

IRBMED Seminar Series

Revisions to the Federal Policy for the Protection of Human
Subjects ('Common Rule') – Changes Ahead

Scope of the Revisions

April 4, 2017

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Refresher

- What is the “Common Rule?”

Federal Policy for the Protection of Human Subjects published in 1991 and codified in separate regulations by 15 Federal departments and agencies

- **45 CFR Part 46 - Department of Health and Human Services (HHS)**
- Other Federal adopters include:
 - 10 CFR Part 745 - Department of Energy
 - 32 CFR Part 219 - Department of Defense
 - 34 CFR Part 97 - Department of Education
 - To see the complete list:
 - <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html>

HHS Regulations, 45 CFR part 46

Include four subparts:

1. **subpart A, also known as the Federal Policy or the “Common Rule”;**
 - IRB Membership
 - IRB Review Procedures
 - Criteria for Approval
 - Informed Consent
 - Suspension
 - Termination
 - Expedited Reviews
 - Exempt Categories
2. subpart B, additional protections for **pregnant women, human fetuses, and neonates;**
3. subpart C, additional protections for **prisoners;** and
4. subpart D, additional protections for **children**

This has been a long road...



1991-Common Rule

2011-ANPRM

2015-NPRM

2017-Final Rule

The road ahead...

Jan. 2020-Single IRB Compliance Date

Jan. 2018-Compliance Date

Jan. 2017-Final Rule



Intention behind the Final Rule

BETTER PROTECT
ENHANCE MODERNIZE
STRENGTHEN
MORE EFFECTIVE REDUCING BURDEN
SIMPLIFY

What's included in this Final Rule?

- Harmonization across departments and agencies when appropriate and feasible
 - FDA 21 CFRs have NOT been updated
 - HHS and FDA harmonization through 21st Century Cures law
 - Applicability of Common Rule
 - Federal Funding
 - FWA “Checking the Box”
 - Use of Single IRBs for domestic, Multi-Site research

What's Included in this Final Rule?

- Exemption
 - Three new categories
- Continuing Reviews
- Informed Consent Process and Documentation
 - Participant focused content changes
 - Future Use

What's Included in this Final Rule?

- New & Revised Definitions
 - Clarify Meaning and Oversight
 - Legally Authorized Representative (LAR)
 - Revised
 - Vulnerable Populations
 - Revised
 - Human Subject
 - Revised
 - Clinical Trial
 - New

LAR



- Current Language:

“Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research. “

LAR



- **Additional New Language:**

“If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject’s participation in the procedure(s) involved in the research.”
- You can find our local policies if you go to the Informed Consent guidance on our website and look for the document, “Who can Consent or Provide Permission for Participation in Research”

Vulnerable Populations

- Final Rule no longer includes pregnant women or “handicapped” or physically disabled individuals as examples of populations that are potentially vulnerable to coercion or undue influence within 45 CFR 46 Subpart A.
- REMEMBER: Subpart B, additional protections for **pregnant women, human fetuses, and neonates** is not part of the Common Rule and has not changed.

Research involving vulnerable populations – Previous Lang.

- §__.111(a)(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

Research involving vulnerable populations – Removed Lang.

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Research involving vulnerable populations – Revised Lang.

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Human Subject

- This definition has been expanded to clarify work with bio-specimens that are considered to be research activities.
 - “includes research in which an investigator obtains, uses, studies, analyzes, or **generates identifiable biospecimens** or identifiable private information”

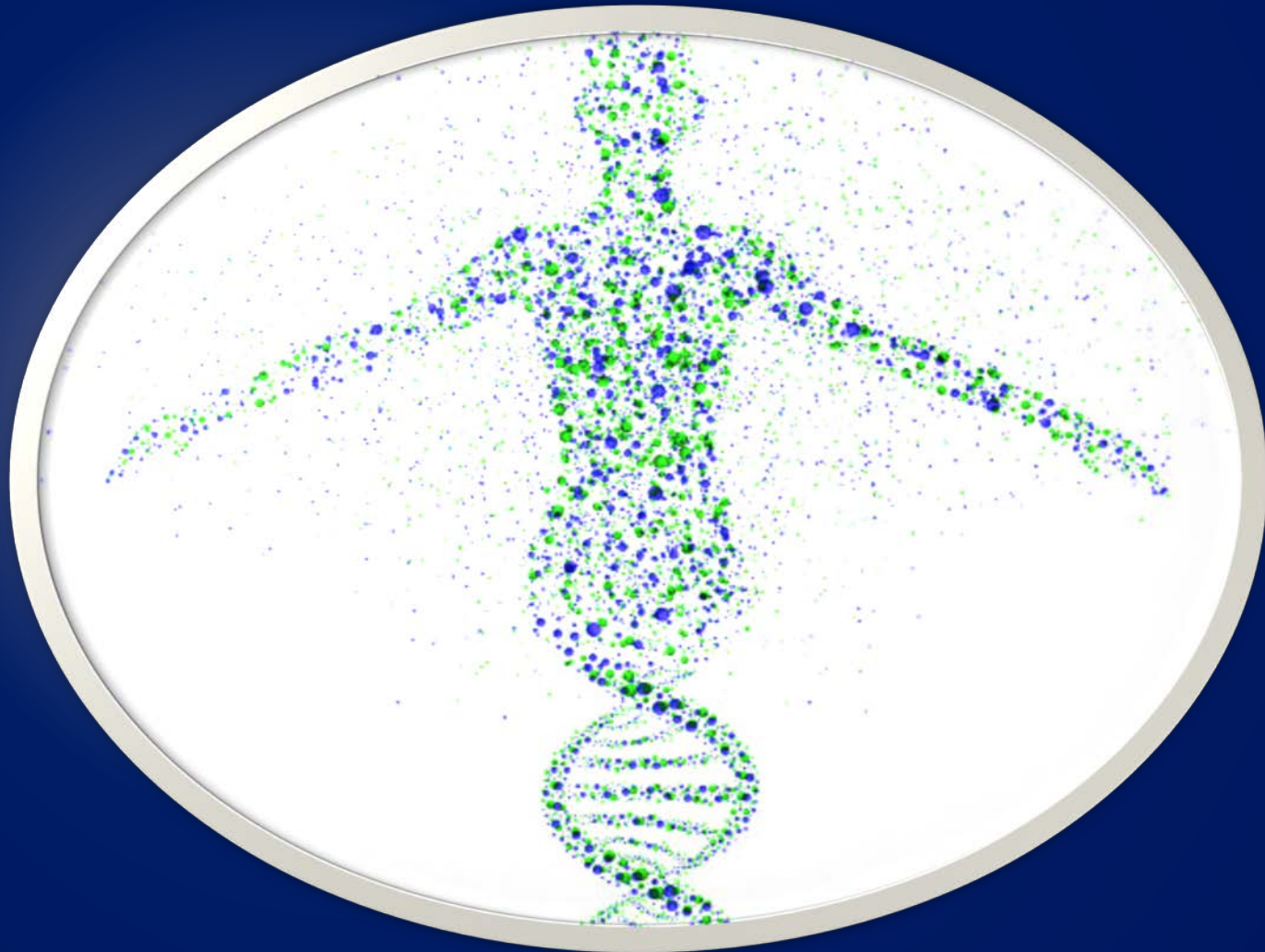


Human Subject

- Added to the definition
 - (6) *An identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
- Example:
 - Name
 - MRN
 - Code w/ Link



Identifiable Biospecimen



Identifiable Biospecimen

(7)(i) (ii) Upon consultation with appropriate experts, assess whether there are **analytic technologies or techniques** that should be considered by investigators to generate “identifiable private information,” as defined in paragraph (e)(5) of this section, or an “identifiable biospecimen,” as defined in paragraph (e)(6) of this section. **This assessment shall take place within 1 year and regularly thereafter (at least every 4 years).**

Clinical Trial

- §__.102(b) *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.

- New Definition

Helps to support and clarify aspects of the Final Rule

This definition will be useful when determining what consent forms will need to be made publicly available

Tribal Law

- “if the official governing body of a tribe passes a tribal law that provides additional protections for human subjects, the Common Rule does not affect or alter the applicability of such tribal law.”

Cooperative Research__114((b)

(b)(2) Research not subject to (b)(1) If single IRB required by law (including tribal law)

Conclusion of Scope

- Common Rule = 45 CFR part 46 subpart A
- Common Rule Published in 1991
- Final Common Rule Published in January 2017
 - Compliance Date will be January 2018
 - Single IRB Compliance Date will be January 2020
- Revisions, Additions, and New Definitions
 - Add Clarity
 - Better Qualify
 - Adapts to Technology
- Modernize the Regulations
- Protect those who volunteer and participate