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Approval Criteria – Informed Consent

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Criteria for Approval

45 CFR 46.111

25 CFR 56.111

- Minimized Risks
- Reasonable Risk/Benefit Ratio
- Equitable Subject Selection
- Informed Consent Process
- Informed Consent Documentation
- Data Monitored for Safety
- Confidentiality/Privacy Maintained
- Vulnerable Populations Protected

Approval Criteria
Informed Consent Process

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

What is §46.116?

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General Requirements for Informed Consent

- Investigator must give the subject sufficient time and opportunity to consider whether they want to participate or not
- Investigator must make all efforts to minimize the possibility of coercion or undue influence.
- Information must be presented in language that the subject can understand
- There must be no exculpatory language through which the subject is made to waive any legal rights or releases the investigator, sponsor, or institution from liability for negligence.

8 Basic Elements of Informed Consent

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1. Study involves research; study description

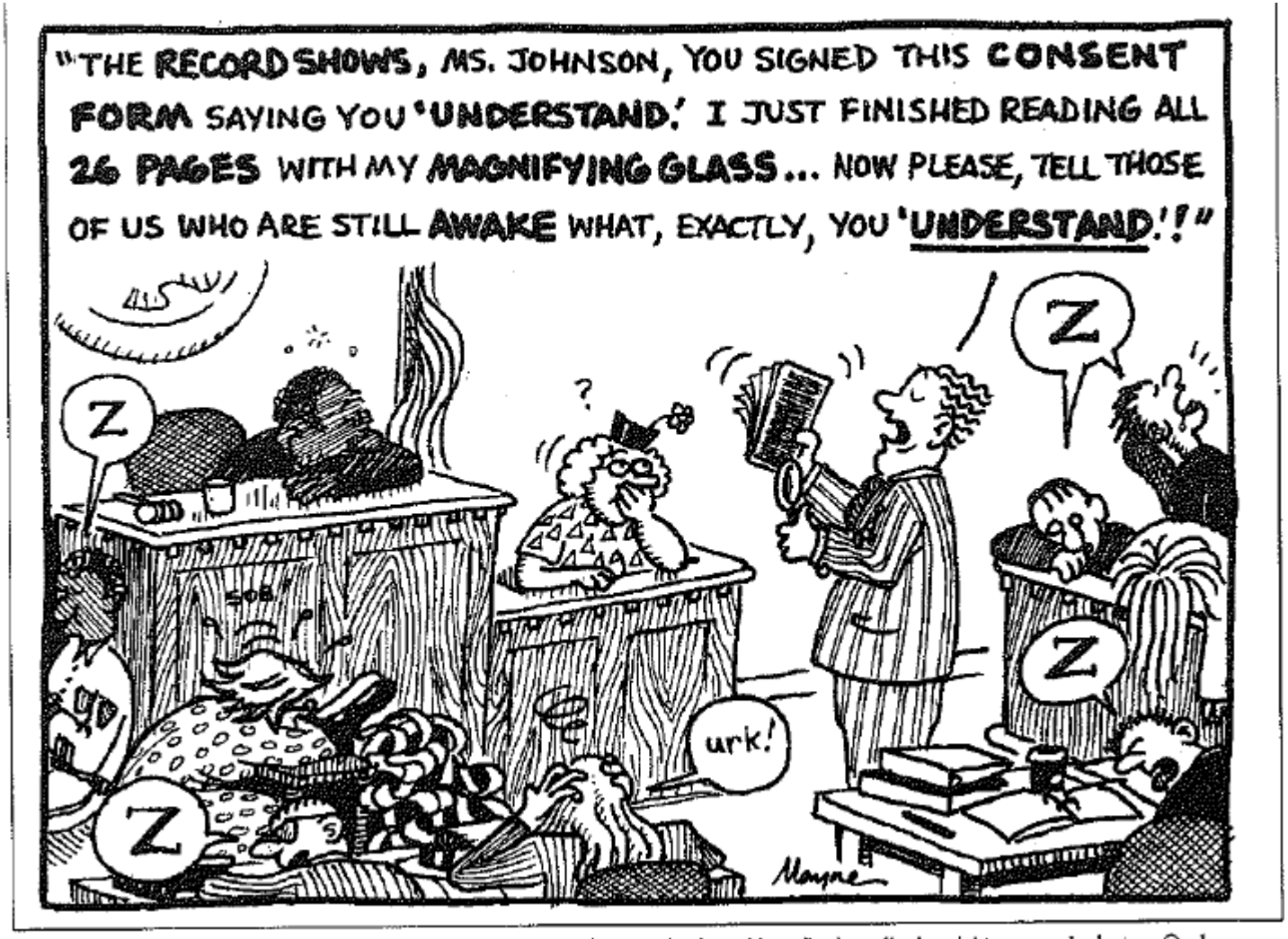
- Research acknowledgement
- Purpose of the study
- Expected duration of the subject's participation
- Procedures (description)
- Specify which procedure are experimental

2. A description of any reasonably foreseeable risks or discomforts
3. A description of any benefits to subject and/or society
4. A disclosure of any alternative procedures, if any
5. A statement describing the extent, if any, to which confidentiality will be maintained.

6. Compensation and treatment for research related injuries
7. Contact Information
8. Voluntary Participation
    - Refusal to participate will involve no penalty or loss of benefit to which the subject is otherwise entitled
    - Informed consent is an ongoing process – the subject can withdraw at any time.

When appropriate, one or more of the following elements may also be provided.

- Risks that are currently unforeseeable
- Investigators may terminate participation
- Additional costs to the participant
- Consequences of subject's withdrawal
- New findings that may alter subject's willingness to participate Number of subjects involved in the study.



The IRB has special powers

The IRB can approve a consent process that leaves out or alters some or all of the elements that we just talked about.

The IRB can even waive the requirement to obtain informed consent all together.

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How/When can the IRB Alter or Waive Consent?????

1. Research activities present no more than minimal risk
2. Waiver or alteration will not adversely affect rights and welfare of subjects.
3. Research could not practicably be carried out without the waiver or alteration.
4. When appropriate, subjects will be given pertinent information after participation

Approval Criteria
Documentation of Consent

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

What is §46.117?

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Consent Documentation

- It must be signed and dated by the subject/Legally Authorized Representative (LAR)
- A copy must be given to the person signing the form
- Subject must be given adequate time to read it before signing it
- Short form consent process – used when dealing with subjects whose primary language is not English

More special powers of the IRB

The IRB may waive the requirement for documentation, in certain circumstances (§46.117(c))

- (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

- (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

What about the FDA?

21 CFR § 50.20

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Language for Clinical Trials

"A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

The FDA can inspect records

There must be a statement in the confidentiality section of the consent form to note “the possibility that the FDA may inspect the records”

The subject cannot be given the option of having their data removed from the study database upon withdrawal.

Waivers and Documentation

The FDA does not allow waivers of consent or documentation of consent except:

21 CFR 50.23

- Subject is in a life threatening situation
- Military operations
- Public health emergencies

21 CFR 50.24

- Emergency research

21 CFR 56.109 (c)(1)

- Documentation may be waived if the IRB determines there is no more than minimal risk and no procedures which written consent would normally be required.

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