Overview of the Revised Common Rule

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- Provides leadership in protecting the rights, welfare and wellbeing of human subjects in research conducted or supported by HHS
- Enforces the Federal Policy for the Protection of Human Subjects at 45 CFR 46
  - Subpart A is referred to the Common Rule
  - Key protections: Institutional assurance, IRB review, Informed consent
- Distinct role from NIH and FDA (although both HHS agencies)

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Revision of the Common Rule

- Originally promulgated in 1991
- Revisions needed to meet the challenges of the rapidly changing landscape of research
- Goals:
  - To better protect research subjects
  - To reduce administrative burdens so that IRBs can better serve their role
- Revised rule was published in January 19, 2017
- Implementation date for most of the rule:

January 19, 2018

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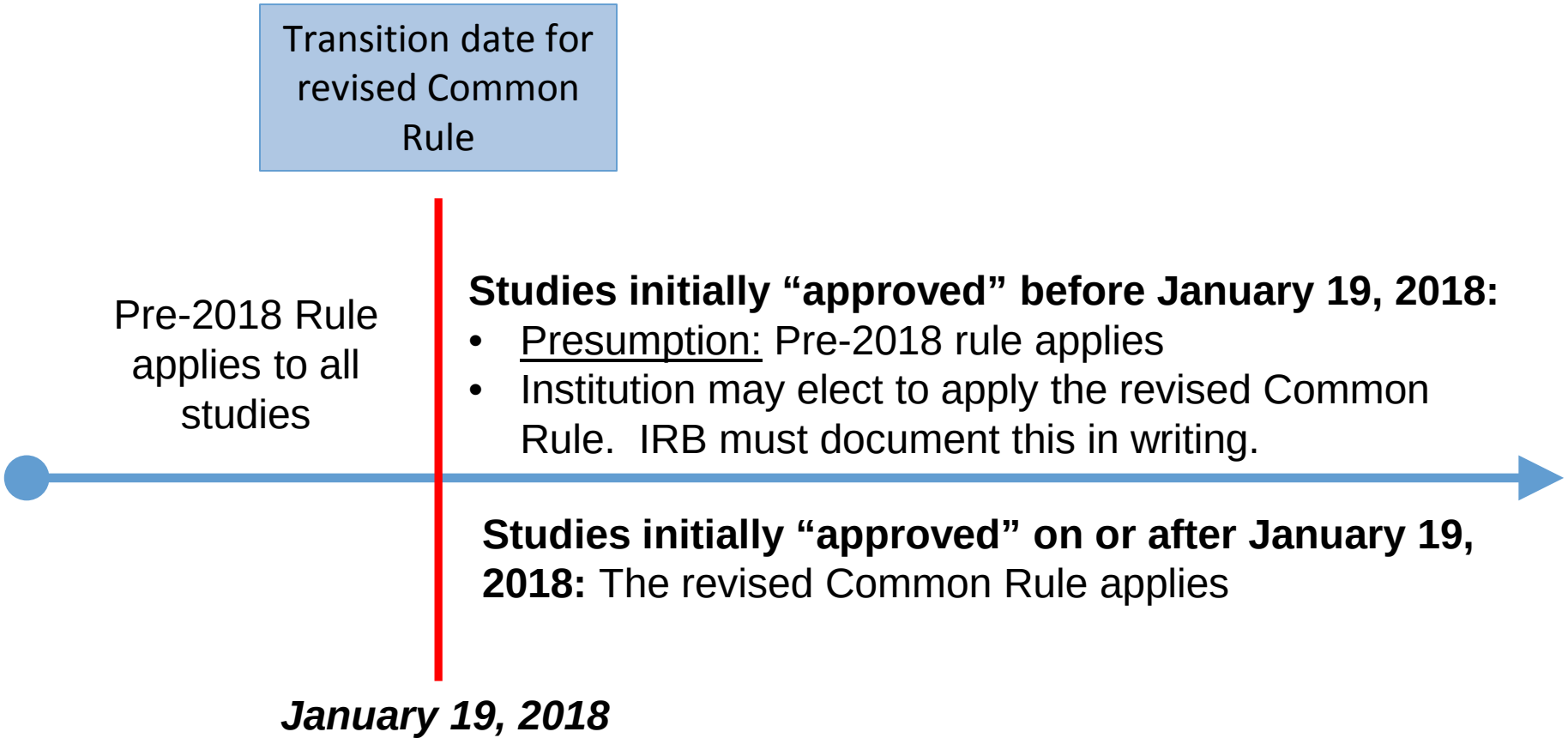
General Implementation of the Transition Provision



The requirement for single IRB review in multi-institutional studies goes into effect **January 20, 2020**

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Summary of Key Changes

- **Promoting individual autonomy**
  - Changing requirements of informed consent
  - Adding broad consent option for secondary research
- **Reducing administrative burden, streamlining IRB processes**
  - Removing activities from the definition of research
  - Expanding exempt research
  - Updating and simplifying expedited review
  - Eliminating certain continuing reviews
  - Using single IRB review

Definition of “Research”

Research refers to a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge

What’s new?

- 4 sets of activities specifically deemed not to be research

Activities Deemed Not to be Research in the Revised Common Rule

1. Scholarly and journalistic activities that focus directly on the specific individuals about whom the information is collected
2. Public health surveillance activities limited to those necessary to identify, monitor, assess, or investigate conditions of public health importance
3. Collection and analysis of materials for criminal justice purposes
4. Authorized operational activities for national security purposes

§__.102(l)

Definition of "Human Subject": Terms Clarified

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)

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Addressing the Evolving Concept of "Identifiability"

- **Definition**: [materials] *for which the identity of the subject is or may readily be ascertained by the investigator or associated with the* [materials]
- Federal agencies' commitment to collaborate at least every 4 years to:
  - Re-examine the meaning of identifiability
  - Identify analytic techniques capable of generating identifiable private information or biospecimens

§__.102(e)(5)-(7)

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Summary of Changes to Exemptions

Pre-2018 Rule (Current)	Revised Common Rule
1: Educational practices	Restrictions added
2: Educational tests, surveys, interviews, observation of public behavior	Expanded
3: Research on public officials	Removed and replaced with new
4: Research on existing data	Expanded old and added new
5: Public benefit service	Expanded with changes
6: Taste and food evaluations	No change
	+ New Exemption # 7
	+ New Exemption # 8
	*New - limited IRB review

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Exemption 1: *Restrictions Added*

Normal educational practices in established or commonly accepted educational settings

What's 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)

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Exemption 2: *Expanded*

Research that only includes interactions involving educational tests, surveys, interviews, and observations of public behavior, exempt when

i. Information recorded cannot be readily linked back to subjects, **or**

ii. Any information disclosure would not place subjects at risk of harm, **or**

iii. Identifiable information recorded, with limited IRB review for privacy and confidentiality protection under §__.111(a)(7)

§__.104(d)(2)

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Exemption 3: *New Replacement*

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:

A. Information recorded cannot be readily linked back to subjects, **or**
B. Any information disclosure would not place subjects at risk of harm, **or**
C. Identifiable information recorded, with limited IRB review for privacy and confidentiality protection under

§__.111(a)(7)

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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 investigator has no reason to think the subjects will find the interventions offensive or embarrassing

- Includes authorized deception research

§__.104(d)(3)(ii)-(iii)

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)

Concept of Secondary Research

Research use of information or biospecimens collected for:

- Research studies other than the proposed one, **or**
- Non-research purposes (e.g., clinical care, public health, education)

Reminder: Secondary research use of nonidentifiable materials (data or biospecimens) is not human subjects research

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Exemption 4: *Expanded and Added New*

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

i. Identifiable private information or identifiable biospecimens are publically available, **or**

ii. 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**

Exemption 4, cont'd

(…) secondary research use of identifiable private information or identifiable biospecimens if:

iii. Investigator's use is regulated under HIPAA as "health care operations," "research," or "public health", **or**

iv. Research is conducted by, or on behalf of, a Federal agency using data collected or generated by the government for nonresearch purposes, and the information is protected by federal privacy standards

§__.104(d)(4)

Exemptions 7 and 8: *New*
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)&(8)

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Use of Broad Consent

- **Optional:** An alternative to traditional informed consent or waiver of informed consent
- Applicable to:
  - Secondary research
  - Involving identifiable private information or identifiable biospecimens
- Broad consent includes a defined set of elements that cannot be omitted or altered
- When declined, IRB cannot waive informed consent

§__.116(d)-(f)

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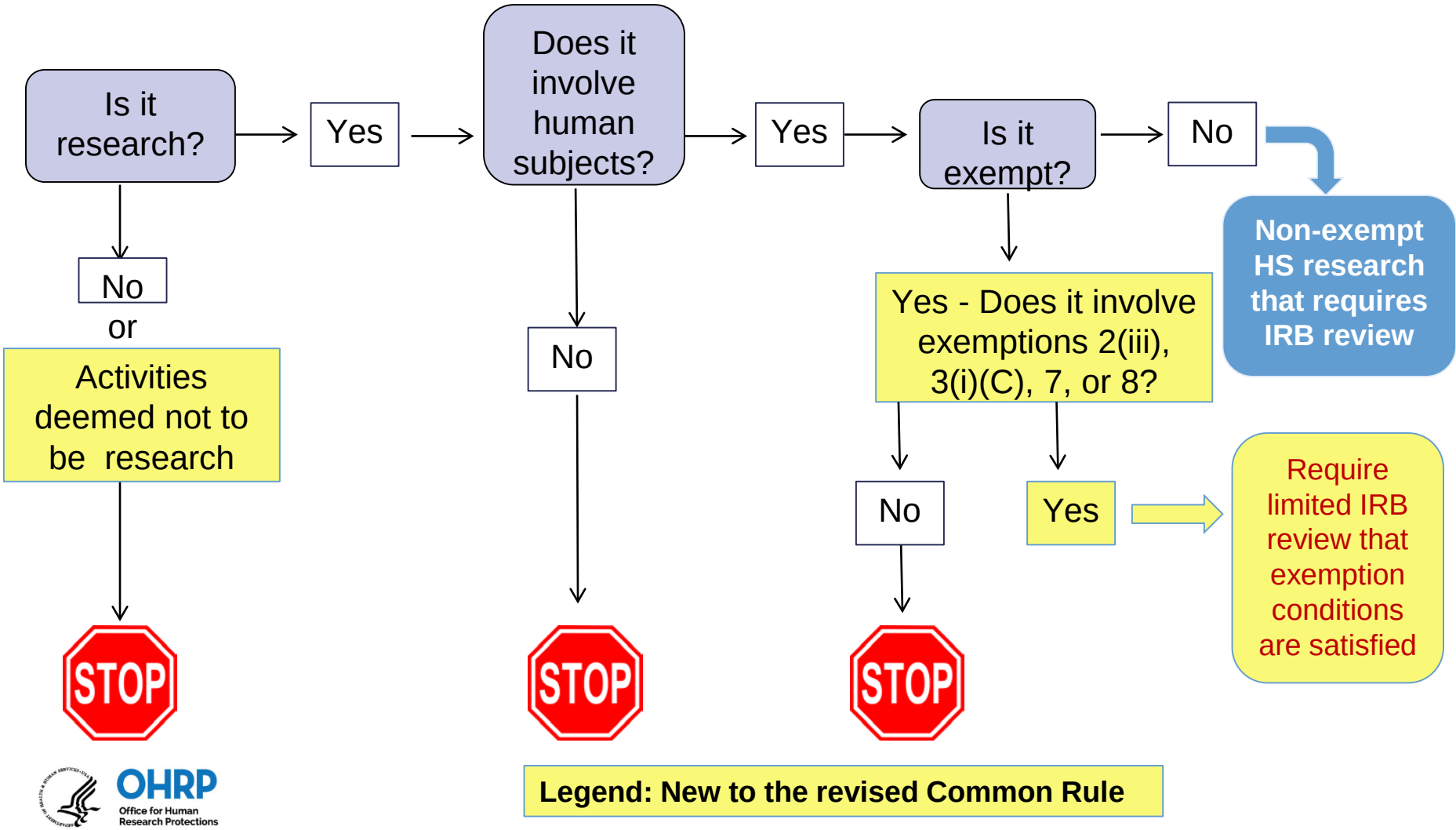
Limited IRB Reviews: *New*

- 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

Making a Determination of Non-Exempt Human Subjects Research



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Changes to IRB Reviews

- **Expedited review**:
  - List will be reviewed every 8 years
  - Research on list is expeditable unless the reviewer determines that the study involves more than minimal risk
- **Continuing review**: eliminated for the following
  - 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

§__.110, §__.109(f) & §__.115(a)(3) & (8)

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
- Implementation: by January 20, 2020

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§__.114(b)

Improvements in Informed Consent

- Information that a **reasonable person** would want to have in order to **make an informed decision** about whether to participate (§_.116(a)(4))
- **Key information** must be provided at the beginning
  - *Concise and focused* presentation of *key information* regarding why one might or might not want to participate (§__.116(a)(5)(i)
- Information presented in **sufficient detail**, and **organized** and presented in a way that facilitates subjects' understanding of why one might or might not want to participate (§__.116(a)(5)(ii))

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Basic Elements of Informed Consent

<u>Added one new</u>

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)

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Additional Elements of Informed Consent

Added three new:

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

§__.116(c)(7)-(9)

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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

§__.116(f)(3)(iii)

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

§__.116(f)(1)

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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)

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Please refer to the text of the revised Common Rule available on OHRP's website for a complete and accurate description of the regulatory requirements

Questions About the Revisions?

- OHRP will be developing resources to explain the revised Common Rule. Check out www.hhs.gov/ohrp

- Submit your questions to OHRP@hhs.gov

THANK YOU FOR YOUR ATTENTION

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