Changes to the UIS Human Research Protection Program

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Material adapted from the Office for Human Research Protections https://www.hhs.gov/ohrp/

Outline

1. Overview of changes at the federal level (handout)
2. How those changes affect IRB review
3. Changes to informed consent documents
4. EU GDPR
5. Q&A

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)

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Legend: New with 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 biospecimens**

§_.102(e)(1)

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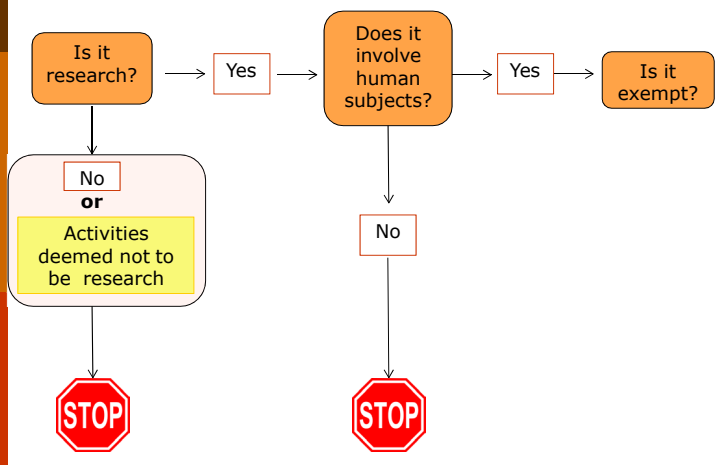

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Question 3: Is the Human Subjects Research Exempt?

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

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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 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 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.

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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)

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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**

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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

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§_.104(d)(7) and (8)

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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

UIS not adopting

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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)

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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

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Exemptions Applicability Subparts C & D

	Pre 2018 Rule (Current)	Revised Common Rule
Subpart C *Prisoners Research*	• **None apply**	• **Research expanded:** Exemptions do not apply **except** for research aimed at involving a broader subject population that only *incidentally* includes prisoners
Subpart D *Research with Children*	• **Exemption 2 does not apply** for research involving survey or interview procedures or observations of children by investigators who participate in the activity being observed • **Other exemptions apply**	• **Same restrictions** as before for exemption 2 • **Plus** new provision §_.104(d)(2)(iii) also not applicable (identifiable information obtained, and limited IRB review) • **New exemption 3 does not apply**

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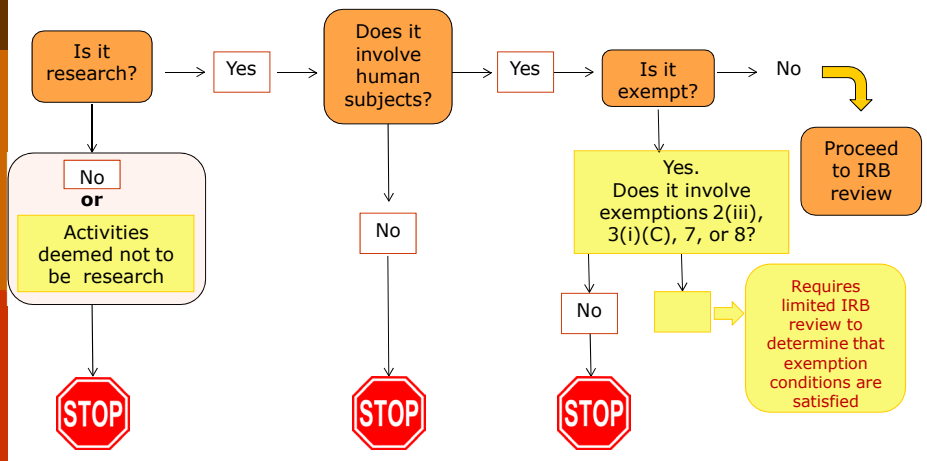

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Legend: New with the revised Common Rule

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Changes to Informed Consent Documentation

- Prioritize key information essential to decision making
  - Presented first in the consent discussion
  - Appearing at the beginning of the consent document
- Provide information that a *reasonable person* would want to have
  - Opportunity to discuss that information
- Electronic signatures allowed
- Added category for waiver of signature requirement
  - Cultural norms

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

Training materials on the new Common Rule available *for free* through UIS' subscription to CITI (www.citiprogram.org)

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Research involving residents of the EU

General Data Protection Regulation (GDPR)

- Applies to persons *residing in* the European Economic Area (EEA—comprised of the European Union (**"EU"**) and the countries of Iceland, Norway, and Lichtenstein)
- New consent document templates (draft)
- Decision trees for when to use

https://go.uillinois.edu/gdpr

Questions About Revisions to UIS policies and procedures?

www.uis.edu/research

- Submit your questions to ora@uis.edu

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