Office of the Vice President for Research at the university of georgia ®

Let's get familiar with the new Common Rule – Part 1

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Why make changes?

- Research landscape has changed
- Reduce burden for researchers
- Enhance protections for participants
- Let's face it – after 26 years, it needed to be updated

Revised Exemption Categories

Exempt 1: Restrictions Added

- Current Rule: Normal educational practices in established or commonly accepted educational settings.
- New Rule: Normal educational practices that are not likely to adversely impact:
  - Students' opportunity to learn required educational content, or
  - Assessment of educators who provide instruction

Revised Exemption Categories

Exempt 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.

Revised Exemption Categories

Exempt 3: New

Research involving benign behavioral interventions with collection of information – verbal or written (including data entry) or audiovisual recording – from adults who prospectively agree 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.

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What is a "benign behavioral intervention"?

- 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

Revised Exemption Categories

Exempt 4: Expanded

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 is recorded in an unidentifiable manner, or (note: no requirement that all data be existing at the time of submission)

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 information collected or generated by the government for nonresearch purposes, and the information is protected by federal privacy standards.

Revised Exemption Categories

Exempt 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

Revised Exemption Categories

Exempt 6: No Change

Taste and food quality evaluation and consumer acceptance studies.

Revised Exemption Categories

Exempt 7: New

Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research

Broad Consent, Limited IRB Review

Revised Exemption Categories

Exempt 8: New

Secondary research using identifiable private information or identifiable biospecimens

Criteria:

- Limited IRB review of whether the research falls under the broad consent
- Documentation or waiver of documentation of consent provisions has occurred
- Limited IRB review of the privacy and confidentiality safeguards
- The investigator does not include returning individual results to subjects as part of the study plan except when required by law.

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

The 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.

Limited IRB Review

- Required for exemptions 2, 3, 7, and 8
- Expedited review can be used
- One time only, no continuing review required
  - Exempt 2 and 3 review for privacy and confidentiality protection
  - Exempt 7 and 8 review for other safeguards related to privacy and confidentiality protection, and broad consent

You can find the text of the revised Common Rule on OHRP's website (hhs.gov/ohrp) for a complete and accurate description of the regulatory requirements.