

A Tentative Introduction to the Revised Common Rule for the Protection of Human Subjects

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Objective

To provide a cursory introduction to the revised Common Rule, with a particular focus on those aspects that are relevant for those engaged in planning and conducting pragmatic clinical trials.

Caveats

- This a new, deceptively complex rule, so my presentation reflects a ‘first reading’
- No one has experience implementing this rule and federal guidance regarding interpretation and related provisions are forthcoming
- It is uncertain whether the rule will be retained or rescinded

Timeline

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Common
Rule (1991)

ANPRM
(7/24/2011)

NPRM
(9/8/2015)

Final Rule
(1/19/2017)

<https://www.minnpost.com/sites/default/files/asset/c/cj29v0/cj29v0.jpg>

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Federal Policy for the Protection of Human Subjects

AGENCY: Department of Homeland Security; Department of Agriculture; Department of Energy; National Aeronautics and Space Administration; Department of Commerce; Social Security Administration; Agency for International Development; Department of Housing and Urban Development; Department of Labor; Department of Defense; Department of Education; Department of Veterans Affairs; Environmental Protection Agency; Department of Health and Human Services; National Science Foundation; and Department of Transportation.

ACTION: Final rule.

- *Preamble* 110 pp
- *Rule* 15pp

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The New England Journal of Medicine

The Common Rule, Updated

Jerry Menikoff, MD, JD, Julie Kaneshiro, MA, and Ivor Pritchard, PhD

2017 Jan 19. doi: 10.1056/NEJMp1700736. [Epub ahead of print]
PubMed PMID: 28103146.

Timeline

Common
Rule (1991)

ANPRM
(7/24/2011)

NPRM
(9/8/2015)

Final Rule
(1/19/2017)

Compliance for
Most Provisions
(1/19/2018)

Compliance for
Cooperative
Research
(1/20/2020)

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

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Consent

- Specified order of disclosure
- Emphasis on comprehension
- New basic element
- Posting of consent forms

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

Emphasis on 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

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

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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

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

Exempt Research

- Limited review
- Certain identifiable health information

Limited Review

Identifiable Data and Specimens

- Survey/interview/observational research
- “Benign” behavioral interventions
- Broad consent for storage or maintenance for secondary research
- Broad consent for secondary research

Certain Identifiable Health Information

Secondary research for which consent is not required and one of three criteria are met:

- Data are publicly available
- Human subject not identifiable to the investigator; and
- “The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b)” §___.104.d.4

Cooperative Research/Single IRB

- “each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.” §__.114.a
- “Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States.” §__.114.b.1
- Exemptions permitted where multiple IRBs required by law; and if a federal determination is made in a particular context. §__.114.b.2

Continuing Review

- Based on degree of risk, but not < once/year
- Unless determined otherwise not necessary for research:
 - Eligible for expedited review
 - That received ‘limited’ review
 - That has progressed
 - Data analysis
 - Follow-up clinical data subjects would undergo as part of clinical care §__.109.e

Additional Changes of Note

- Human subject definition
- Activities not deemed to be research
- Identifiable information
- Minimal risk
- Written

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Human subject

“means a living individual about whom an investigator (whether professional or student) conducting research:(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.”
§__.102.e

Activities not Deemed to be Research

- Scholarly and journalistic activities
- Public health surveillance
- Collection and analysis of information, biospecimens or records by or for a criminal justice agency
- Authorized operational activities

§__.102.1

Identifiable Information

- Reexamination of within 1 year and then regularly ever 4 years

§__.102.e.7.i

Minimal risk

- No change!

“the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

§__.102.j

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

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“Although the new administration and Congress could overturn the regulations, the rule’s overarching objectives of facilitating clinical research while maintaining critical human subject protections and reducing administrative and regulatory burdens and delays, as well as the longstanding need to modernize the federal oversight of clinical research, may decrease the likelihood of repeal.”

Barth et al. Life Sciences Law & Industry Report, 11 LSLR 03, 02/03/2017.

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