

# Final Rule

~~JANUARY 19, 2018~~

~~JULY 19, 2018?~~

JANUARY 21, 2019!

# General Idea

- ▶ Better protect human subjects
- ▶ Facilitate research/reduce regulatory burden
- ▶ Remove ambiguity
  
- ▶ Implementation date: ~~January 19, 2018~~
  - ▶ On October 7, 2017, proposed to delay implementation date for one year.
  - ▶ Delayed 6 months. July 19, 2018???
  - ▶ April 18, 2018 proposal to delay another 6 months (January 21, 2019).

# Changes: IRB Operation

- ▶ Single IRB review (1/20/20)
  - ▶ IRB Authorization Agreements
  - ▶ Split work and review by Institution
- ▶ Continuing review: No longer required for expedited projects
  - ▶ How to track when projects are complete?
  - ▶ Will researchers think they don't need to submit amendment requests?

# Changes: Revised Definitions

- ▶ Human Subject: includes biospecimens and adds “obtaining, storing, using, studying, analyzing or generating identifiable private information” as trigger points
- ▶ Research: Clarifies what is NOT research
- ▶ Vulnerable populations: no longer includes pregnant women, handicapped or physically disabled. Revised “individuals with impaired decision-making ability”.

# Changes: New Definition

- ▶ Clinical Trial: 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.

# Definition Comparison

Definitions: Old vs New	
Common Rule (Old)	Final Rule (New)
<p><i>Certification</i> means the official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance. <b>46.102(j)</b></p>	<p><i>Certification</i> means the official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance. <b>46.102(a)</b></p>
N/A	<p><b><i>Clinical trial</i> 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. 46.102 (b)</b></p>
<p><i>Department or agency head</i> means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated. <b>46.102(a)</b></p>	<p><i>Department or agency head</i> means the head of any Federal department or agency, <b>for example, the Secretary of HHS</b>, and any other officer or employee of any <b>Federal</b> department or agency to whom the authority <b>provided by these regulations to the department or agency</b> head has been delegated. <b>46.102 (c)</b></p>
N/A	<p><b><i>Federal department or agency</i> refers department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (e.g., the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency). 46.102 (d)</b></p>
<p><i>Human subject</i> means a living individual about whom an investigator (whether professional or student) conducting research obtains</p>	<p><i>Human subject</i> means a living individual about whom an investigator (whether professional or student) conducting research:</p>

# Changes: Informed Consent

- ▶ Summary paragraph at top of document
  - ▶ Focused presentation of “key information”
  - ▶ “Organized and presented” in a way to facilitate comprehension

# Consent: Key Information

- ▶ Consent is being sought for research and participation is voluntary
- ▶ Purpose(s) of research, duration and procedures
- ▶ Risks
- ▶ Benefits
- ▶ Alternative procedures, if any



# Consent: Key Information

## Key Information:

*{Be concise and focused in this section as you will elaborate on each key item later}.*

- You are being invited to participate in a research study
- The purpose of the study is *{briefly sum up the research purpose}*.
- This research will take place *{where}*, will consist of *{survey, interview, etc.}*, and will take approximately *{minutes/hours}*.
- *{If applicable, include alternative procedures, if not, delete}*
- There are minimal risks, including loss of confidentiality *{briefly identify any other risks}*.
- You may benefit from your participation in this research by *{briefly identify any benefits to the participants}*.
- Your participation in this research is voluntary

# Consent: New Element

- ▶ Include one of these two statements:
  - ▶ Identifiers might be removed and de-identified information or biospecimens used for future research without consent
  - ▶ Information or biospecimens will not be used or distributed for future use even if identifiers removed

# Consent: Additional Elements

- ▶ Statement that biospecimens may be used for commercial profit and if subject will share in profit
- ▶ If clinically relevant research results will be disclosed to subjects (and when)
- ▶ Whether the research with biospecimens might include whole genome sequencing

# Consent: Waiver of Written Consent

- ▶ Added the following justification:
  - ▶ If subjects are members of a distinct cultural group or community in which signing a document is not the norm AND no more than minimal risk to subjects AND consent is documented another way

# Revised ICF Templates

- ▶ Two exempt templates
- ▶ Two expedited/convened templates

# Consent: Screening

- ▶ No informed consent if:
  - ▶ Obtain information orally or via written communication with potential subject
  - ▶ Obtain information (or biospecimens) by accessing records
- ▶ Still has to be described in IRB application form and adequate measures in place for privacy.

# Changes: Exempt Categories

- ▶ X1: REVISED:
  - ▶ Added that won't adversely impact students' opportunity to learn required educational content
- ▶ X2: REVISED:
  - ▶ Only include interactions
  - ▶ Plus limited IRB review option (E7)

# Changes: Exempt Categories

- ▶ X3: NEW:
  - ▶ Like X2 but includes interventions. Same criteria as X2, including new limited IRB review
- ▶ Benign behavioral interventions:
  - ▶ Brief in duration
  - ▶ Painless and harmless
  - ▶ Not physically invasive
  - ▶ Not likely to have significant adverse lasting affect in subjects
  - ▶ No reason to think subjects will find it offensive or embarrassing



# Changes: Exempt Categories

- ▶ X4: REVISED:
  - ▶ For our purposes, added information related to biospecimens
  - ▶ Clarified that researchers can't contact participants
  - ▶ Clarified that researchers can't try to re-identify participants

# Changes: Exempt Categories

- ▶ X5: REVISED: N/A
- ▶ X6: SAME: Taste and food quality studies
- ▶ X7 & X8: NEW: Broad consent for data repositories (limited IRB review)

# Transition

- ▶ All studies approved before 01/21/19, continue complying with Common Rule.
- ▶ However, most institutions are planning to transition at the time of continuing review.
- ▶ Will need:
  - ▶ Information on website
  - ▶ Updated forms and templates
  - ▶ Updated procedures

# Tentative Procedures

- ▶ Exempt – Revised application questionnaires and ICF with no key info paragraph
- ▶ Expedited/Convened – Revised application questionnaires with modified ICF information
- ▶ Very simple annual update form for exempt/expedited projects.
- ▶ Same continuing review procedure for Full Board projects

# Tentative Procedures

- ▶ Transition Expedited and Full Board projects at the time of continuing review (submit revised consent form)
- ▶ Clinical Trials may need to post consent form to government website (is this just certain funded studies and where?)

Q/A