Informed Consent Requirements and Elements - Revisited

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General Requirements of Informed Consent 45 CFR 46.116 (OHRP)

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

American Medical Association: Health Literacy Video

http://www.youtube.com/watch/v@BgTuD7l7LG8&feature@related

General Requirements, cont.

- May not include exculpatory language

"I waive any possibility of compensation for injuries that I may receive as a result of participation."

Not acceptable

"This hospital makes no commitment to provide free medical care for any unfavorable outcomes as a result of this research."

Acceptable

Factual statements versus ones that require agreement or concurrence.

45 CFR 46.116(a)

- Basic elements of informed consent
- Consists of 8 necessary and 7 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

(1) Study involves research; study description

- Research acknowledgement
- Purpose of the study

(2) & (3) Reasonably foreseeable risks/benefits

- What are the risks (physical, psychological, social) and 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

(4) Disclosure of alternative procedures or treatments

…that might be advantageous to the subject

(5) Confidentiality of records

Plan for maintaining, using and disclosing records

(6) Compensation and treatment for injury

- For research involving **>** than minimal risk
- Explanation of compensation and medical treatments that will be provided in the event of an injury, if any

(7) Contact Information

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

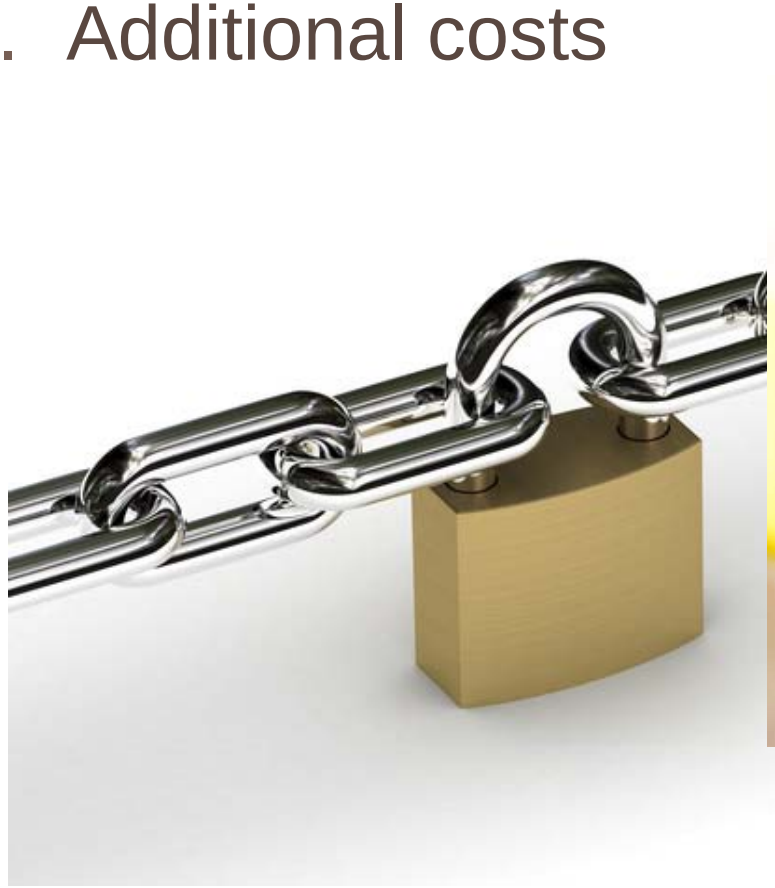
(8) Voluntary Participation

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

7. New clinicaltrials.gov requirement for informed consent - coming soon…

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"

Clarity is key!

In conclusion…

- Accuracy, completeness, brevity and flow
- Readability
- Clarity
- Required elements

Thank you!