



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	Unforeseeable
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)

What would be an example of a benefit to a subject participating in SBR?



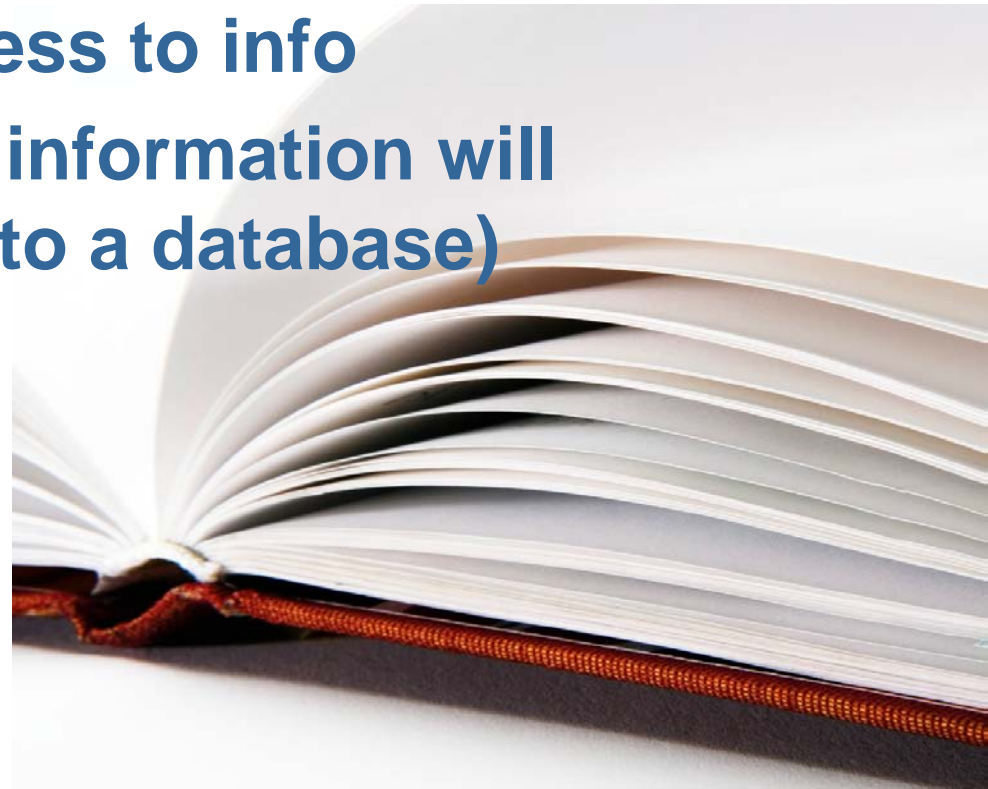
Disclosure of alternative procedures or treatments

...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., if the information will contribute to a database)



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

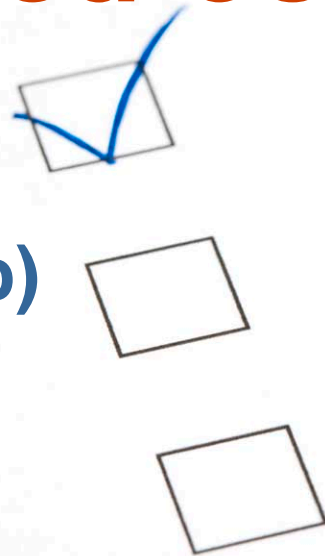
Refusal to participate will involve no penalty or loss of benefits

to which the subject is otherwise entitled



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”

