

Common Rule Changes to Exempt Categories

Pre-2018 Rule

Revised Common Rule

Exempt Category 1



Restrictions added to exemption

Exempt Category 2



Existing exemption expanded

Exempt Category 3



Exemption removed and replaced with a new exempt category 3

Exempt Category 4



Existing exemption expanded and new added

Exempt Category 5



Existing exemption expanded with changes

Exempt Category 6



No Change

NEW!

New Exempt Category 7

New Exempt Category 8

New Limited IRB review

Common Rule Changes to Exempt Categories

Exemption 1:

Normal educational practices in established or commonly accepted educational settings

- What's new?
 - o Research must not adversely affect students' opportunity to learn required educational content or the assessment of educators who provide instruction

Exemption 2:

Research that includes ONLY educational tests, surveys, interviews and observations of public behavior

- What's new?
 - o If the research is collecting information that is identifiable or sensitive, limited IRB review is required
 - o Clarification that this exemption does not apply to interventions, collection of biospecimens or children (when obtaining and recording identifiable private information)
 - o Information recorded cannot be readily linked back to subjects

Exemption 3:

Research involving benign behavioral interventions

- What's new?
 - o THE WHOLE EXMEMPTION IS NEW!
 - o Limited to research involving adults who prospectively agree when information collected is limited to verbal or written responses, data entry, or audiovisual recording, AND
 - Information cannot readily be linked back to subjects, or
 - Disclosure of the information would not reasonably place subjects at risk of certain harms, or
 - Identifiable information is recorded and limited IRB review is conducted.
 - o Benign behavioral intervention defined as:
 - Brief in duration
 - Harmless and painless
 - Not physically invasive
 - Not likely to have a significant adverse lasting impact on subjects
 - No reason to think subjects will find it offensive or embarrassing
 - o Authorized deception allowed

Exemption 4:

Secondary research use of identifiable private information and identifiable biospecimens for which consent is not required if one of four categories is met

- What's new?

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- Allows for research on information or biospecimens that is not yet in existence when study is proposed
- Allows for secondary use of PHI

Exemption 5:

Research designed to study, evaluate, improve or otherwise examine public benefit or service programs

- What's new?
 - Expanded to apply to federally supported research, not just federally conducted research
 - Federal agencies must publish a list of research supported under this provision on a publicly accessible website prior to beginning the research

Exemption 6:

Taste and food quality evaluation

- What's new?
 - NOTHING! The Final Rule retains the exemption from the pre-2018 rule

Exemptions 7 and 8:

Two new exemptions related to identifiable data and biospecimens for future research

- What's new?
 - EVERYTHING!
 - Category 7: storage or maintenance of identifiable private information or identifiable biospecimens for secondary research
 - Category 8: secondary research use of identifiable private information or identifiable biospecimens
 - BOTH require broad consent and limited IRB review