

2018 Common Rule Changes to Exempt Research

Summary

The 2018 Common Rule includes an expansion of exemption categories for human subjects research, as well as revisions to existing categories. With these changes, a new **limited IRB review** process is now required for some exempt research to ensure adequate privacy and confidentiality safeguards are in place. This document provides a summary overview of the major changes to the 2018 Common Rule related to exempt human subjects research.

Please see the guidance documents – [Exempt Research-General Information](#) and [Exempt Research-Modifications](#) for additional information related to exempt research under the new 2018 Common Rule.

Exemption 1: Research in established or commonly accepted educational settings involving normal educational practices.

This category applies only to normal educational practices, meaning activities that occur in the educational setting for instructional purposes. Language has been revised to include an explicit condition that the research must not be likely to have adverse impacts on student learning or evaluation of educators.

Research must not be likely to adversely impact students' opportunity to learn required educational content

Exemption 2: Surveys and Interviews (with adults), Educational Tests, Observations of public behavior

The updated regulation allows for exemption of research with **adults** as long as one of the following criteria is met:

1. Information obtained is not identifiable (directly or indirectly)
2. Disclosure outside of the research would not put subjects at risk
3. If information is identifiable, the IRB has conducted a **Limited IRB Review*** process to ensure adequate privacy and confidentiality provisions are in place

*New process: Limited IRB Review

The 2018 Final Rule allows for research involving collection of identifiable information provided that the IRB has determined that there are “adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.” This new requirement is referred to as a “**Limited IRB Review.**”

Limitations for research *with children* under Exemption 2:

1. Surveys and interviews with children are not eligible for exemption under this category.
 2. Observation of public behavior of children may be granted exemption only if the investigator(s) do not participate in the activities being observed.
 3. Research involving educational testing with children may not be granted exemption if information is sensitive and identifiers are collected with responses.
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Exemption 3: Research involving Benign Behavioral Interventions with Adults

This is a **new category** of exempt research. This exemption allows for research involving *benign behavioral interventions* in conjunction with the collection of information from an adult subject via written or verbal response or audiovisual recording, if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

1. Information obtained is not identifiable - directly or indirectly
2. Disclosure outside of the research would not put subjects at risk
3. If information is identifiable, the IRB has conducted a **Limited IRB Review** process to ensure adequate privacy and confidentiality provisions are in place

The research may involve minor deception (e.g., withholding the purpose or nature of the study) if the subjects prospectively agree, via informed consent, that they may be unaware of or misled regarding the nature of purpose of the study. \The deception cannot involve misleading subjects about anything that may cause distress or be upsetting, and the information cannot be likely to impact willingness to participate. Additionally, the deception cannot preclude disclosure of risks or discomforts or the voluntary nature of participation.

Benign Behavioral Interventions:

- Brief in duration,
- Harmless and painless,
- Not physically invasive,
- Not likely to have a significant adverse lasting impact on the subjects,
- The investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

Exemption 4: Secondary use of information or biospecimens

The 2018 Common Rule clarifies the exemption category related to secondary use of data. This exemption applies if at least one of the following is met:

1. Identifiable private information of biospecimens are publicly available
2. Information is recorded in such a way that the identity of subjects cannot be readily ascertained and the investigator will neither contact nor re-identify subjects
3. Use of identifiable health information when that use is regulated by HIPAA regulations (45 CFR 160 and 164) for “health care operations,” “research,” or “public health activities and purposes” as defined in the HIPAA regulations.
4. Conducted by a government agency using government data obtained for non-research purposes and adheres to federal privacy standards.

Note:

Data is no longer required to be *existing* prior to the research study to be eligible for exemption under the new 2018 Common Rule regulations.

Exemption 5: Federal research and demonstration projects

Exemption 5 covers a *limited scope* of federally funded or supported research designed to study, evaluate, improve, or otherwise examine public benefit or service programs.

The 2018 regulations have been expanded to allow this exemption when this research is *funded by a federal agency* (not just conducted by). The scope is also expanded to include research with a focus on improving these programs (not just evaluating/examining). Additionally the new regulations include examples of the types of public benefit and service programs included in the exemption.

The federal agency that conducts or supports this research must identify and list the research and demonstration projects conducted under Exemption 5 on a publicly accessible website. Each project must be published on this list before human subjects research activities begin.

Exemption 6: Taste and food quality evaluation and consumer acceptance studies

No changes were made to this category which applies to taste tests of foods that contain ingredients at or below the level and for a use found to be safe by the FDA. The exemption does not apply to research involving investigational products or research intended to support applications to the FDA for marketing of a food additive, alcohol consumption, vitamins or dietary supplements.

Exemption 7 and 8: Broad consent

At this time, exemptions 7 and 8 will not be implemented at Iowa State University. These exemptions involve the implementation of a new type of consent process called “broad consent.” Use of broad consent requires permanent, errorless record keeping regarding each individual participant’s decision of how their data may be used. Broad consent cannot be waived and each individuals’ decision must be permanently honored by the initial investigators as well as all future users of the data. No federal guidance on implementation expectations and practices is available as such the ISU IRB has not been able to assess the feasibility of implementing these exemptions.

Research with Prisoners

Revisions to the 2018 Common Rule now allow for the inclusion of prisoner subjects in exempt studies when the research examines a broader subject population and only incidentally includes prisoners.

Please see the guidance document [Research Involving Prisoners](#) for additional information related to conducting research with subjects who are prisoners.

Document History

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