FINDING YOUR FIT:
Navigating the New IRB Exemption Categories

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Summary of Changes

1. Educational practices  
   Restrictions added

2. Educational tests, surveys, interviews, observation of public behavior  
   Expanded*

3. Research on public officials  
   Removed and replaced*

4. Research on existing data  
   Expanded with changes

5. Research on public benefits  
   Expanded with changes

6. Taste and food evaluations  
   No changes

7. New exemption  
   MSU not using (Broad Consent)

8. New exemption  
   MSU not using (Broad Consent)

*Limited IRB Review may be required
Exemption 1: Restrictions Added

■ Research in established or commonly accepted educational settings
  – *E.g.*, classrooms, after-school programs, or online education

■ Involving normal educational practices
  – *E.g.*, research on instructional techniques, or classroom management

■ **NEW RESTRICTION:** the research must not be likely to adversely impact:
  – Students’ opportunity to learn required educational content, or
  – The assessment of educators who provide instruction
Exemption 1: Example

A research study testing an instructional technique to teach algebraic equations that takes significant additional classroom hours away from other required topics.
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A research study testing an instructional technique to teach algebra equations that takes significant additional classroom hours away from other required topics.

- Research in an established educational setting?
  - Check The classroom

- Involving normal educational practices?
  - Check An instructional technique

- Likely to adversely impact students’ opportunity to learn required educational content?
  - X Research takes significant classroom time away from other math topics and may negatively affect students’ scores
Remember

It doesn’t mean that the research cannot be done. It only means that it would not qualify for this exemption and would need another level of review.
Exemption 2: Language Clarification

Research that includes only interactions involving educational tests, surveys, interviews, and/or observations of public behavior.

- Clarifies OHRP’s position under the old Common Rule:
  - Exemption 2 applies only to research involving interactions of the types listed
  - Exemption 2 is not applicable to research involving interventions
  - Much social, behavioral, and educational research that includes interventions will now be exempt under the new exempt category 3 (to be discussed shortly)
Exemption 2: Expanded

Research that only includes interactions involving educational tests, surveys, interviews, and/or observations of public behavior if the information is:

i. Recorded in non-identifiable manner (i.e., cannot be readily linked back to subjects), OR

ii. Not sensitive (i.e., low risk of harm if disclosed), OR

iii. **NEW**: Identifiable information (that might be sensitive) with Limited IRB review of privacy and confidentiality protections
What is Limited IRB Review?

- Limited to the appropriateness of privacy and confidentiality protections
  - Use of the information
  - Extent of sharing
  - Retention period
  - Security controls
  - Potential risk should information be lost

- This can be done employing the expedited review mechanism and does not require continuing review
Exemption 2: Example

Subjects are asked to answer an anonymous questionnaire about cocaine use.
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✓ Research consists only of survey procedures (interaction), and

✓ Information is recorded anonymously (regardless of the sensitivity of the topic)
Exemption 2: Example (cont’d)

Subjects are asked to answer an anonymous questionnaire about cocaine use.

In addition, subjects are asked to attend a brief substance abuse training and then answer an anonymous questionnaire to determine if the training affected the subjects’ perception of the issues.

- Now there is an intervention (attending the training) aiming to alter the subjects’ opinions/perceptions/environment

* May qualify for new exemption 3 for benign behavioral interventions (to be discussed shortly)
Exemption 2: Example

A study interviews rape victims and their ER physicians to rate their interactions with one another. The data is recorded in an identifiable manner.
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A study interviews rape victims and their ER physicians to rate their interactions with one another. The data is recorded in an identifiable manner.

X Old rule: exemption 2 does not apply: Data is recorded in an identifiable manner and is sensitive

✓ New rule: exemption 2 may apply, but only after a Limited IRB review of privacy and confidentiality protections
Old Exemption 3: Removed

- Became superfluous after clarifications and changes in the new Common Rule
  - Exemption 3 was often erroneously applied to activities that do not meet the regulatory definition of research
Old Exemption 3: Example

A journalist investigates how the policies of the town’s mayor have contributed to the opioid crisis in the town.
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A journalist investigates how the policies of the town’s mayor have contributed to the opioid crisis in the town.

- **This activity focuses directly and exclusively on the one individual about whom information is collected and does not contribute to generalizable knowledge**

- **The new Common Rule explicitly clarifies that historical and journalistic activities that focus on one person do not meet the regulatory definition of “research”**

- **Public Officials are accountable to journalistic inquiries without the protections that the Common Rule provides for research subjects**
Old Exemption 3: Removed (cont’d)

- Became superfluous after clarifications and changes in the new Common Rule
  - *Old Exemption 3 applied to research that was not covered by Exemption 2 if subjects were elected or appointed officials or there was a Federal statute protecting confidentiality*
  - *Usually not covered under old Exemption 2 because they collected both sensitive and identifiable information*
  - *Now that Exemption 2 has been expanded to include both sensitive and identifiable information after Limited IRB review there is virtually nothing left for the old Exemption 3 to cover*
Old Exemption 3: Example

A series of interviews with elected officials seek to determine whether political scandals increase their personal net worth.
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A series of interviews with elected officials seek to determine whether political scandals increase their personal net worth.

- Study meets the definition of “research” because it seeks to produce generalizable knowledge about all elected officials
  - If data recorded in non-identifiable manner → Exemption 2 applies
  - If data collected is not sensitive → Exemption 2 applies
  - If data is identifiable and sensitive → Exemption 2 applies after Limited IRB review

* Public officials that are human subjects in research are afforded the same protections as any other subjects
Exemption 3: Replaced

Research involving benign behavioral interventions with adults who prospectively agree when information collected is limited to verbal or written responses (including data entry) or audiovisual recording, and:

i. Information recorded cannot be readily linked back to the subjects, OR

ii. Not sensitive (i.e., low risk of harm if disclosed), OR

iii. Identifiable and sensitive information with Limited IRB Review for privacy and confidentiality protections
Why Benign Behavioral Interventions?

- Full IRB review is likely to add little additional protection to subjects
  - Autonomy should continue to be protected, thus the requirement for prospective agreement (to be discussed shortly)

- Expands the number of social, behavioral, and educational research that can be exempted under the revised Common Rule
  - Interventional research can now be exempt under new Exemption 3, if it meets the requirements
  - Facilitates the conduct of low-risk research and reduces workload
Exemption 3: Replaced

- Same requirements as Exemption 2 (not identifiable, not sensitive, or Limited IRB review)

- Additional requirements:
  - Behavioral interventions only; not applicable to biomedical research
  - In adults; not applicable to research with children
  - Must be benign in nature
    - Brief in duration
    - Harmless, painless, and not physically invasive
    - Not likely to have a significant adverse lasting impact on the subjects
    - No reason to think the subjects will find the interventions offensive or embarrassing
Exemption 3: Replaced (cont’d)

- Adult subjects must prospectively agree to the benign behavioral intervention
  - Prospective agreement must be meaningful and not coerced
  - This is NOT the same as the regulatory requirements for informed consent and documentation of consent

- Includes authorized deception
  - Subjects are informed that they will be deceived about some aspects of the research, and they prospectively agree to the deception
Exemption 3: Example

Investigators ask adult subjects to be interviewed after watching a 30-minute video about clinical trials to determine if it influences their feelings about clinical research.
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- Adults
- Prospective agreement
- The intervention (i.e., watching the video) is brief (i.e., 30 minutes)
- Watching the video is harmless, painless, and not physically invasive
- Watching the video is not likely to have a significant adverse lasting impact on the subjects
- There is no reason to think that subjects will find watching a video about clinical trials particularly offensive or embarrassing
Exemption 3: Example (cont’d)

Investigators ask adult subjects to be interviewed after watching a 30-minute video about clinical trials to determine if it influences their feelings about clinical research.

If subjects are further interviewed weekly for the next 3 months...

✓ Exemption 3 still applies because the intervention (i.e., watching the video) remains brief in duration
Exemption 3: Example

Adult subjects are interviewed after watching a political campaign video to determine if gender affects their opinion. They are told that they will be informed about the purpose of the interview after they finish. Subjects agree to participate.
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✔ Subjects are aware that they do not have all the information about the study and have agreed to participate (assuming all other requirements are met)

What if the subjects are not informed that they are being video taped to analyze their facial expressions?

✗ Does not qualify for Exemption 3 – this is not authorized deception

* It doesn’t mean that the research cannot be done – only that it would not qualify for this exemption
Exemption 4: Expanded with Changes

Secondary research use of identifiable private information or identifiable biospecimens, and:

**NEW:** Materials no longer need to be “existing”

i. Identifiable materials are publicly available, OR

ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subject cannot be readily ascertained directly or through identifiers linked to the subjects, and the investigator does not contact the subjects or re-identify subjects, OR

iii. EXPANDED: Investigator’s use is regulated under HIPAA as “health care operations,” “research,” or “public health,” OR

iv. EXPANDED: Research is conducted by, or on behalf or, a Federal agency using data collected or generated by the government for nonresearch purposes, and the information is protected by federal privacy standards.
What is Secondary Research?

Research use of information or biospecimens originally collected for:

- *Non-research purposes* (e.g., blood left over from routine clinical tests, general information collected for census purpose), OR

- *Research studies other than the proposed one* (e.g., researchers obtain blood samples left over from a study evaluating a new diabetes drug to conduct a new study on genetic predisposition of diabetic patients to Alzheimer’s disease)
What is NOT Secondary Research?

When investigators interact or intervene with living individuals to obtain their data or biospecimens *specifically for the proposed research*
What is Identifiability?

No change in the definition of identifiability:

 [...]information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information or biospecimens [...]

What about Secondary Research with Nonidentifiable Materials?

Secondary research use of nonidentifiable private information or nonidentifiable biospecimens:
- *Does not involve human subjects, and therefore, does not meet the regulatory definition of “research”*

Secondary research use of coded private information or coded biospecimens, and:
- *Not collected specifically for the research in question, AND*
- *Investigator(s) cannot readily ascertain identity of the individual(s), then*
- *Does not involve human subjects, and therefore, does not meet the regulatory definition of “research”*
Exemption 4: Example

The Graduate School conducts a student satisfaction survey each year. The survey contains basic demographics, including some identifiable information and 5 questions on general satisfaction. A student will be given access to the surveys and record responses to the 5 satisfaction questions for her research.
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X Materials are existing

X Publicly available

✓ Data is recorded in a nonidentifiable manner and the investigator will not attempt to re-identify or contact the research subjects
Exemption 5: Expanded with Changes

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

- Old Common Rule: Research had to be *conducted* by a Federal agency to qualify for the exemption

- New Common Rule: **EXPANDED:** Applies also to research that is *funded* by a Federal agency (e.g., through a grant)

- New Common Rule: **NEW:** Federal agency conducting or sponsoring the research must publish a list of projects covered by this exemption
Exemption 5: Example

The Centers for Medicare and Medicaid Services (CMS) funds through a grant for MSU to evaluate a CMS program that reimburses beneficiaries for nursing care at home.
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X Old rule: exemption 5 would not apply

✓ New rule: exemption 5 would apply because research is funded by a federal agency
Research Involving Prisoners
Research Involving Prisoners

- Old Common Rule: no exemption applies to prisoners
- New Common Rule: exemptions generally do not apply to research involving prisoners as subjects unless the research is aimed at involved a broader subject population that only incidentally includes prisoners
  - *If some subjects become prisoners, the study would not lose its exempt status*
Research Involving Children
Research Involving Children

- Exemption 2 did not apply under the Old Common Rule and these restrictions remain in place. Additionally, the new provision for research that collects sensitive and identifiable information with Limited IRB review is **NOT** applicable to research with children.

- Exemption 3 for benign behavioral interventions is **NOT** applicable to research with children.

- Other exemptions continue to apply.
Questions?

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