

Exempt Review of Research

Exempt research is human participant research of minimal risk where the entire research project falls within one or more of the specific regulatory categories. The revised Common Rule revised and expanded the categories for exempt research. New categories were added and two new processes were introduced: limited IRB review and broad consent. Below is a summary of the changes to each of the exempt categories from 46.104(d).

It is important to note that “exempt” does not always mean exempt from all of the requirements of the Common Rule.

Category 1: Research in Established or Commonly Accepted Educational Settings

This category has been amended from the pre-2018 rule to include a condition that the research is not likely to have adverse impacts on students learning required educational content or assessment of educators who provide instruction. The exemption may only be used for studies about normal educational practice.

Category 2: Educational Tests, Surveys, Interviews, Observations of Public Behavior

During the time of the pre-2018 rule, this was the category most used by researchers in the social and behavioral sciences. Under the pre-2018 rule, research in this category may be exempt if the identity of the subjects could not be readily ascertained either directly or indirectly and if the disclosure of identifiable data would not cause harm.

The new regulation allows for exemption as long as one of the three criteria is met:

1. Information obtained is not identifiable
2. Disclosure outside of the research would not put subjects at risk of harm
3. Information obtained can be identifiable but the IRB has done a limited IRB review in keeping with 46.111(a)(7), which relates to there being adequate provisions for protecting privacy and maintaining confidentiality.

Importantly, the revised Common Rule eliminated the “and” – instead there is an “or.” That is, research could be exempt that is any of the following:

1. Not identifiable
2. Does not pose any risk if there is disclosure (regardless if identifiable or not)
3. Does not pose any risk if there is limited IRB review in keeping with the 46.111(a)(7) criteria

Also, the Final Rule revised this category to include visual and auditory recording as research methods. Surveys also cannot include collection of biospecimens or interventions, as those additional activities would disqualify the research from this category.

When the research is subject to Subpart D and includes children, Category 2 still does not allow surveys or interviews or the observer participating with children (public behavior observation without intervention is permitted).

Category 3: Benign Behavioral Interventions in Conjunction with the Collection of Information From Adult Subjects

This is a new category. Benign behavioral interventions are defined as “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 intervention offensive or embarrassing.”

Research using deception is not eligible for exemption in this category unless the subjects prospectively agree that they will be unaware of or misled regarding the nature and purpose of the research.

As with research in Category 1, exemption is permitted if the data are recorded in such a way that the identities of the subjects cannot be readily ascertained either directly or indirectly or if the identities can be ascertained, a disclosure of the subjects’ responses outside the research setting would not reasonably place the subjects at risk of harm. Alternatively, if the subjects’ identities can readily be ascertained and if a disclosure of subjects’ responses has potential to harm subjects, the exemption is permitted if the IRB conducts a limited review and determines that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of the data.

Important Notes about Category 3:

- Deception is allowed if certain criteria are met
- This exemption is only for benign behavioral research with adults, and is not applicable to children

Category 4: Secondary Research for Which Consent is Not Required

This category covers secondary research uses of identifiable private information or identifiable biospecimens. The Final Rule revised and clarified the pre-2018 rule category for the use of secondary use of data. Category 4 does not require informed consent if at least one of the criteria listed below is met.

There are four available options for use of the exemption:

1. Use of publicly available identifiable private information or identifiable biospecimens.
2. Information recorded by the investigator in such a way that the identity of the subjects cannot be readily ascertained, and the investigator will neither contact the subjects nor re-identify subjects.
3. Research use of identifiable health information when that use is regulated by HIPAA as health care operations, research, or public health activities and purposes as those terms are defined in HIPAA.
4. Analysis of data on behalf of a federal agency or department – as opposed to an investigator-initiated analysis of federally supplied data – if the requirements of certain federal laws are met.

It is important to note that data do not need to be existing (“on the shelf”) at the time of the research study, as was previously required by the pre-2018 rule. The data can be collected prospectively and still be used for exempt research under Category 4 in the Final Rule.

Category 5: Research and Demonstration Projects that Are Conducted or Supported by a Federal Department or Agency

This category has been revised to: allow research supported by a federal agency (not just conducted) to qualify for this exemption; provide examples of the types of public benefit and service programs covered by the exemption; and clarify the federal components for which the exempt research is subject to approval (for example, delegated subordinate agencies).

Category 6: Taste and Food Quality Evaluation and Consumer Acceptance Studies

This is the only unchanged category.

If wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.