Overview of the Revised Common Rule

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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 “research”
  - Definition of “human subject”
  - Exemptions
  - Informed consent
  - Continuing review
  - Single IRB review

Revision of the Common Rule

- Why revise the rule?
  - Better protect research subjects
  - Reduce administrative burdens
- Brief overview of the rulemaking process

ANPRM
July 2011
Public
Comment

→

NPRM
Sept. 2015
Public
Comment

→

Revised Common Rule
Published
Jan. 19, 2017

Implementation date for most of the rule:

January 19, 2018

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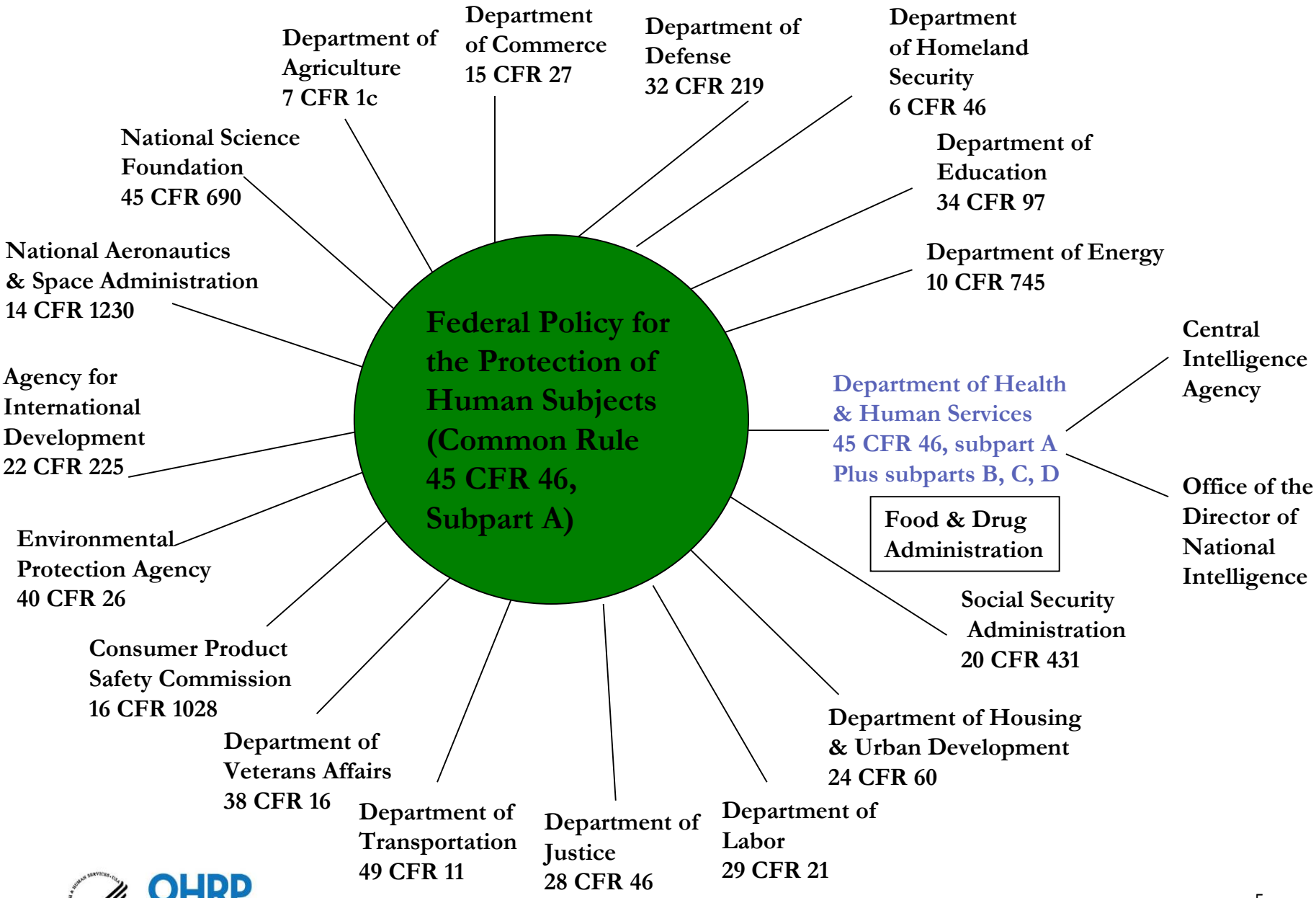
Common Rule Departments & Agencies



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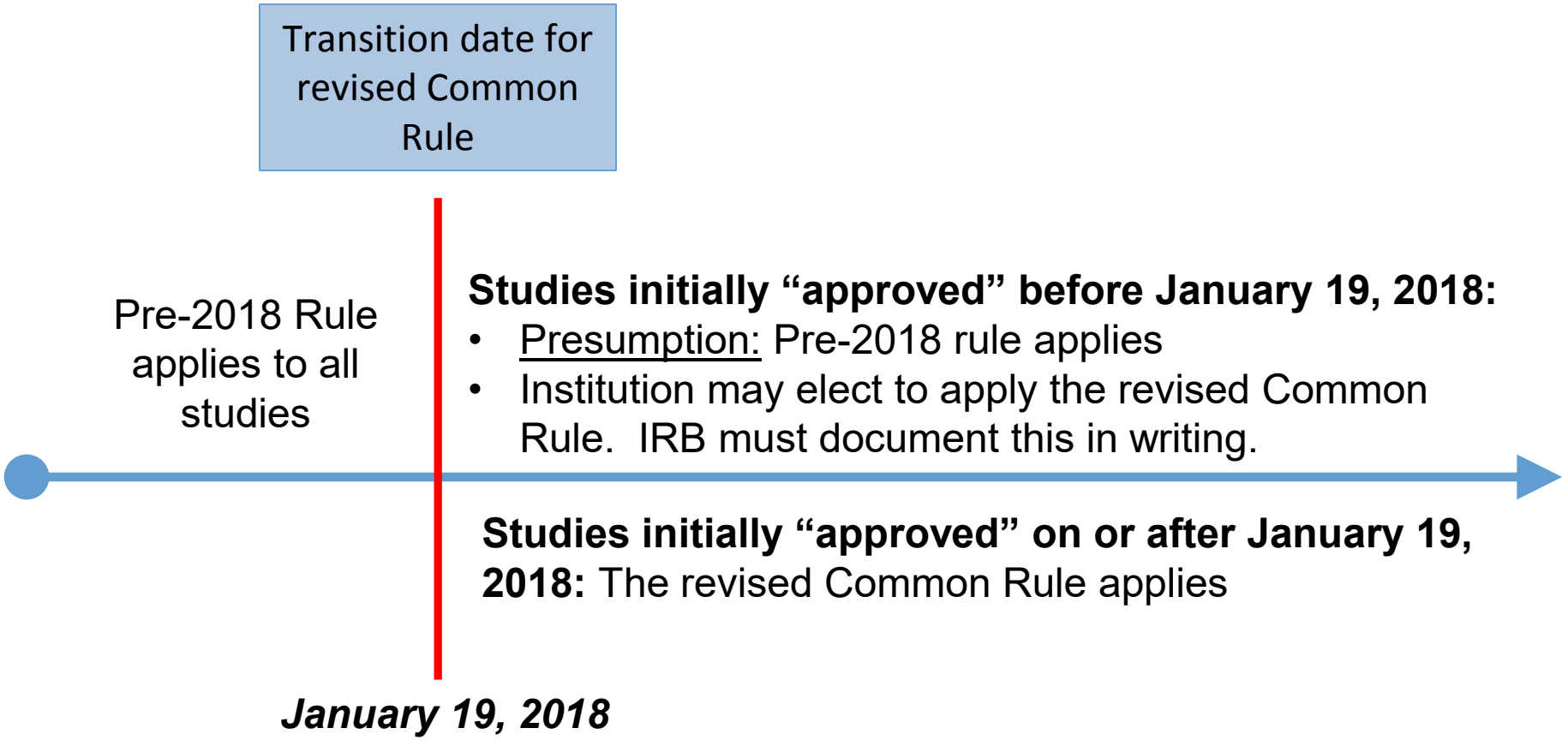
General Implementation of the Transition Provision



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

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

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

Summary of Key Changes

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Activities Deemed Not to be Research in the **Revised Common Rule**

- 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

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§__.102(l)

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)

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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)

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Summary of Changes to Exemptions

Pre-2018 Rule (Current)		Revised Common Rule
• Exemption 1	→	Restrictions added
• Exemption 2	→	Expanded
• Exemption 3	→	Removed and replaced with a new exemption 3
• Exemption 4	→	Expanded old and added new
• Exemption 5	→	Expanded with changes
• Exemption 6	→	No change
		*New Exemption 7
		*New Exemption 8
		*New - limited IRB review

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Changes to Informed Consent

- General Improvements to Informed Consent
- Broad Consent

Promoting Autonomy

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

General Improvements

- Some key changes related to the form and content of the consent:
  - Provide the information *a "reasonable person" would want to have to make an informed decision about whether to participate*
  - *Organize and present information to facilitate understanding of why one might or might not want to participate*
  - *Present key information first, focused on why one might or might not want to participate*. This would often include (though is not limited to) information about purposes, risks, benefits and alternatives.

New Elements of Informed Consent

Basic element:

- Notice about possible future use of data stripped of identifiers

Additional elements:

- Notice about possible commercial profit
- Notice about whether clinically relevant research results will be given to subjects
- Notice about whether research might include whole genome sequencing

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

- Form must be posted after recruitment closes, no later than 60 days after the last study visit
- Federal department or agency may permit or require redactions

§_.116(h)

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BROAD CONSENT FOR SECONDARY RESEARCH

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)

Broad Consent for Secondary Research

Broad consent:

- Applies to the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens
- Allows information and biospecimens to be stored and used for *unspecified future research* – in contrast with consent for a specific study
- Generally not allowed under pre-2018 rule
- Requires limited IRB review to be exempt (new exemptions)
- Serves a very different function than in the earlier proposal

§_.116(d)

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Continuing IRB Reviews: Eliminating Certain Requirements

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) & §__.115(a)(3)

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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)

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

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