Exempt Research Under the Revised Common Rule

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Session Objectives

• Explain why changes were made to the Common Rule
• Detail exempt research revisions
• Provide submission tips
What is the Common Rule?

- Federal Policy for the Protection of Human Subjects
- Published in 1991
- Influenced by the Belmont Report
- 15 participating agencies
- HHS regulations, 45 CFR 46
Why Were Revisions Made?

• To modernize, simplify, and enhance the current system of oversight
• To better protect human subjects while:
  o Facilitating research
  o Allowing more flexibility
  o Reducing burden, delay, and ambiguity for investigators involved in low-risk research
Exempt Changes

• Several categories have been revised
• Addition of a new category
• Addition of “limited IRB review”
• Significantly impacts how certain types of very minimal risk research is reviewed

* Two new exempt categories (7 and 8) that include Broad Consent are not being implemented at Ohio State
Who can make exempt determinations?

- Pre-2018 Rule does not dictate who should make exempt determinations
- No change in the Final Rule
  - Institutions can implement their own polices
  - OHRP advises that investigators not make their own determinations
  - At Ohio State, ORRP staff will continue to make exempt determinations
Exempt Categories

Revised Common Rule
Exempt Category #1

Research conducted in an established educational setting, that involves no changes to the curriculum for the purposes of the research

- Research on regular instructional strategies that will not impact the students ability to learn
- Research that compares instructional techniques, curricula, or classroom management methods
Exempt Category #1 Examples

• Researchers want to analyze student coursework and grades from two introductory chemistry course sections; one using a standard classroom teaching method and the other where classes are held online

• A researcher wants to conduct an end of semester student survey to evaluate the effectiveness of a new curriculum implemented by the college
Exempt Category #1 Submission Tips

• Researchers can only conduct research on their own classroom (i.e., be in a position of authority) if the identity of participants will not be known until after grades are posted.
• No changes can be made to the curriculum for research purposes.
Exempt Category #2

Research involving the use of standard educational tests, surveys (online or in-person), interviews, or observation of public behavior. To qualify, one of the following must be met:

- All data collected will be anonymous,
- If subjects can be identified, the research would not reasonably place them at any risk (such as legal, reputation, employability, etc.), or
- If there is risk to identifiable participants, the IRB has conducted “limited IRB review” to ensure privacy and confidentiality are protected.
Category #2

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) uninfluenced by the investigator and at least one of the specific criteria is met. If choosing this category, also select at least one sub-option (these will appear once the category is selected).

(Note: The exemption under Category 2 DOES NOT APPLY to research involving survey or interview procedures or observation of public behavior when individuals under the age of 18 are subjects of the activity except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.)

Apply for category #2

Category 2 type

- a) The information obtained is not identifiable (i.e., no direct or indirect identifiers)
- b) Disclosure outside of the research would not reasonably place the subjects at risk of harm (e.g., legal, financial, reputational, employability)
- c) The information obtained is identifiable but there are adequate protections in place for protecting privacy and maintaining confidentiality
New – Limited IRB Review

- Pre-2018 Rule required IRB review for survey/interview studies that included any potential risks to participants
- The addition of “limited IRB review” allows an IRB member to determine studies with some level of risk to be exempt if researchers adequately address participant privacy and confidentiality safeguards.
- The confidential page will be expanded to request additional information.
Confidentiality of Data

All fields marked with an * are required.

Methods for handling and storing data (including the use of personal computers and portable storage devices) must comply with university policies. Restricted data, including protected health information, must be encrypted if stored or used on portable devices, if removed from a secure university location, or if electronically transmitted. For more information, see Policy on Institutional Data and Research Data Policy.

Explain how information is handled, including storage, security measures (as necessary), and who will have access to the information. Include both electronic and hard copy records.*

Explain if any personal or sensitive information that could be potentially damaging to participants (e.g., relating to illegal behaviors, alcohol or drug use, sexual attitudes, mental health, etc.) will be collected.*

☑ Not Applicable

Explain any circumstances (ethical or legal) where it would be necessary to break confidentiality.*

☐ Not Applicable
Primary research data should be retained for a minimum of five years after final project closeout. For more information, see the university's Research Data Policy. Other research-related records should be retained for a period of at least three years after the research has been discontinued (i.e., no further data collection, long term follow-up, re-contact, or analysis of identifiable/coded data.)

Indicate what will happen to identifiable data at the end of the study*

- [ ] Identifiable data will not be collected
- [x] Identifiers will be permanently removed from the data and destroyed (resulting in de-identified data)
- [ ] Identifiable/coded(linked) data will be retained and stored confidentially (as appropriate)
- [ ] Identifiable data will be retained and may be made public with participant consent (e.g., ethnographic research)
Exempt Category #2 Examples

- An online anonymous survey concerning the media’s impact on voting
- An interview to determine the criteria that individuals use when selecting a healthcare provider
- An online survey to uncover the circumstances in which employees would justify lying to their employers (limited IRB review)
Exempt Category #2 Submission Tips

- Children are excluded from interactions
- Consider demographic data being collected
- Risks are relative to the location and culture
- If interviews will be open-ended, submit baseline questions
- Consider privacy/confidentiality risks during all research phases (recruitment, data collection, and analysis)
Exempt Category #3 (pre-2018 Rule)

Research involving surveys or interviews with publicly elected officials regarding subjects related to their position

* This category has been removed (as it fits the criteria for exempt category #2). Instead a new exempt category has been created.
Exempt Category #3

Research involving “benign behavioral interventions”

• Brief in duration,
• Harmless, painless, and non-invasive,
• Not likely to have a significant adverse lasting impact, and
• The investigator has no reason to think that the participants will find the interventions offensive or embarrassing.
Exempt Category #3 (cont.)

The data collected must:
• Be anonymous, or
• If potentially identifiable, the research would not reasonably place participants at risk (i.e., legal, reputation, employability), or
• If there is risk to participants, the IRB has conducted “limited IRB review” to ensure privacy and confidentiality are protected.
Exempt Category #3 Examples

- Researchers conduct an economic experiment in which participants complete an online auction to determine bids based upon the aggressiveness of other bidders.
- After completing a pre-test, participants are exposed to campaign commercials for 30 minutes and then complete a post-test to determine the effect viewing the campaign ads had on participant voting.
Exempt Category #3 Submission Tips

New: Deception is allowed if the participant prospectively agrees that the true purpose of the study will not be revealed until the end of the experiment.

For studies using deception (via prospective agreement) the following statement must be included:

• “You will not be fully informed about the nature of the study before your participation.”

If a debriefing script will be used, also add:

• “After the study, you will receive more information and have the option to withdraw from the study if you so choose.”
Exempt Category #4

Secondary research of identifiable information or bio-specimens when consent is not required and at least one of the following criteria is met:

• The information/bio-specimens are publicly available;
• Researchers will not record any information that would make participants identifiable, and will not contact or re-identify participants;
• Information is identifiable, but regulated by HIPAA; or
• The research is conducted on behalf of a federal department or agency and the study involves the use of federally generated non-research information.
Category #4

Secondary research for which consent is not required. Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the specific criteria is met. If choosing this category, also select at least one sub-option (these will appear once the category is selected).

For purposes of HRPP policy, health information is de-identified when it does not contain any of the [18 identifiers] (which include dates more specific than year and zip codes) specified by the HIPAA Privacy Rule at 45 CFR Part 164, or when it has been determined to be de-identified by a statistician in accordance with the standards established by the Privacy Rule. There must be at least 25 individuals/specimens that meet study inclusion criteria in order to be determined potentially able to be de-identified. It is important to note that data do not need to be existing ("on the shelf") at the time of the research study.

Apply for category #4

Category 4 type

- a) The identifiable private information or identifiable biospecimens are publicly available

- b) The Information, which may include information about biospecimens, is recorded by the investigator in such a way that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, and the investigator does not contact the subjects or try to re-identify subjects

- c) The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated by HIPAA as health care operations, research, or for public health activities and purposes as defined in HIPAA

- d) The research is conducted by, or on behalf of, a federal department or agency and involves the use of federally generated non-research information, provided that the original collection was subject to specific federal privacy protections and continues to be protected
Exempt Category #4 Examples

• Researchers will access patient medical records collected between January 2000 and December 2018 to examine the number of cases within the emergency room that required an outside consult. None of the 18 HIPAA identifiers will be collected.

• Same study; however, MRN and dates of service will also be collected (formerly required IRB review).
Exempt Category #4 Submission Tips

• For the data to be considered de-identified, a minimum of 25 participants must meet the inclusion criteria.
• To access previously collected identifiable data, it must be from a HIPAA-regulated source.
• Prospective data collection of secondary use data still requires IRB review.
Exempt Category #5

• Evaluation research on public benefit and service programs, and
• Research and demonstration projects that are conducted or supported by a Federal department or agency

* Each Federal department or agency must establish a publicly accessible federal website to publish a list of these projects prior to beginning the research
Exempt Category #6 (no changes)

Taste and food quality evaluation and consumer acceptance studies if wholesome foods without additives are consumed or the food contains ingredients at or below the level and for a use found to be safe by the Food and Drug Administration
Exempt Category #6 Examples

• Researchers conduct a taste test with potential consumers sampling potato chips fried in different types of oils
• Researchers conduct a taste test of a new FDA-approved sugar substitute in coffee
Exempt vs IRB Review

- Note: there are no procedures for submitting amendments to exempt applications.
- Changes to existing exempt research requires a new submission, whereas amendments can be submitted for IRB applications.
Summary Overview

• Final Rule contains extensive exempt changes
• Final Rule affects majority of social and behavioral sciences research
• Majority of previous expedited category # 5 projects will now be exempt from IRB review
• Please send questions via e-mail to: Exemptinfo@osu.edu
Resources

Common Rule Revisions:
http://orrp.osu.edu/irb/common-rule-revisions/

OHRP Website:

ORRP Office Hours:
http://orrp.osu.edu/irb/investigator-guidance/studentassist/