

# Overview of the Revised Common Rule

Federal Demonstration Partnership

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# Disclaimer

The opinions expressed are those of the presenter and do not necessarily reflect the policy of the U.S.

Department of Health and Human Services.

# Broad Overview

- Brief background on the revised rule
- Implementation dates and transition provision
- Major NPRM proposals **not** adopted
- Summary of key changes:
  - ❖ Definition of “human subject”
  - ❖ Definition of “research”
  - ❖ Informed consent
  - ❖ Exemptions
  - ❖ Expedited review
  - ❖ Continuing review
  - ❖ Single IRB review
  - ❖ Other changes that reduce burden and create flexibility

# Why Revise the Common Rule?

- Better protect research subjects
- Reduce administrative burdens



# Brief Overview of Rulemaking Process



# Implementation Dates

- Before January 19, 2018, all activities must comply with the pre-2018 rule
  - Note that you can implement revised Common Rule provisions that do not conflict with the pre-2018 rule
- Any study started on or after January 19, 2018 must comply with the revised Common Rule
- The requirement for single IRB review in multi-institutional studies goes into effect January 20, 2020

# General Implementation of the Transition Provision

Transition date for revised Common Rule

Pre-2018 Rule applies to all studies

**Studies initially “approved” before January 19, 2018:**

- Presumption: Pre-2018 rule applies
- Institution may elect to apply the revised Common Rule. IRB must document this in writing.

**Studies initially “approved” on or after January 19, 2018:** The revised Common Rule applies

*January 19, 2018*

# Major NPRM Proposals **Not** Adopted

- Extension of Common Rule to cover research using non-identified biospecimens, that would almost always require consent
- Extension of Common Rule to clinical trials that are not federally funded
- Creation of an exemption decision tool
- Creation of a broad consent template
- Development of standardized privacy safeguards



# Definition of “Human Subject” – Clarifying Changes

Human subject - a living individual about whom an investigator conducting research

- (1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

§\_.102(e)(1)(i)

# Addressing the Evolving Concept of “Identifiability”

Federal agencies’ commitment to collaborate at least every 4 years to:

- Reexamine the meaning of identifiability
- Identify analytic techniques capable of generating identifiable private information or biospecimens

§\_.102(e)(7)

# Definition of “Research: Activities Deemed Not To Be Research

- Scholarly and journalistic activities
  - Focus on the specific individual about whom information is collected
  - Excludes certain activities, not entire academic fields
- Government functions with separately mandated protections
  - Public health surveillance activities
  - Collection of information for criminal justice purposes
  - Operational activities for national security purposes

# Public Health Surveillance Activities Deemed Not to be Research

- Limited to:
  - Those conducted, supported, requested, ordered, required or authorized by a “public health authority.”
  - Those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance, including trends, signals, risk factors, patterns of diseases, or increases in injuries from using consumer products.

§\_.102(I)

# Changes to Informed Consent

1. General Improvements to Informed Consent
2. Broad Consent
3. Posting of Consent Form for Clinical Trials
4. Waiver and Alteration of Informed Consent

# Promoting Autonomy

- Changes are intended to make informed consent more meaningful so that research subjects will have the necessary information to make informed decisions

# General Improvements

The revised Common Rule explicitly establishes a new standard: to provide the information that a **reasonable person** would want to have in order *to make an informed decision about whether to participate*

§.116(a)(4)

# General Improvements

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

- *Not merely provide lists of isolated facts*



§\_.116(a)(5)(ii)

# General Improvements

The revised Common Rule has a new requirement that certain key information must be provided first

§\_.116(a)(5)(i)

# Concise and Focused: Key Information

That first section must provide a *concise and focused* presentation of *key information* regarding *why one might or might not want to participate*

§\_.116(a)(5)(i)

# *Basic* Elements of Informed Consent

One new element:

- Notice about possible future research use of information or biospecimens stripped of identifiers:
  - Notifying prospective subject that subjects' information or biospecimens could be used for future research without additional consent; or
  - Notifying prospective subject that subjects' information or biospecimens will not be used for future research.

§.116(b)(9)

# *Additional* Elements of Informed Consent

Three new additional elements:

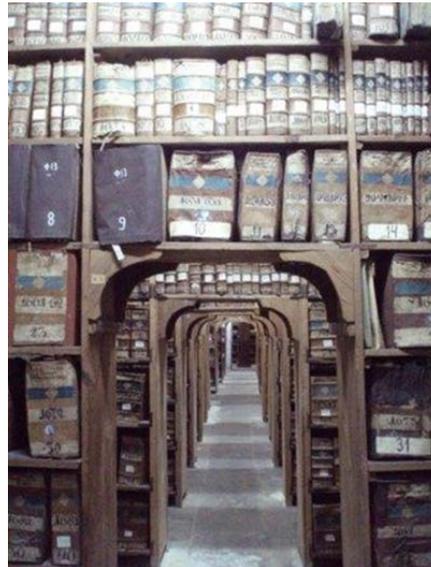
- Notice about whether clinically relevant research results, including individual research results will be given to subjects, and if so, under what conditions
- Notice about possible commercial profit, and whether subject will share in this profit (for research involving biospecimens)
- Notice about whether research might include whole genome sequencing (for research involving biospecimens)

# Allowing the Use of Broad Consent for **Secondary Research**

- **Optional**: An alternative to traditional informed consent or waiver of informed consent
- Applicable to:
  - The storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens
  - Collected for either a different research study, or for non-research purposes
- Creates future regulatory flexibilities

# What is Secondary Research?

Research use of information or biospecimens collected for either research studies other than the proposed research, or for nonresearch purposes (e.g., clinical care, public health, education)



# Posting of Consent Forms for Clinical Trials

- For clinical trials supported by federal funding, one IRB-approved consent form used to enroll participants must be posted on publicly available Federal website to be designated
- Post after recruitment closes, no later than 60 days after last study visit
- Federal department or agency may permit or require redactions



§\_.116(h)

# Waiver of Consent

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

- The IRB must determine that the research could not *practicably* be carried out without accessing or using identifiers

*Non-identified* information should be used whenever possible in order to respect subject's autonomy

§\_.116(f)(3)(iii)

# No Waiver if Broad Consent Refused

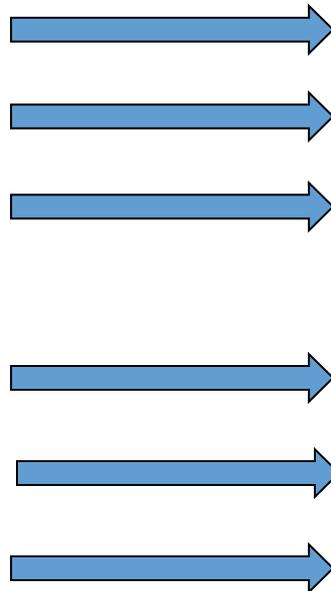
IRB cannot waive consent if individuals were asked, and refused, to provide broad consent to the storage, maintenance and use of identifiable private information or identifiable biospecimens

§\_.116(f)(1)

# Summary of Changes to Exemptions

## Pre-2018 Rule (Current)

- Exemption 1
- Exemption 2
- Exemption 3
- Exemption 4
- Exemption 5
- Exemption 6



## Revised Common Rule

Restrictions added

Expanded

Removed and replaced with a new exemption 3

Expanded old and added new

Expanded with changes

No change

\*New Exemption 7

\*New Exemption 8

\*New - limited IRB review

# Exemptions Applicability - Subparts C & D

- Pre-2018 Rule (Current)
  - Subpart C prisoners research – none apply
  - Subpart D children research - exemption 2 for research involving survey or interview procedures or observations of children by investigators who participate in the activity being observed does not apply; other exemptions apply
- Revised Common Rule
  - Subpart C prisoners research expanded – exemptions do not apply **except** for research aimed at involving a broader subject population that only incidentally includes prisoners
  - Subpart D children research:
    - Same restrictions as above for exemption 2 **plus** new provision §\_.104(d)(2)(iii) also not applicable
    - New exemption 3 does not apply

# Exemption 1: Restrictions Added

- Normal educational practices in established or commonly accepted educational settings
- New : normal educational practices that are not likely to adversely:
  - Impact students' opportunity to learn required educational content, or
  - The assessment of educators who provide instruction

§\_.104(d)(1)

# Expanding Exempt Research: Exemption 2

Educational tests, surveys, interviews, and observations of public behavior exemption when

- Information recorded cannot be readily linked back to subjects, or
- Any information disclosure would not place subjects at risk of harm, or
- Identifiable information recorded with limited IRB review for privacy and confidentiality protection under §\_.111(a)(7)

§\_.104(d)(2)

# What Happened to Exemption 3?

- Removed in revised rule: Pertained to research involving the use of educational tests, survey procedures, or observation of public behavior if:
  - The human subjects are elected or appointed public officials or candidates for public office, or
  - Federal statute requires protects confidentiality without exception.
- Almost all such research would be exempt under the new exemption 2. If researchers record sensitive identifiable information about public officials, it must be kept confidential.

# Expanding Exempt Research: New Exemption 3

New exemption for research involving benign behavioral interventions with adults who prospectively agree when information collection is limited to verbal or written responses (including data entry) or audiovisual recording, and:

- Information recorded cannot be readily linked back to subjects, or
- Any information disclosure would not place subjects at risk of harm, or
- Identifiable information recorded with limited IRB review for privacy and confidentiality protection under §\_.111(a)(7)

# Exemption 3, Cont'd

- Explanation of term “benign behavioral interventions”

These are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing

- Includes authorized deception research

§\_.104(d)(3)

# Expanding Exempt Research: Exemption 4

Secondary research use of identifiable private information or identifiable biospecimens (materials no longer need to be “existing”) if:

1. Identifiable private information or identifiable biospecimens are publically available, OR
2. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects or re-identify subjects, OR

# Expanding Exempt Research: Exemption 4, cont'd

Secondary research use of identifiable private information or identifiable biospecimens for which consent is not required, if:

3. Investigator's use is regulated under HIPAA as "health care operations," "research," or "public health" OR
4. Research is conducted by, or on behalf of, a Federal agency using data collected or generated by the government for non-research purposes, and the information is protected by federal privacy standards

§\_.104(d)(4)

# Exemption 5: Expanded

## Public benefit and service programs research and demonstration projects

- 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

§\_.104(d)(5)

# Exemption 6: No Change

- Taste and food quality evaluation and consumer acceptance studies

§\_.104(d)(6)

# Expanding Exempt Research

## New Exemptions 7 and 8: Require Broad Consent

- Exemption 7: Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research
- Exemption 8: Secondary research using identifiable private information or identifiable biospecimens

§\_.104(d)(7) and (8)

# Limited IRB Reviews

- Required for exemptions 2(iii), 3(i)(C), 7, and 8 in the revised Common Rule
- Exemptions 2(iii) and 3(i)(C) review:
  - For privacy and confidentiality protection under §\_111(a)(7)
- Exemptions 7 & 8 reviews:
  - For other safeguards related to privacy and confidentiality protection, and broad consent

# Updating and Simplifying Expedited Review

- List will be reviewed every 8 years and updated if necessary
- Presumption that activities listed are minimal risk
  - Unless expedited reviewer determines otherwise, which would make the study not expeditable and would need to be documented
- Limited IRB review has been added to list of permissible use of expedited review mechanism

§\_.110, §\_.109(f) and §\_.115(a)(8)

# Eliminating Certain Continuing IRB Reviews

In general, no continuing review required for:

- Research approved by expedited review
- Exempt research requiring limited IRB review
- Research has completed interventions and only involves:
  - Analyzing data, including analyzing identifiable private information or identifiable biospecimens
  - Accessing follow-up clinical data from clinical care procedures

IRB can override this default and require continuing review, but this must be documented

§\_.109(f) and §\_.115(a)(3)

# Requirement for Single IRB Review

## Applicability

- U.S. institutions engaged in cooperative research for the portion of the research conducted in the U.S.
- Does not apply:
  - When more than single IRB review is required by law (including tribal law)
  - Whenever any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context – flexibilities allowed

§\_.114(b)

# Other Burden Reductions and Flexibilities

- Eliminating IRB roster reporting to OHRP
- Eliminating grant application review
- Eliminating the option on the Federalwide Assurance to “check the box”

# Questions About the Revisions?



- OHRP will be developing resources to explain the revised Common Rule. Check out [www.hhs.gov/ohrp](http://www.hhs.gov/ohrp)
- Submit your questions to [OHRP@hhs.gov](mailto:OHRP@hhs.gov)