Informed Consent

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Objectives

- To become aware of the regulations governing consent, the writing of consent documents and the consent process.

Definition

- *A process by which a subject **voluntarily** confirms his or her willingness to participate in a particular trial, after having been **informed** of all aspects of the trial that are relevant to the subjects decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.*
  - *International Conference on Harmonisation (ICH) Guidelines for Good Clinical Practice*

Consent Sample 1

- Read Sample Consent #1 titled:

  "Positron topographic liver imaging with ^{68}Gacolloid"

  – Does this meet the ***definition*** of informed consent from the previous slide?

    - Why or Why not?

Preparing the Informed Consent Document

Basic requirements for Informed Consent:

1. Must completely and accurately describe all of the activities required by the protocol and what the subject's participation will involve

2. Must be understandable by the study subjects

3. Must contain all the elements required by regulation (21 CFR 50)

1st requirement: Activities and Participation

What potential research subjects must know:

- Details about study and *participant involvement*
- Study required *tests & procedures*
  - including description of the impact on participants
- *When* each activity must take place?
- *How long* will activity take?
- *How often?*
- *Potential benefits and risks*
- That this is *RESEARCH*

Sample Consents 1 & 2

- Sample # 1: “Positron topographic liver imaging with ^{68}Gacolloid”

- Look at Sample #2:
  - (1) The Laryngeal Vestibule and Voice Quality
  - (2) Semi-Automatic Voice Evaluation

- Which sample did a better job of describing activities and participation? Why?

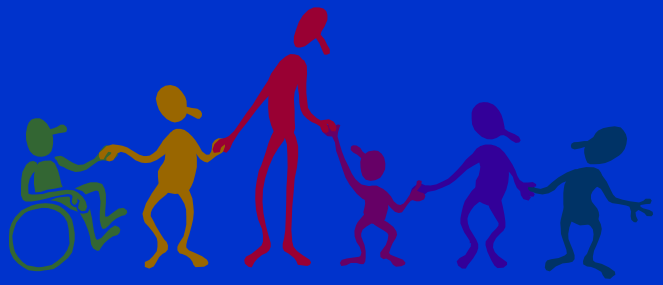
Sample # 3

- **“Investigating the Neurobiology of Tinnitus”**
  - **What’s different in this consent sample from the other two?**
  - **Does this consent do a better job of outlining the activities and participation? Why or why not?**

- **Remember the consent document is only part of the process. You need to spend time with the potential participant going over the study**

2nd requirement: Understandable (Readability & Comprehension)

- Write at language level understandable to the participant.



- Use:
  - Shorter sentence structure
  - Fewer syllables per word
  - Terminology used in everyday living – “teaspoon”, “sick to stomach”
  - Consider your target population
- Is one sample consent more understandable than the others? Why?

Many things can affect a potential participant's ability to fully comprehend what is being conveyed…

- Information saturation point
- Pain
- Newly diagnosis disease or progression of life threatening disease
- Unrelated social issues (recent loss of loved one, job)
- Fear

Remember to consider their reading & comprehension skills…

- Be respectful and provide opportunity for patients to be forthcoming.
- "Test" patients on their comprehension of study requirements.

Conversing with the participant

- A big part of making the consent document understandable is the time you take explaining the study to the research participant.
  - Here's how I like to do it.
    - Private/semi-private area; discuss each element; time for questions; PI not in room; with children parents may not be in room; sending additional materials home before/after day of consent; reaffirming/re-consenting each time participant comes in for next visit
  - Do any of you have tips as well?

3rd requirement:
8 Required Elements of Consent

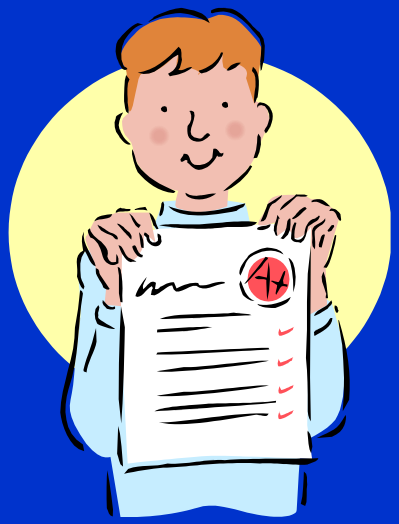
- Statement that the study involves research
- Description of any reasonably foreseeable risks or discomforts
- Description of any benefits
- Disclosure of any appropriate alternatives to participation
- Statement describing confidentiality of records
- Statement regarding compensation and treatment of injury
- Statement of contacts for questions regarding research rights
- Statement that participation is voluntary

Additional Elements
if appropriate to the study

- Statement regarding any risk to embryo or fetus that may be unforeseeable
- Potential circumstances of termination of participation by the investigator
- Potential additional costs to the subject
- Description of participant withdrawal and any consequences
- Disclosure of any new findings to subjects
- Number of subjects expected to be enrolled -locally and group-wide

Note about HIPAA Authorization

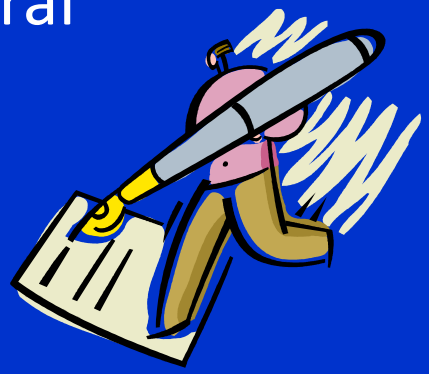
- If you are using, creating, storing, sharing protected health information, you need HIPAA authorization language in your consent form.
  - PHI = identifiable health information
    - That is… information that goes into to or out of a medical record.
  - At WU, PHI is used on the medical school campus, Danforth psychological services and Danforth student services.



Which Sample Consent (1, 2 or 3) did a better job of covering the elements of consent? Why?

Tips for Writing a Consent Form

- Use language understandable to a general population (lay language)
- Use larger font for text
- ***Emphasize*** important items
- Provide information on the clinical trials or study in general
- Provide a summary of highlights &/or details
- Provide a glossary with a definition of terms used
- Use graphics and video



Non-English Speaking Participants

- If you plan to enroll this population, you must have provisions for consent and translations. No WU office does this for research.

- If you encounter a non-English speaker and your study is not already approved to enroll such, contact HRPO for guidance at 633-7400.

- See HRPO Non-English Speaking Subjects guidance at http://hrpohome.wustl.edu/study_team/guidelines.aspx under Guidelines, Vulnerable Populations

Other Options for Consent

- Always select the most appropriate type of consent for your study and population(s).
  - You may have more than one type of consent as you may have more than one population you are enrolling.
- Anytime you inform a participant about a research study, letting him/her know that it is a research study, you are providing some type of consent.
- Pay attention to funding sources as FDA regulations prohibit the use of some consent alternatives.
  - FDA regulated studies use drugs, devices or biologics

Other Consent Options

	When used	Non FDA regulated	FDA Regulated	HIPAA issue
Partial Waiver of HIPAA authorization	To screen records prior to HIPAA authorization	Allowed	Allowed	Can not access PHI without Authorization or a waiver
Short Form Written Consent	Need to present information orally. Use of Witness	Allowed	Allowed	HIPAA waiver must be granted if PHI involved
Alteration or elimination of one of the 8 required elements	Must omit information or study involves deception	Allowed	Not allowed	Consent normally used so authorization obtained if PHI involved
Waiver of Written Consent	Verbal or implied consent. No signed document	Allowed	Only for minimal risk studies	HIPAA waiver needed
Waiver of Consent	No consent obtained.	Allowed	Not allowed	HIPAA waiver needed

Common Problems

- All possible options for consent were not considered when designing the study; now you must obtain written consent for all populations or submit a modification
- Written Consent form poorly written/hard to understand.
- Consent forms pre-signed by WU person obtaining consent
- Timing Issues:
  - study procedures being done before consent is signed
  - study details &/or patient questions are not addressed adequately
  - Proper signatures not obtained
  - Potential coercion
  - Date participant signs is weeks before WU person obtaining consent and no note to file present to explain disparity

Key Things to Remember

- Informed consent document (ICD) is the cornerstone of the ethical conduct of clinical research
- Consent documents must be approved by the IRB before use
- Consent must be obtained before a subject enters a study
- Consent must be documented
- Proper preparation of forms and conduct of the consent procedure is vital to ensure truly informed consent
- Consent is usually required for all subjects involved in a research project
- There are exceptions to the informed consent process under certain circumstances.

Ok…get going!