Objectives

- Describe key provisions of the revised common rule related to consent.
- Understand opportunities associated with these provisions.
- Relate anticipated challenges with implementing these provisions.

Timeline

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<td>Compliance for Most Provisions (1/19/2018)</td>
<td>Compliance for Cooperative Research (1/20/2020)</td>
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https://www.hhs.gov/ohrp/interim-final-rule-common-rule.html

https://www.youtube.com/watch?v=ZzbKaDPMoDU
Major Changes

- New requirements for the informed consent process
- Allows broad consent for storage, maintenance, and secondary research use of identifiable private information and identifiable biospecimens
- New categories of exempt research
- Requirement for a single IRB for U.S.-based institutions engaged in cooperative research
- Removes the requirement to conduct continuing review of some research

82 Fed Reg 7150
Why focus on consent?
- Represent some of the major changes
- Can be a means to protect participants' rights and welfare
- Often the focus of IRBs
- Some data available to place consent provisions into context and optimally implement them

Ethics and consent
- Two senses of consent
- The process of consent
- Functions of consent

Two Senses of Informed Consent
- Autonomous authorization
- Social rules of consent

Autonomous Authorization
- Ethical principle of respect for persons
- Right to liberty

Two Senses of Informed Consent
- Autonomous authorization
- Social rules of consent

Social Rules
- Consent of minors
- Special forms
- Witnesses
Informed Consent Process

**Threshold**
- Decision-making capacity
- Voluntariness

**Information**
- Disclosure
- Understanding

**Authorization**
- Indication of agreement
- Documentation

**Functions of Consent**
- Participant-centered
  - Providing transparency
  - Allowing control and authorization
  - Promoting concordance with participants’ values
  - Protecting participants’ welfare interests
- Procedural
  - Promoting trust
  - Satisfying regulatory requirements
  - Promoting the integrity of research and researchers

**Selected Provisions of the Revised Common Rule**

- New required elements
- Goal of comprehension
- Consent forms
- Broad consent

**Additional Required Elements**

- Basic
- Additional

**New Required Basic Element**

“One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(ii) A statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.” §__.116.b.9

**Additional Elements**

- The possibility of commercial use of biospecimens [x__.116.c.7]
- Whether clinically relevant research results will be disclosed to subjects [x__.116.c.8]
- Whether whole genome sequencing will be used [x__.116.c.9]

**Goal of Comprehension**

- A laudable goal, but is it achievable?
- Specified order

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Goal of Comprehension

“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.a.5.i

Specified Order

“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.a.5.i

Consent Forms

- Waiver
- “Written”
- Posting
- A metric for compliance

Additional waiver provision

- Permitting the use alternative mechanisms for documenting consent for minimal risk research in settings where there are cultural barriers to signing documents [x__.117.c.1.iii]

Written

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

§__.102.m

Posting of Clinical Trial Consent Forms

- Required for clinical trials* federally supported or conducted
- “must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject.” §__.116.h

*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. §__.102.b

A Metric for Compliance

- A “reasonable person standard” in determining what information needs to be provided to those asked to provide consent [x__.116.a.4]
- Versus a professional or subjective standard
- Potential role for formative research

Broad Consent

- Permissibility
- Requirements
- Potential implications

Broad Consent

“Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted as an alternative to the informed consent requirements” §__.116.d
Requirements for Broad Consent

- Includes selected standard elements as well as additional elements
- Types of research that may be conducted
- What information/biospecimens will be used
- Period of time of storage and maintenance
- If applicable, the subject will not be informed about specific research studies
- Disposition of clinically relevant research results
- Contact information

§ 116.d

Broad Consent
Potential Implications for Waiver or Alteration of Consent

“If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements … of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.” § 116.f

Concluding Comments

- The revised Common Rule aims at the meritorious goal of enhancing informed consent for research
- Some provisions will be easy to apply and promise to promote this goal, but others will be more challenging
- Raising these issues now is important to prompt efforts to clarify and appropriately implement them