Informed Consent Improvements

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What’s New in Informed Consent

• General Improvements to Informed Consent
• Waiver and Alteration of Informed Consent
• Screening, Recruiting, or Determining Eligibility
• Documentation of Informed Consent
• Legally Authorized Representative
• Broad Consent
GENERAL IMPROVEMENTS TO INFORMED CONSENT
Promoting Autonomy

Changes are intended to make informed consent more meaningful, so research subjects have the necessary information to make informed decisions.
General Improvements

The revised Common Rule explicitly establishes a new standard:

to provide the information needed to make an informed decision about whether to participate
General Improvements

*Reasonable person* standard is used to determine what information to include

- Long history in clinical informed consent
- Considered most consistent with ethical principles
General Improvements

Information presented in **sufficient detail**, and **organized and presented** in a way that facilitates subject’s understanding of why one might or might not want to participate

*Not merely a list of isolated facts*
General Improvements

• New requirement that certain *key information* must be provided *first*

• Key information
  • About *why one might or might not want to participate*—often include (though not limited to) information about purposes, risks, benefits and alternatives
  • Must be presented in *concise and focused* manner
Basic Elements of Informed Consent

One new element:

- Notice regarding possible future use of data stripped of identifiers
Additional Elements of Informed Consent

Three new additional elements:

• Notice about possible commercial profit
• Notice about whether clinically relevant research results will be given to subjects
• Notice about whether research might include whole genome sequencing
Posting of Clinical Trial Consent Forms

For clinical trials supported by Federal funding, one IRB-approved consent form used to enroll participants must be posted on designated public Federal website

• Must be posted after recruitment closes, no later than 60 days after the last study visit
• Federal department or agency may permit or require redactions
WAIVER AND ALTERATION OF INFORMED CONSENT
Waiver of Consent

New waiver criterion for research with identifiable private information or identifiable biospecimens:

• The IRB must determine that the research could not *practically* be carried out without using such information or biospecimens in an identifiable format

*Non-identifiable* information should be used whenever possible, out of respect for autonomy
SCREENING, RECRUITING, OR DETERMINING ELIGIBILITY
Screening, Recruiting, or Determining Eligibility

Eliminates pre-2018 requirement for IRB to waive consent to conduct certain early research activities

• IRB may approve proposal for investigator to obtain information or biospecimens to **screen, recruit, or determine eligibility** of prospective subjects without informed consent, if obtained through:
  • Oral or written communication with subject/LAR, or
  • Accessing records or stored identifiable biospecimens
DOCUMENTATION OF CONSENT
Waiver of Signature Requirement

Obtaining subject’s signature can be waived if:

• Subjects are members of a distinct community in which signing forms is not the norm,
• Research involves no more than minimal risk, and
• An alternative method for documenting consent is used
Electronic Signature

Signatures in electronic format are permissible
LEGALLY AUTHORIZED REPRESENTATIVE
Legally Authorized Representative (LAR)

Currently:
If there is no applicable law (state or local) about who can serve as a legally authorized representative (LAR) for purposes of research consent, OHRP allows use of law that specifies LAR who has authority to consent to the procedures *for clinical purposes*.
In some states, there is no law (statutes, regulations, or court decisions) about who can serve as LAR for clinical decisions.

- Nonetheless, such clinical decisions are made thousands of times a day using institutional policies.
- Currently, different outcomes occur, for purposes of the Common Rule, in those states compared to states that have pertinent laws.
Legally Authorized Representative (LAR)

Revised Common Rule makes outcome more similar in states with such laws compared to those without

If no applicable law on who can serve as LAR:

- LAR can be an individual *recognized by institutional policy* as acceptable for providing consent *in the nonresearch context* to the subject’s participation in the *procedures involved in the research*
BROAD CONSENT FOR SECONDARY RESEARCH
Broad Consent for Secondary Research

• Applies to the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens

• Allows information and biospecimens to be stored and used for *unspecified future research* – in contrast to consent for a specific study

• An IRB cannot waive consent if individuals were asked, and refused, to provide broad consent