Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Exempt Review

Exempt Review

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Associate Vice Chancellor for Research

1.0 Purpose

The policy describes the research that does not require IRB review and outlines the process for determinations of exemption.

2.0 Scope

The SOP applies to all exempt human subject research falling under the purview of the University of Missouri Institutional Review Board.

3.0 Policy/Procedure

In accordance with federal regulations and institutional requirements, any undertaking in which any MU faculty, staff, or students investigate and/or collect data on human participants for research purposes is subject to the MU HRPP and review by the Institutional Review Board (IRB) regardless of the funding source or exempt status.

Transition of Exempt Research to the Revised Common Rule

Studies determined to be exempt prior to January 21, 2019 will not be transitioned to the revised exempt categories/review process UNLESS the research is federally funded. Federally funded, exempt research will receive a revised category of exemption prior to January 21, 2019. For those studies requiring limited IRB review, the review will be conducted at that time. Additional information regarding limited IRB review is included below.

The MU IRB has determined the revised common rule exempt categories will be utilized for all studies, regardless of funding, determined to be exempt after January 21, 2019 as they allow more flexibility than the pre-2018 categories (see pre-2018 categories below).

Exempt Categories of Research

Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt under applicable regulations and guidelines 45 CFR 46.104 and 21 CFR 56.104, 105.

General Exclusions from Exempt Determinations:

a. Prisoners can only be involved if the research is aimed at involving a broader subject population that only incidentally includes prisoners.

b. Research cannot be FDA regulated under #1-5.

c. Randomized controlled trials which may include potentially sensitive and identifiable information.

d. Sponsored activities that do not allow exempt determinations and require nonexempt IRB review. Certain grants will identify the allowable review categories/levels and must be taken into consideration by the investigator prior to submitting the IRB application. Certain restrictions need to be communicated to the IRB.

Category 1:

Research conducted in established or commonly accepted educational settings that specifically involve 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 and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Clarifications:

1. The research can only be conducted in established or commonly accepted educational settings. This includes, but is not limited to, schools and colleges.
2. It may include other sites where educational activities regularly occur.
3. Children may fall under this category.
4. Collection of sensitive and identifiable information for research only purposes will be excluded from this exemption.
5. New, unproven educational practices/activities will not be exempt.

Category 2:

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 is met:

(i) 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;
(ii) 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
(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects. The study cannot involve children under this option. The IRB must conduct limited IRB review under this option.

Clarifications:

1. Children can only be involved if their participation is limited to (1) educational tests or (2) observations of public behavior when the investigator(s) do not participate in the activities being observed. Children cannot fall under item (iii).
2. Educational Tests: These do not have to be administered in an educational setting like category 1.
3. Survey & Interview Procedures: This is not meant to include activities that will influence or change a participant's social, behavioral, or educational outcomes or abilities. This activity should be limited to completing a survey or an interview/focus group.
4. Observation of Public Behavior: To be considered public, the subjects would not have an expectation of privacy. It would reasonably be expected that observations or recordings could take place.

Category 3:

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 the following criteria is met:

(i) 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;
(ii) 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

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to subjects. The IRB must conduct limited IRB review under this option.

Clarifications:

1. ***** 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.
    a. This would exclude any type of biomedical interventions.
2. Examples could include playing an online game, solving puzzles under noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
3. If the study involves deceiving the subjects regarding the nature or purposes of the research, this exemption does not apply 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.

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 following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;
(ii) Information, which may include information about biospecimens, 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, and the investigator does not contact the subjects, and the investigator will not re-identify subjects;
(iii) The research involves only information collection and analysis, that either:

(a) involves the investigator's use of identifiable health information when that use is regulated under HIPAA for the purposes of "health care operations," or "research," or "public health activities and purposes" as defined by HIPAA; OR

(b) involves research conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 or Privacy Act of 1974, 5 U.S.C 552a.

Clarifications:

1. HIPAA only applies to protected health information (PHI), not to biospecimens without associated PHI. Biospecimens themselves are not covered under option iii(a) above.

Category 5:

Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of federal department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects). The research is designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

The research must be conducted pursuant to specific statutory authority of the US federal government. There is no statutory requirement that an IRB review the research. The research does not involve significant physical invasions or intrusions upon the privacy of participants.

Category 6:

Taste and food quality evaluation and consumer acceptance studies: (i) if wholesome foods without additives are consumed; or (ii) 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.

Categories 7 and 8:

The MU HRPP/IRB does not to allow the use of exempt categories 7 and 8 of the revised common rule.

Application Submission and Review Process

The investigators must submit the IRB Application for exempt review. The IRB staff will review the application to determine if it meets the criteria. The IRB staff has the authority to represent the institution and will have no direct involvement in the activity he or she is examining. The person making the decision will be familiar with laws, regulations, codes, and guidance governing research, organizational policies, and the nature of the research to make sound judgments. If the application meets the criteria for exemption, the IRB staff member will document the category or categories of exemption utilizing the exempt reviewer checklist. The exempt determination will also be included in the IRB approval letter.

Exempt research will be evaluated to determine if it fulfills MU's ethical standards:

1. All investigators must have up-to-date CITI basic human subject research training.
2. The research must involve no more than minimal risk.
3. The must be equitable subject selection.
4. If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data.
5. If there are interactions (in person or online) with participants, investigators will confirm within the IRB application that subjects and/or their legal guardians will be informed of the following utilizing a consent process:
    a. A statement the activity involves research
    b. A description of the procedures, including duration
    c. A statement participation is voluntary
    d. A statement about compensation, if any
    e. The name and contact information for the researcher
    f. The HRPP/IRB and research advocate contact information
6. If there are interactions, there are adequate provisions to maintain the privacy interests of participants.
7. For identifiable protected health information reviews with no consent, a HIPAA waiver must be approved by the IRB Chair or designated board member.
8. For studies including recruitment materials, the materials will follow the same standards described in the Recruitment Process SOP.
9. Investigators must receive and document permission to conduct the study if permission beyond the IRB approval is required.

Exempt Projects Conducted in Other Countries

The investigator must complete the International Research Subform as part of the IRB exempt application. Laws and regulations in some countries do not allow exemptions, and in that case even though the research may be covered by DHHS regulations, exemptions would not be allowed.

Exempt Projects Conducted with Non-English-Speaking Subjects

When a study involves non-English speaking subjects, the MU IRB will approve the English versions of documents that will be communicated or shown to subjects, and the investigator must translate the documents to match the approved versions. The translated documents do not need to be submitted to the MU IRB for review and approval.

Limited IRB Review

If the study falls under category #2(iii) and/or #3(iii), the Chair or IRB member designee (experienced IRB member) performs a limited IRB review to determine if there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. This will be documented utilizing an IRB reviewer checklist in eCompliance.

1. The IRB reviewer may not disapprove the research under limited IRB review. Full board review will be required if disapproval is recommended.

2. The IRB or institution retains the authority to suspend or terminate approval of research approved under limited IRB review.

Annul Updates

On an annual basis, the investigator must submit an Annual Exempt Form to keep the study open if so desired. When the study is complete, an Annual Exempt Form or the Completion Report must be submitted to close the study. The Annual Exempt Form is processed automatically with eCompliance based on their status request to remain open or close.

Exempt Amendment Review

An Exempt Amendment Form must be submitted to the IRB for review and approval prior to initiating any changes to the exempt study. The IRB will confirm the study still meets the exempt criteria. If changes are proposed regarding the provisions to protect the privacy of subjects or to maintain the confidentiality of the data and falls under exempt categories 2(iii) or 3(iii), limited IRB review will be conducted.

Personnel changes can be made on the Personnel Change Form.

Non-Compliance

The investigator must report non-compliance within 5 business days on an exempt study. For exempt research, non-compliance is typically reviewed administratively, and education is provided. The IRB may request the Event Report to be submitted or simply document the issue and resolution in eCompliance.

a. If the issue may have resulted in serious or continuing non-compliance, the issue will follow the Non-Compliance SOP.
b. If the issue may have resulted in an unanticipated problem, the issue will follow the Unanticipated Problems SOP.
c. If the issue may result in suspension or termination, the issue will follow the Suspension or Termination SOP.

Research Activities Determined not to be Exempt

If the application does not meet criteria for exemption, the Principal Investigator will be notified. The notification will indicate either that the project did not meet requirements for human subject's research, what modifications are necessary to allow the research to be exempt, or to request the investigator complete the expedited and full board sections of the application.

Project Approval

The Principal Investigator will be notified in writing of the approval of the project, including projects utilizing limited IRB review. The IRB determination letter can be found in eCompliance attached files.

The project number, title, Principal Investigator's name, and other study information will be included in the monthly board meeting packet. See Board Meeting Procedures and Minutes SOP for more information.

Reference: Pre-2018 Exempt Categories:

Category 1:
Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Category 2:
Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless (i) information obtained is recorded in such a manner that human subjects can be identified, directly, or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Note: This category of exemption cannot be used for research involving survey or interview procedures or observation of public behavior with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Category 3:
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 category 2, 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.

Category 4:
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.

Category 5:
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 (i) Public benefit or service programs; (ii) Procedures for obtaining benefits or services under those programs; (iii) Possible changes in or alternatives to those programs or procedures; or (iv) Possible changes in methods or levels of payment for benefits or services under those programs.

Note: The program under study has to deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services provided under the Older Americans Act), the project must be conducted pursuant to specific federal statutory authority, there can be no statutory requirement that an IRB review the project, the project cannot involve significant physical invasions or intrusions upon the privacy of participants, and OHRP has to concur that this exemption category is appropriate for the research.

Category 6:
Taste and food quality evaluation and consumer acceptance studies (i) If wholesome foods without additives are consumed, or (ii) 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 FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

References:

Policy Revision Dates Prior to January 21, 2019:
January 22, 2001; April 12, 2002; February 24, 2006; May 2006; December 1, 2006; June 10, 2010; August 12, 2010; July 1, 2011; July 2, 2014; March 1, 2015; July 1, 2015; June 8, 2017; May 3, 2018