IRBMED Seminar Series

Final Common Rule Revisions to the Requirements for Informed Consent

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Belmont Report

Belmont Principles (1979)	IRB Approval
Autonomy – A recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy. Respect for persons.	**Voluntary participation** ❑ Consent document and process ❑ Privacy ❑ Vulnerable subjects
Beneficence - An obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm.	**Risks justified by potential benefits** ❑ Study design minimizes risks ❑ Conflicts of interest managed
Justice - An obligation to assure that the benefits and burdens of research be distributed fairly.	**Equitable subject selection** ❑ Most likely to benefit are not excluded ❑ Avoid exploitation of subject populations of convenience

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Overview of Major Changes

- Consent must begin with a presentation of ‘key information’
- Content, organization, and presentation of information should facilitate a prospective subject's decision about whether to participate or not
- Option to obtain ‘broad consent’
- Additions to the ‘basic’ and ‘additional’ elements of consent
- Screening, recruiting, or determining eligibility without waiver of informed consent
- For clinical trials, posting an IRB-approved version of a consent form to a Federal website

Informed Consent Regulations

§ __.116 General Requirements for Informed Consent

- (a) General
- (b) Basic Elements of Informed Consent
- (c) Additional Elements of Informed Consent
- (d) Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens
- (e) Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials*
- (f) General waiver or alteration of consent
- (g) Screening, recruiting, or determining eligibility
- (h) Posting of clinical trial consent form
- (i) Preemption*
- (j) Emergency medical care*

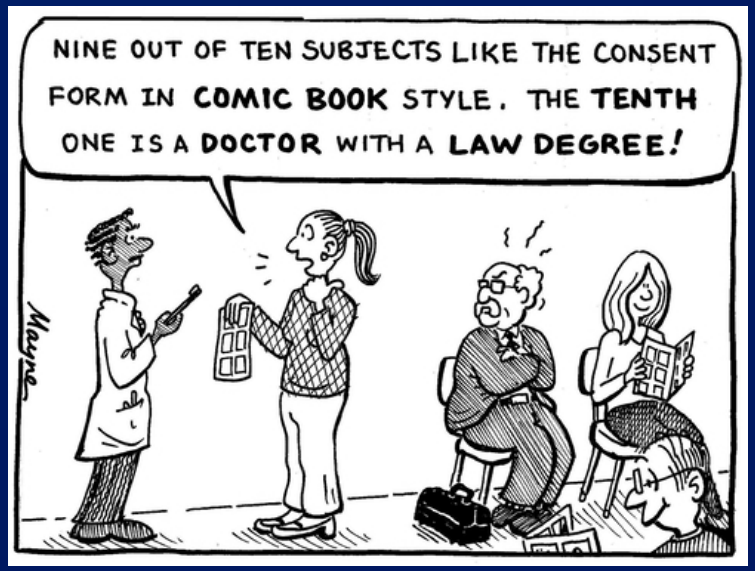
§ __.117 Documentation of informed consent

HHS News Release—January 18, 2017

"Over the years, many have argued that consent forms have become these incredibly lengthy and complex documents that are designed to protect institutions from lawsuits, rather than providing potential research subjects with the information they need in order to make an informed choice about whether to participate in a research study."

Jerry Menikoff, MD,

Director, Office for Human Research Protections



New General Requirements of Informed Consent

"The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information."

§ __.116(4)

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New General Requirements of Informed Consent—Continued

‘Key Information’

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.

This part of the informed consent must be organized and presented in a way that facilitates comprehension.

§ __.116(5)(i)

‘Key Information’— Continued

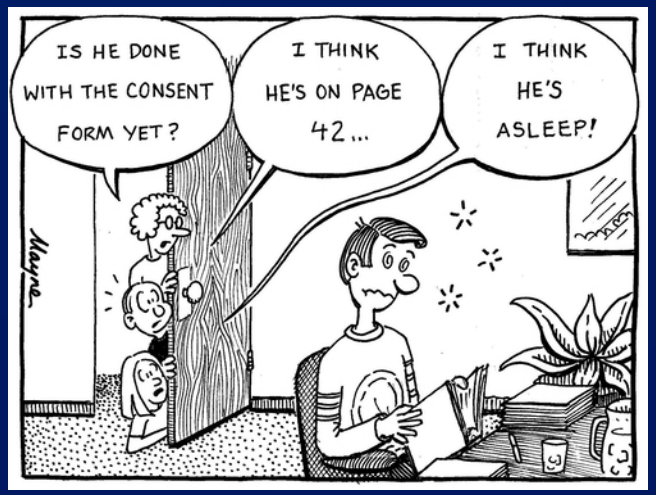
The beginning of an informed consent process/form would include a concise explanation of the following:

1. The fact that consent is being sought for research and that participation is voluntary;
2. Purposes of the research, expected duration of participation, and procedures to be followed in the research;
3. Reasonably foreseeable risks or discomforts
4. Benefits to the subject or others that may reasonably be expected from the research; and
5. Appropriate alternative procedures or courses of treatment, if any, that might be advantageous

New General Requirements of Informed Consent—Continued

"Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate."

§ __.116(5)(il)



New Basic Element of Informed Consent:

When research involves collection of identifiable private information or identifiable biospecimens the informed consent must include:

- whether identifiers might be removed, and
- if information or biospecimens could be used for future research without additional informed consent

New Additional Elements of Informed Consent

Statements to be used when appropriate:

- That the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

- Whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
  - WGS generates an extremely large amount of information about people (and their family members), including factors that will contribute to their future medical conditions.

Broad Consent

Broad Consent allows participants to agree to researchers' using their identifiable private information or identifiable biospecimens (collected for other research studies or other purposes such as clinical care) for future, yet-to-be specified research studies.

Broad consent will be an optional alternative that an investigator may choose instead of:

1. obtaining consent for a specific study
2. having an institutional review board (IRB) waive the requirement for informed consent, or
3. conducting the research on non-identified information and non-identified biospecimens

Screening/Recruiting/Determining Eligibility

Addition of an exception for informed consent for screening, recruiting, or determining the eligibility of prospective subjects

- "Waiver of Consent" in eResearch will not need to be requested in eResearch for these activities in the scope of the main project

- Still will have to follow HIPAA Requirements!
  - Including asking for a HIPAA waiver

Posting Clinical Trial Consent Forms

- Applies only to federally-conducted or supported clinical trials
    - Reminder:

      "Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes."

- Consent must be posted on a "publically available Federal Web site"
    - It may be ClinicalTrials.gov

Posting Clinical Trial Consent Forms—Continued

- Only one IRB-approved version used to enroll subjects is required
  - Even if multiple exist, multisite study, or different subject groups
- Posting can take place any time after recruitment closes but no later than 60 days after the last study visit by any subject
- Federal department or agencies may permit/require redactions to the posted information
  - e.g. confidential commercial information
  - could determine that the very existence of a particular clinical trial should not be publicly disclosed, in which case no posting would be required (rare)

Revisions to ‘Documentation of Informed Consent’

- A Waiver of Documentation of Consent is allowed for members of a distinct cultural group or community when
  - Signing documents is not the norm
  - Research presents no more than minimal risk of harm, and
  - An appropriate alternative mechanism for documenting that informed consent was obtained

Revisions to 'Documentation of Informed Consent'—Continued

- Electronic formats for consent are acceptable

"Informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed **(including in an electronic format)** by the subject or the subject's legally authorized representative. A **written** copy shall be given to the person signing the informed consent form."

Definition: "*Written,* or *in writing,* for purposes of this part, refers to writing on a tangible medium (*e.g.,* paper) or in an electronic format."

Electronic Consent must meet requirements of HHS, FDA, and HIPAA as applicable, including:

- Ensuring privacy, security, and confidentiality
- Verification of the identity of the person signing
- Providing written copies of the consent to person signing

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