THE OHIO STATE UNIVERSITY

Common Rule Changes

(And Other NIH Changes)

Office of Responsible Research Practices

Winter 2018

Session Objectives

- Provide overview of Common Rule revisions
- Discuss NIH definition of clinical trial
- Describe changes to NIH Certificate of Confidentiality policy

Major Common Rule Changes

1. Continuing Review
   - Annual Status Reports (ASR)
   - FDA regulated research ASR ineligible
2. Exemptions
3. Informed Consent
4. Single IRB (January 20, 2020)
   NIH Single IRB effective January 25, 2018

Impact for Existing Studies

Actions taken before the compliance dates are "grandfathered."

Ongoing research studies that were initially approved by an IRB, or determined to be exempt before 19 January 2018, will not be required to comply with the changes in the Final Rule, and may continue to completion or closure without change.

OHRP's Role

OHRP has regulatory authority for the Federal Policy for the Protection of Human Subjects at 45 CFR 46

- **Subpart A – The Common Rule**
- Subpart B – Pregnant women and fetuses
- Subpart C – Prisoners
- Subpart D – Children
- Subpart E – IRB Registration

Revised Common Rule published January 19, 2017
(general implementation date is currently January 19, 2018)

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Applying the Regulations: Revised Common Rule

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Question 1: Does the Activity Involve Research?

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

Revised Common Rule

- Citation moved from §46.102(d) to §_.102(l) in the revised rule
- **New:** four types of activities specifically deemed not to be research

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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

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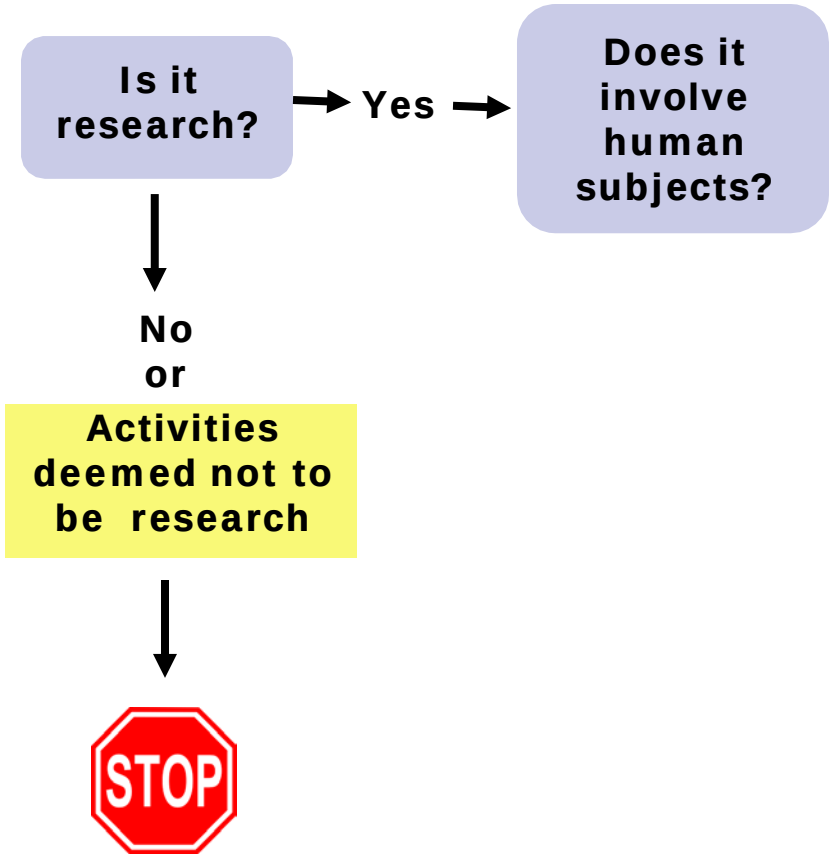
§_.102(l)

Applying the Revised Common Rule



Sections in yellow apply only to the revised Common Rule

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Question 2: Does the Research Involve Human Subjects?

No substantive change in the interpretation of human subject definition in the **Revised Common Rule**

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 bio-specimens**

§_.102(e)(1)

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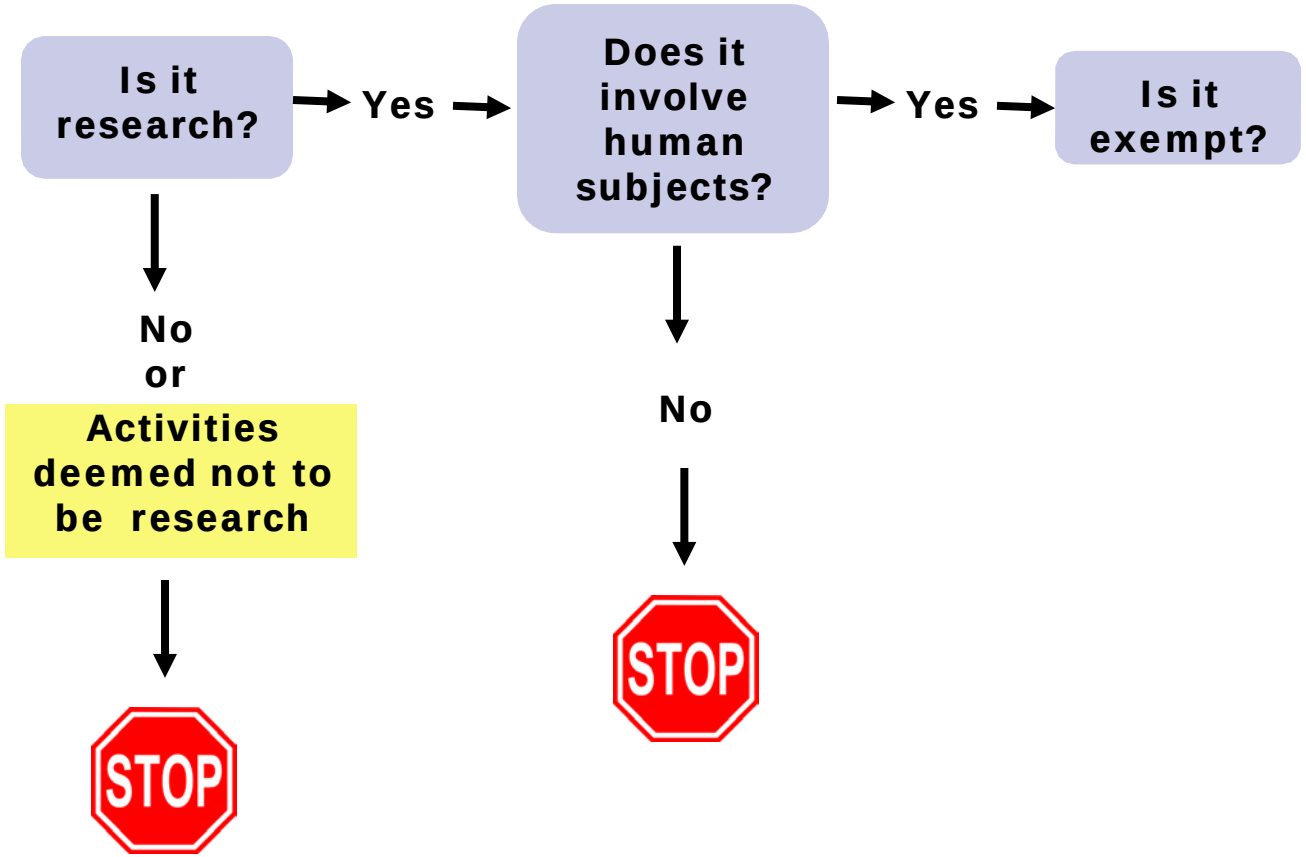

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Exemptions

Question 3: Is the Human Subjects Research Exempt?

Pre-2018 Rule

- 6 exemptions found under §46.101(b)(1)-(6)

Revised Common Rule

- 8 exemptions found under §_.104(d)(1)-(8)
- Exemptions 3, 7, and 8 – new
- Exemption 1, 2, 4, and 5 – modified
- Exemption 6 – no change

Summary of Changes to Exemptions

Pre-2018 Rule		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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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 when

- Information recorded cannot be readily linked back to subjects, **or**
- Any information disclosure would not place subjects at risk of certain harms (including to educational advancement), **or**
- Identifiable information recorded, and IRB conducts limited IRB review for privacy and confidentiality protection under §_.111(a)(7)

§_.104(d)(2)

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What Happened to Exemption 3?

Removed in revised Common 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 protection of 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.

Exemption 3: *New*

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 certain harms, **or**
- Identifiable information recorded, and IRB conducts limited IRB review for privacy and confidentiality protection under §_.111(a)(7)

§_.104(d)(3)

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Exemption 3 (cont.)

- 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)

Exemption 4: *Expanded*

NEW: materials no longer need to be "existing"

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

Secondary research use of identifiable private information or identifiable biospecimens for which consent is not required, 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 non-research purposes, and the information is protected by federal privacy standards

§_.104(d)(4)

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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)

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Exemption 6: *No Change*

Taste and food quality evaluation and consumer acceptance studies

§_.104(d)(6)

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Exemptions 7 and 8: *New*

Two new exemptions

- 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

Both require:

- Broad consent
- Limited IRB review

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

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No Waiver if Broad Consent Refused

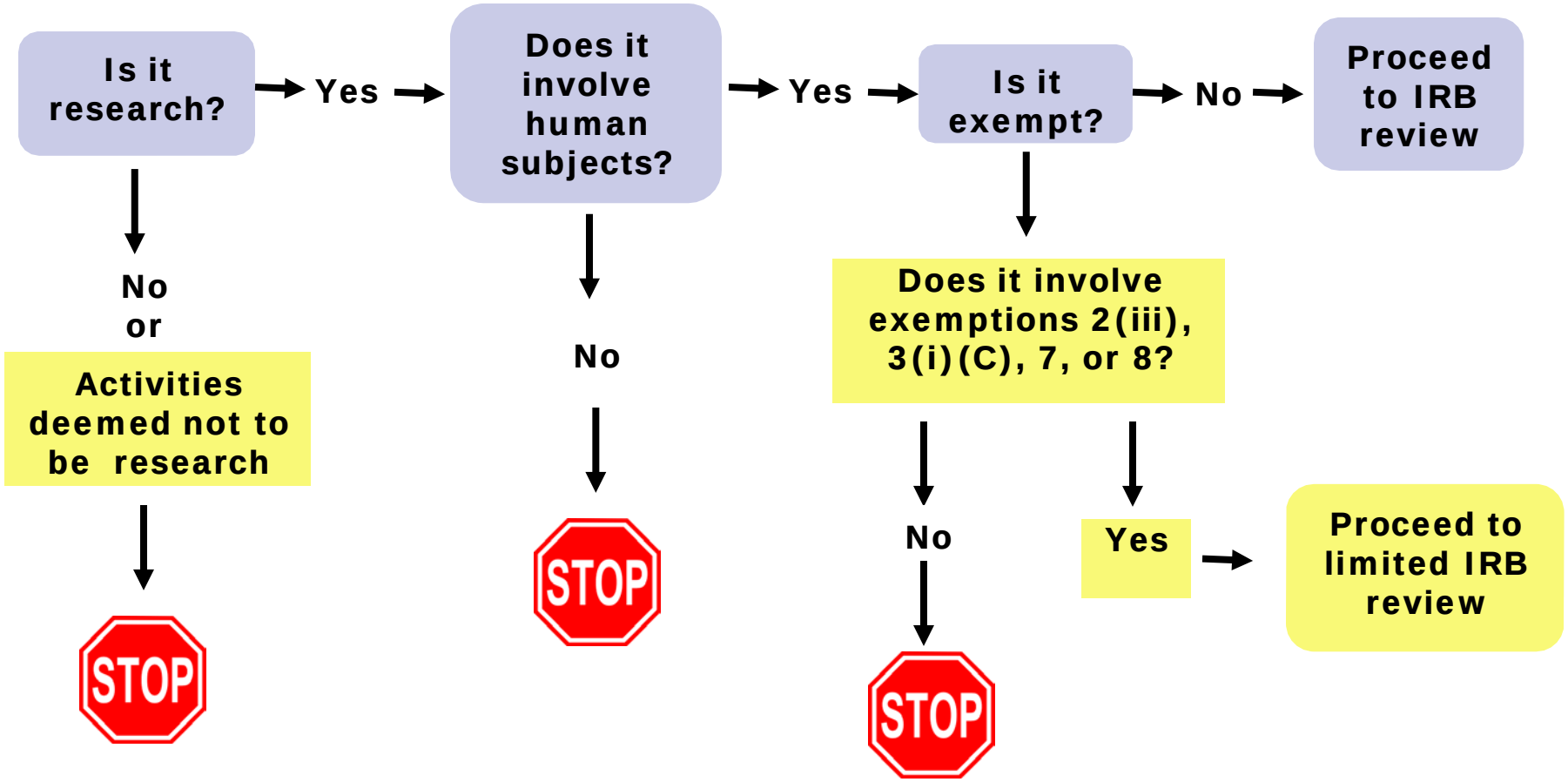
IRB cannot waive consent if individuals were asked, and refused, to provide broad consent to the storage, maintenance and use of identifiable private information or identifiable biospecimens

§_.116(f)(1)

Limited IRB Review

- Required for exemptions 2(iii), 3(i)(C), 7, and 8 in the revised Common Rule
- Expedited review can be used
- One time only, no continuing review required
  - **Exemptions 2(iii) and 3(i)(C)** review:
    - For privacy and confidentiality protection under §_.111(a)(7)
  - **Exemptions 7 and 8** review:
    - For other safeguards related to privacy and confidentiality protection, and broad consent

Applying the Revised Common Rule



Sections in yellow apply only to the revised Common Rule

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Continuing Review

Continuing Review

- Annual status report format
  - Expedited minimal risk studies (unless reviewer justifies conducting CR)
  - Data and/or specimen analysis only (old expedited category 8)
- Continuing review currently required for FDA regulated research

Informed Consent

Changes to Informed Consent

- General improvements to informed consent
- Broad Consent – PAUSE AT OHIO STATE
- Posting of consent form for clinical trials
- 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

§_.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)

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Basic Elements of Informed Consent

One new element:

Notice about possible future research use of information or bio-specimens stripped of identifiers:

- Notifying prospective subject that subjects' information or bio-specimens could be used for future research without additional consent; or
- Notifying prospective subject that subjects' information or bio-specimens 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 subjects will share in this profit (for research involving bio-specimens)
- Notice about whether research might include whole genome sequencing (for research involving bio-specimens)

§_.116(c)(7)-(9) 22

Broad Consent for Secondary Research

Clinical Trial (new term)

“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.

This definition is used for determining which studies require posting of the IRB-approved consent form

Posting 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 determined)

Post after recruitment closes, no later than 60 days after last study visit

Federal department or agency may permit or require redactions

§_.116(h)

Single IRB

Common Rule implementation date:
January 20, 2020

NIH Single IRB effective January 25, 2018

Please refer to the text of the revised Common Rule available on **OHRP's website (hhs.gov/ohrp)** for a complete and accurate description of the regulatory requirements

Questions About the Revised Common Rule?

- OHRP has developed resources about the Revised Common Rule at: www.hhs.gov/ohrp
- Submit your questions to OHRP@hhs.gov
- Stayed connected! Join the OHRP listserv at: https://www.hhs.gov/ohrp/news/sign-up-for-announcements/index.html

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Certificates of Confidentiality

Certificates of Confidentiality

- 21st Century Cures Act
- Policy effective October 1, 2017
- Applies to NIH-funded research that was active on December 13, 2016 or subsequently approved
- Automatically issued for studies collecting and/or using sensitive, **identifiable** information
- No “certificate” provided

Certificates of Confidentiality (cont.)

- Participant notification is **required**
- Studies with ongoing accrual will amend consent document to describe additional protection

QUESTIONS?

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