# Key Changes to the Common Rule

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# Common Rule

Federal Policy for the Protection of Human Subjects published in 1991 and codified in separate regulations by 14 Federal departments and agencies

| | |
|---|---|
| DHHS | Dept of Commerce |
| NSF | Consumer Product Safety Commission |
| DOD | USAID |
| Dept of Justice | Dept of Housing and Urban Development |
| Dept of Agriculture | Dept of Education |
| Dept of Energy | Dept of Transportation |
| NASA | VA |

# Changes

Broad changes

- Scope
- IRB Operations
- Informed consent
- Exemptions
- Requires single IRB review of research involving external collaborators (effective 1/20/2020)

# What's not Changing?

Minimal change to IRB review of projects that involve:

- More than minimal risk
- Drugs / biologics / medical devices (FDA-regulated)

# Changes to Scope

Definition of research

Defines what's not research, certain journalistic, public health surveillance, and criminal justice activities

Definition of human subject

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 bio-specimens or identifiable private information"

Definition of clinical trial

"….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."

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

# Continuing Review

# Informed Consent

Consent must begin with a presentation of ‘key information’

Content, organization and presentation of information should facilitate a prospective subject’s decision about whether to participate or not

# Consent: General Requirement

‘Key Information’

Begin with “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 consent must be organized and presented in a way that facilitates comprehension

§ __.116(5)(i)

# Informed Consent: Added Element

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# Informed Consent: New Basic Element

Statement to be used when appropriate:

- Subject's bio-specimens may be used for commercial profit (and whether the subject will or will not share in the commercial profit)
- Whether clinically relevant research results, including individual research results, will be disclosed to subjects or not
- For research involving bio-specimens, whether the research will involve whole genome sequencing

# How will we comply?

# Documentation of Informed Consent

Electronic formats are acceptable

> “informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in

# Informed Consent: Posting

Applies only to federally-conducted or supported clinical trials

- Reminder:

  "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-relathae-hBo7

# Informed Consent- Posting

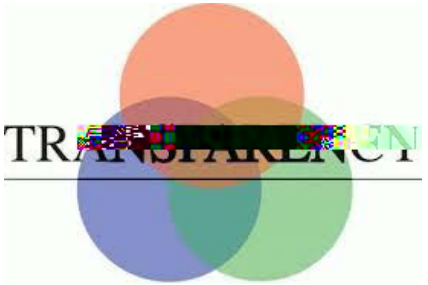
Only one IRB-approved version used to enroll subjects is required

- Even if multiple exist, multisite study, or different subject groups

Posting can take place any time after recruitment closes but no later than 60 days after the last study visit by any subject

Federal department or agencies may permit/require redactions to the posted information

- e.g. confidential commercial information
- could determine that the very existence of a particular clinical trial should not be publicly disclosed, in which case no posting would be required (rare)



# Exemption Changes

(Guidance Sheets are Avaiable for Detailed Information)

# Exemption 1 – Educational Exemption

What's new?

Now must consider "adverse affects" on student learning of required educational content or on assessment of educators

Normal educational practices that are not likely to adversely impact (i) students' opportunity to learn required educational content, or (ii)

# Exemption 2 – Surveys/Interviews/Educational Tests/Public Observation ONLY

What's new?

Projects collecting **sensitive** and **identifiable** data may be exempt after "limited IRB review" (for privacy/confidentiality protections)

Clarifies that the exemption **does not apply** to projects involving:

- Interventions
- Collection of biospecimens
- Linking to additional personally-identifiable data
- Children (except for educational tests or some public observations)

# Exemption 3 – Benign Behavioral Interventions

Information is collected via

- Verbal or written responses (surveys / interviews)
- Data entry
- Observation of subject (including audiovisual recording)

Does not permit data collection via physical procedures

- Physical sensors (e.g. blood pressure monitors, EEG, FitBits)
- Minimally invasive procedures (e.g. blood draw or saliva collection)

# Examples

Solving puzzles under various noise conditions

Playing an economic game

Being exposed to stimuli such as color, light or sound (at safe levels)

Performing cognitive tasks

# Exemption 4 – Secondary Research Uses of Identifiable Private Information or Identifiable Biospecimens

What's new?

- No longer limited to retrospective data review
- Permits secondary use of identifiable protected health information (PHI) (with HIPAA privacy board review)

# Exemption 5 – Public Benefit/Service Programs Research /Demonstration Programs

Expanded to apply to such federally-supported research; no longer limited to federally-conducted research

Added requirement that Federal agency publish a list of projects covered by this exemption prior to commencing the research

# Exemption 6 – Taste/Food Quality Evaluation

Unchanged

(i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

# Exemptions 7 & 8 – Storage and Secondary Use of Data/Biospecimens

Related new exemptions

Exemption 7 covers the storage and maintenance of identifiable data and/or biospecimens for future research collected under broad consent

Exemption 8 covers the use of secondary data/biospecimens collected under broad consent

IRB will not use Exemptions 7 & 8

# Human Research Protection

# sIRB NIH Policy: How To Comply?

Effective 1/25/2018

Currently, USA will not serve as the sIRB of IRB and will request to cede review to an external IRB.

- Finalize Policy and Procedures for Collaborative Research and External IRBs

- Research team completes IRB Reliance Request/Registration Form
  - Application for an External Institution to serve as IRB of Record

# Attributions

U-M website

http://research-compliance.umich.edu/human-subjects/common-rule-other-changes

SACHRP Recommendations

(Secretary's Advisory Committee on Human Research Protections)

https://www.hhs.gov/ohrp/sachrp-committee/recommendations/sachrp-recommendations/index.html

Common Rule

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html