

# *Informed Consent*



Jeffrey M. Cohen, Ph.D., CIP  
President,  
HRP Associates, Inc.



# **Informed Consent**

## ***Beyond the Consent Form***

# The Consent Process

Informed consent is not a single event or just a form to be signed -  
- rather, it is an educational process that takes place between  
the investigator and the prospective subject.

The basic elements of the consent process include:

- **full disclosure** of the nature of the research and the subject's participation,
- **adequate comprehension** on the part of the potential subjects, and
- the subject's **voluntary choice** to participate.

# Tampa Tribune 3/11/00

TAMPA - A lawsuit accusing USF doctors of experimenting on pregnant women without their consent is settled for \$3.8 million.... The experiment wasn't considered risky and no adverse effects were documented, plaintiffs in the suit agree. However, the failure to inform ... pregnant women of various experiments conducted between 1986 and 1990 has cost Tampa General Hospital, USF and the state \$3.8 million.

# Informed Consent

## Basic Elements

46.116(a)

- Research
  - Purpose/Duration
  - Procedures
  - Experimental
- Risks
- Benefits
- Alternatives
- Confidentiality
- Compensation for Injury
- Whom to Contact
- Right to Refuse or Withdraw

# Informed Consent Additional Elements

46.116(b)

- Currently Unforeseeable Risks
- Termination of Participation
- Additional Costs to Subjects
- Consequence of Withdrawal
- Informing of New Findings
- Number of Subjects

# Comprehension

- Informed consent is **not valid unless the prospective subject understands** the information that has been provided.
- It is the **responsibility of the investigator** to do what he/she can to enhance each prospective subject's comprehension of the information.
- The investigator must **consider the nature of the proposed subject population, the type of information to be conveyed, and the circumstances** under which the consent process will take place in determining the appropriate way to present the information.

# Comprehension

- Avoid technical terms
- Translation
- Language is appropriate to their age level
- Different consent procedures may be required with different populations.

# Voluntary Consent

Only legally competent adults can give consent

- Minors cannot give consent
- Incompetent adults cannot give consent
- The evaluation of competence must be made on a **case by case basis**.

# Voluntary Consent

## Assent:

- "knowledgeable agreement" to participate
- whenever the potential subject has sufficient capacity to understand what is happening and express his/her wishes.
- "deliberate objection" is veto of the consent of a parent or guardian (unless there is direct benefit to the subject)

# Voluntary Consent

- In order to be valid, **consent must be freely given**. That means that it is free from all forms of coercion.
- In addition to overt coercion, the investigator needs to be sensitive to more **subtle forms of coercion**, such as social pressure, requests from authority figures, and undue incentive for participation.

# Procedures for Obtaining Consent<sup>46.116</sup>

- Subject has the legal and mental capacity to give consent
  - legally authorized representative;
- Sufficient opportunity is provided to consider
- The possibility of coercion or undue influence is minimized
- Language understandable to the subject
- No “exculpatory” language

# Documentation of Consent

- “Legally effective informed consent”
  - written consent form signed by the subject or the subject's legal representative.
- The consent form is merely the documentation of informed consent
- The fact that a subject signed a consent form does not mean that he/she understood what was being agreed to or truly gave their voluntary consent.
- Informed consent is a process which is documented by a signed consent form.

# Documentation of Consent

It is recommended that consent forms meet four criteria:

- Be brief, but have complete basic information.
- Be readable and understandable to most people.
- Be in a format that helps people comprehend and remember the information.
- Serve as a script for the face-to-face discussions with the potential subjects.

# Documentation of Consent

## Reading Level:

- Maximum 8th grade reading level (preferably lower)
- ordinary language
- active tense
- shorter sentences
- logical sequences

# Documentation of Consent

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Format can help comprehend and remember complex material.

Good format uses: headings; indents; bolded type; lists; extra spacing between sub-topics; repetition; reasonable-size type; and plenty of margins and empty space in general.

# Documentation of Consent

Format can help **comprehend and remember** complex material. Good format uses:

- **headings;**
- **indents;**
- **bolded type;**
- **lists;**
- **extra spacing** between sub-topics;
- **repetition;**
- **reasonable-size type;** and
- **plenty of margins and empty space** in general.

# IRB Flexibility

- Written informed consent is not necessarily appropriate for all research, especially research in the social & behavioral sciences.
- IRBs have considerable flexibility and authority to modify or waive consent requirements and should not hesitate to do so when it is appropriate.

# IRB Flexibility

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IRBs have the authority to waive some or all of the requirements for consent and/or documentation of consent provided the research meets the criteria in the regulations.

# Waiver of Documentation

- Investigators rarely object to obtaining informed consent from their subjects
- Investigators do object to obtaining signed consent forms where it is not appropriate.

# Waiver of Documentation

46.117(c)(2)

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds:

- the research presents no more than minimal risk;
- and**
- the research involves procedures that do not require written consent when performed outside of a research setting.

# Waiver of Documentation

46.117(c)(1)

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds:

- the principle risks are those associated with a breach of confidentiality concerning the subject's participation in the research;

and

- the consent document is the only record linking the subject with the research

# Waiver of Consent

46.116(d)

An IRB may approve a waiver or alteration of some or all of the consent requirements provided that:

- The research involves **no more than minimal risk** to subjects;
- The waiver will **not adversely affect the rights and welfare** of subjects;
- The research **could not practicably be carried out** without the waiver; and
- Whenever, appropriate, the subjects will be provided with **additional pertinent information after they have participated** in the study.

# Points to Remember

- Whenever consent or documentation is waived, IRB must find and document that the research meets the criteria
- Deception research requires a waiver of consent with appropriate documentation
- "Passive consent" or "implied consent" is not consent and requires a waiver with appropriate documentation
- IRBs should not be afraid to exercise their waiver authority if the research meets the criteria and the finding is appropriately documented.

# Summary

- Informed consent is a process, not a piece of paper
- Regulations specify how consent is to be obtained and what information is provided.
- Consent is generally documented through a signed, written consent form
- IRBs have the authority to waive some or all of the requirements for consent and/or documentation of consent