

IRBMED Seminar Series

Exemption Categories and Continuing Review

April 4, 2017

Spring Installment

INTRODUCTION

- Revision to 4 of the 6 current categories
- Retention of 1 current category with no change
- Deletion of 1 current category

- Addition of 3 new categories

- Two review standards for exempt research
 - Exempt determination
 - “Limited IRB Review”

- Clarification regarding application of exemptions to research involving vulnerable subjects

- Continuing review of research

INTRODUCTION:

NOTE: This presentation does not address requirements for FDA regulated research or HIPAA requirements

These changes are NOT currently in effect.

EXEMPTION ONE:

Education

Research, conducted in established or commonly accepted educational settings, **that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.** This includes most research on regular or special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

EXEMPTION ONE: Education

The additional text clarifies that to be exempt, the study is:

“not likely to adversely impact student’s opportunity to learn required educational content or the assessment of educators who provide instruction.”

EXEMPTION TWO:

Surveys, Interviews, Observation

Research **that only includes interactions involving** educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior **(including visual or auditory recording) if at least one of the following criteria are met:**

- The information obtained is recorded **by the investigator** in such a manner that the identity of human subjects **cannot readily be ascertained**, directly or through identifiers linked to the subjects;

EXEMPTION TWO:

Surveys, Interviews, Observation

- Any disclosure of the human subjects' responses outside the research **would not** reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- **The information is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).**

NOTE: Research involving children is not exempt under the last bullet.

EXEMPTION TWO:

Surveys, Interviews, Observation

- Language updated to be in the affirmative
- Addition of “Limited IRB Review”

“When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.”

EXEMPTION TWO:

Surveys, Interviews, Observation

The current Exemption Three has been deleted:

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

EXEMPTION THREE:

Benign Behavioral Interventions

Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of following criteria is met:

- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

EXEMPTION THREE:

Benign Behavioral Interventions

- Any disclosure of human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement, or reputation; or
- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through Identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

EXEMPTION THREE:

Benign Behavioral Interventions

For the purpose of this provision, benign behavioral interventions are 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 interventions offensive or embarrassing.

EXEMPTION THREE:

Benign Behavioral Interventions

Examples:

- Playing an online game
- Having them solve puzzles under various noise conditions
- Having them decide how to allocate a nominal amount of received cash between themselves and someone else.

EXEMPTION THREE:

Benign Behavioral Interventions

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

This is similar to the UM Flexibility Initiative: Exemption 2A

https://research.medicine.umich.edu/sites/default/files/res_irbmed_SP.FlexibilityInitiative.Exemption2A.2015.05.01_0.pdf

EXEMPTION FOUR:

Secondary Use of Identifiable Data

Previous/current Exemption Four:

Research involving the collection or study of **existing** data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

EXEMPTION FOUR:

Secondary Use of Identifiable Data

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable specimens, if at least one of the following criteria is met:

- The identifiable private information or identifiable biospecimens are publicly available;
- Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of human subjects cannot readily be ascertained directly, or through identifiers linked to subjects, the investigator does not contact subjects, and the investigator will not reidentify subjects;

EXEMPTION FOUR:

Secondary Use of Identifiable Data

- The research involves only information collection and analysis involving the investigator's use of identifiable health information, when that use is regulated under 45 CFR parts 160 and 164 [HIPAA]; or,
- The research is conducted by, or on behalf of, a Federal department or agency or using government-generated or government-collected information obtained for nonresearch activities.

EXEMPTION FOUR: Secondary Use of Identifiable Data

The revised Exemption Four eliminates the requirement that the data exist at the time of the exempt determination; data may be collected prospectively.

EXEMPTION FIVE:

Demonstration Projects

Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

1. Public benefit or service programs;
2. Procedures for obtaining benefits or services under those programs;
3. Possible changes in or alternatives to those programs or procedures; or,
4. Possible changes in methods or levels of payment for benefits or services under those programs.

New requirement for agency to maintain public list of such projects and to publish the list before project is conducted.

EXEMPTION SIX:

Taste and Food Quality

Taste and food quality evaluation and consumer acceptance studies:

- 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

No change.

EXEMPTION SEVEN: Storage and Maintenance of Identifiable Information or Biospecimens

Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

EXEMPTION SEVEN:

Limited IRB Review

- Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of [broad consent];
- Broad consent is appropriately documented or waiver of documentation is appropriate; and
- If a change is made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, adequate provisions must be in place to protect the privacy of subjects and to maintain the confidentiality of data.

EXEMPTION EIGHT: Secondary Research for Which Broad Consent is Required

Secondary research for which broad consent is required:
Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

- Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained;
- Documentation of informed consent or waiver of documentation of consent was obtained;

EXEMPTION EIGHT:

Secondary Research for Which Broad Consent is Required

- An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section;
- The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

EXEMPTIONS:

Vulnerable Populations

- Subpart B – Pregnant Women, Fetuses, and Neonates of Uncertain Viability: All exempt categories apply.
- Subpart C – Prisoners: Exemption categories do NOT apply, except “for research aimed at involving a broader subject population that only incidentally includes prisoners.”

EXEMPTIONS:

Vulnerable Populations

- Subpart D – Children:

Exemption One – Applies

Exemption Two – Applies to educational tests and observation of public behavior if the investigator does not participate in the activities being observed. Note: Survey research with children does not qualify for exemption.

EXEMPTIONS:

Vulnerable Populations

- Subpart D – Children:
 - Exemption Three – NOT applicable
 - Exemptions Four through Eight – Applies

CONTINUING REVIEW

Continuing IRB review will not be required for:

- Research eligible for expedited review
- Exempt research which receives limited IRB review
- Research that progressed so that it only involves one or both of the following:

Data analysis, including analysis of identifiable private information or identifiable biospecimens, or

Access to follow-up clinical data from standard clinical care procedures.

This does not eliminate the requirement for reporting AEs/ORIOs and Amendments

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THANK YOU!