General Requirements for Informed Consent

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Informed Consent

Informed Consent is a process in which…

- Researcher discloses relevant information
- Subject has opportunity to ask ?'s
- Subject volunteers

Informed Consent

- Consent form is a record of:
  - Information conveyed
  - Subject's willingness to participate
  - Proof that consent was sought/obtained

General Requirements

- Information must be in language understandable to the subject
- May not include exculpatory language

Cannot waive/appear to waive subject's rights or liability for negligence from the agents of the study

45 CFR 46.116 (OHRP)

- Basic elements of informed consent
- Consists of 8 necessary and 6 additional “when appropriate” elements
- Except for provisions (waiver and alterations) certain information is required to be provided to the participant or their LAR

General Requirements of IC	
Desc	Who, what, where
Risks	Unforseeable
Benefits	May alleviate symptoms
Comp..	Medical costs covered

LAR = legally authorized representative

Study involves research; study description

- Research acknowledgement
- Purpose of the study
- Expected duration
- Procedures
- Identification of experimental procedures

Reasonably foreseeable risks and discomforts

- What are the risks (physical, psychological, social)?
- Are the estimates of the harm or benefits reasonable?
- Is the nature and magnitude of risk distinguished with as much clarity as possible?

Risks that reasonably can or should be anticipated

Benefits

- What are the reasonably expected benefits?
- Most consent forms contain language:
  WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY
- Benefits to “others” as well (e.g., society)

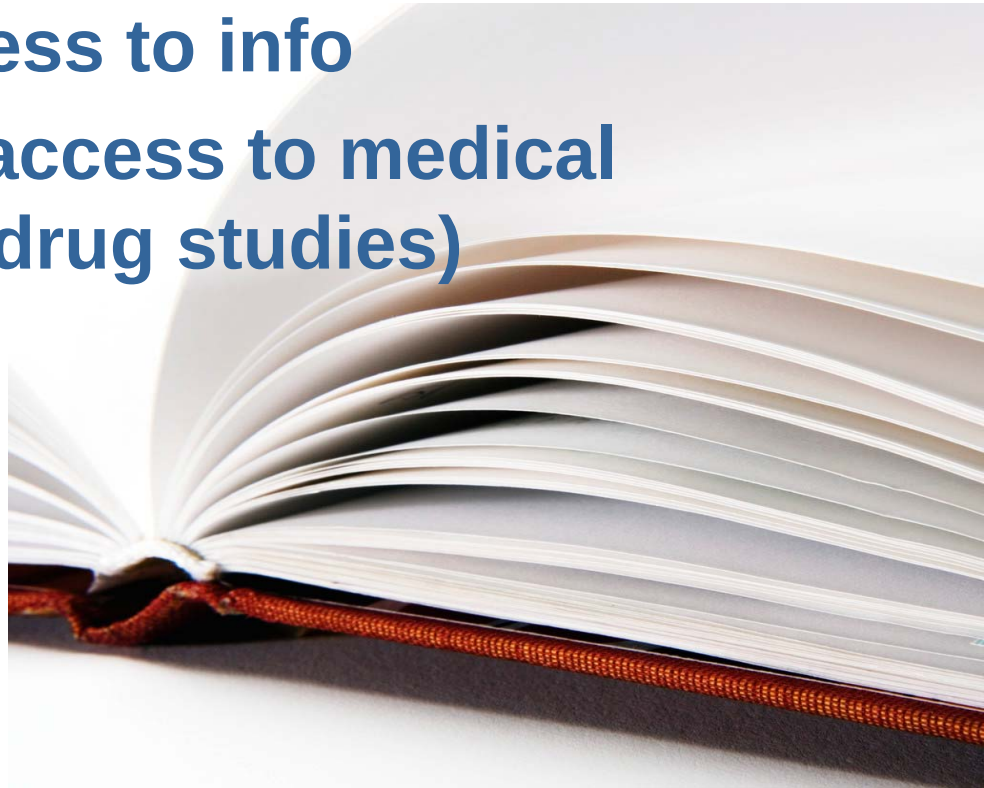
For example, access to a drug or device that the participant would not normally have that might benefit them

Disclosure of alternative procedures or treatments

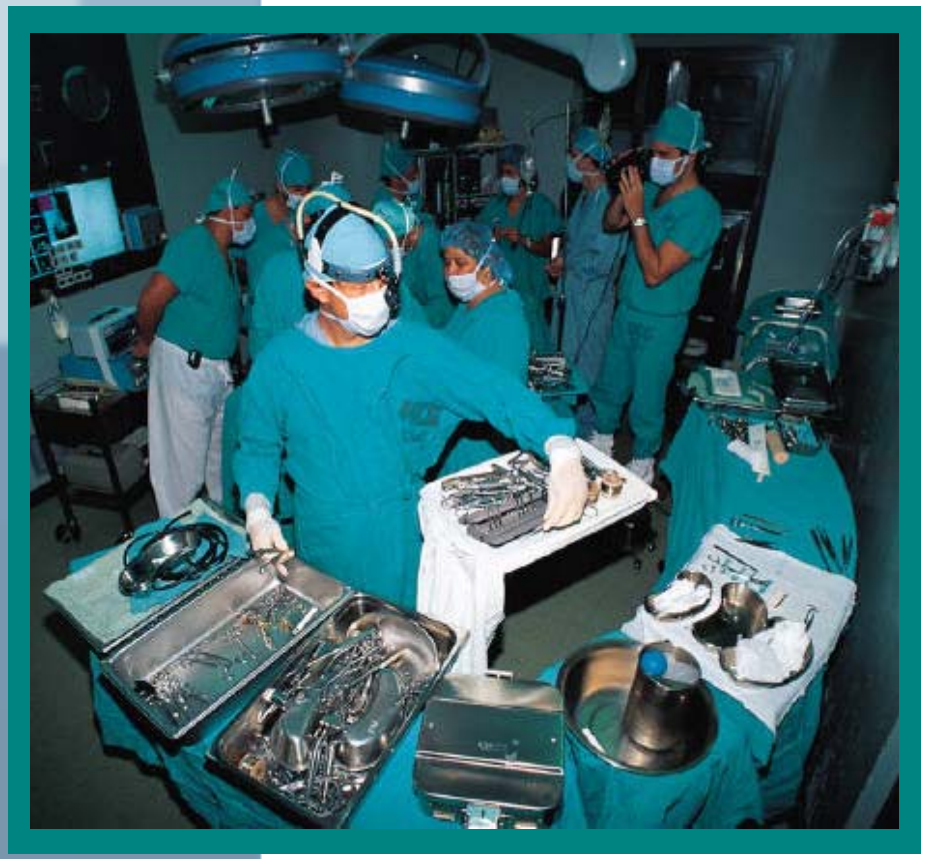
…that might be advantageous to the subject

Confidentiality of records

- The extent that confidentiality of the data will be maintained
- Who knows/needs to know
- Who has access to info
  - (e.g., FDA access to medical records in drug studies)



Compensation and treatment for injury



- For research involving more than minimal risk
- Explanation of compensation, if any
- Explanation of any medical treatments that will be provided in the event of an injury, if any
- Where further information may be obtained

Contact Information

Whom to contact for:

- **Questions about the research**
- **Subject's rights**
- **In case of research-related injury**

Voluntary Participation

Additional elements of Informed Consent

45 CFR 46.116(b) states that:

"When appropriate, one or more of the following elements of information shall also be provided"

1. Risks are currently unforeseeable

2. Investigators may terminate participation

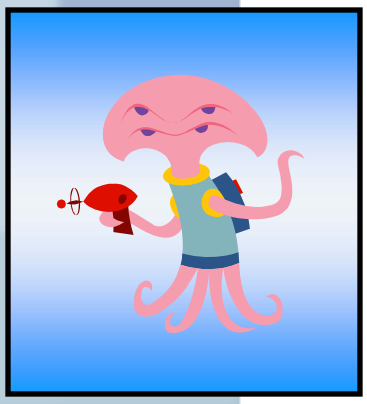
3. Additional costs

4. Consequences of subject's withdrawal

5. Significant new findings

6. Number of subjects participating

Statements from actual consent forms



- “we will insert 3 catheters, one in each arm…”
- “The investigator may terminate the procedures and/or the subjects at any time”
- (translational error, English to Chinese) “double-blind” to “blind in both eyes”