirement and the LAW!
- Protect the rights, safety and wellbeing of subjects
  - Ensure the subject is fully and accurately informed
  - Comprehend the information
  - Decision is voluntary
Why is it referred to as a process?

- **Ongoing interaction** between the subject and research personnel
- Begins with the first contact and exchange of information
- Continues beyond study termination

Each contact is an opportunity to reiterate information and ensure that participation continues to be fully informed and voluntary.
“Beware of false knowledge; it is more dangerous than ignorance”

George Bernard Shaw
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References:


The Code of Federal Regulations, Title 21-Food and Drugs and Title 45, Part 46 Protection of Human Subjects.