Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Exempt Process/Case Reports

Exempt Process/Case Reports

Effective Date:	January 22, 2001	
Original Approval Date:	January 22, 2001	
Revised Date:	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	

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1.0 Purpose

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

2.0 Scope

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

3.0 Policy/Procedure

All applications submitted to the IRB administrative office will be reviewed at one of three levels: 1) Exempt, 2) Expedited, or 3) Full Board.

In accordance with federal and institutional regulations, any undertaking in which any MU/ HSTMVH 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 appropriate Health Sciences or Campus Institutional Review Board (IRB) regardless of the funding source. Specific institutional procedures which correlate with the assurance and cooperative research guidance of the OHRP govern data collection occurring at "off-site" locations. With applicable approvals and written agreements, MU may also use the IRB of another organization to ensure effective and timely research review. As the IRB of record for the HSTMVH and in accordance with VA Handbook 1200.5, the IRB of another organization or a commercial IRB will not be used in the review of VA research.

Prior to final approval being granted on any project, it must be determined that the Principal Investigator has completed the educational training requirement. If the requirement has been met, the project will proceed with notification of the action taken. If the requirement has not been met, the Principal Investigator will be notified of the requirement and means to meet the requirement. The project will not proceed to be decided upon until training has been completed.

All studies or individuals from outside the University of Missouri-Columbia must have an advisor or collaborator from MU on the project.

Exempt

Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from IRB review under applicable regulations and guidelines 45 CFR 46.101 and 21 CFR 56.104, 105. (Please refer to the VA SOP for any additional requirement for VA studies that qualify for exempt review):

A. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

i. Research on regular and special education instructional strategies,

ii. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Note: Research cannot involve prisoners and cannot be FDA regulated.

*UMC evaluates the involvement of children in this category on a case by case basis, most research with direct involvement of children will be expedited.

B. 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. (For VA research, VA regulations require loss of insurability to also be considered.)

Note: The research cannot involve prisoners and cannot be FDA regulated.

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.

C. 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.

Note: The research cannot involve prisoners and cannot be FDA regulated.

D. 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.

Note: The research cannot involve prisoners and cannot be FDA regulated.

* UMC requires all retrospective chart reviews to be submitted on the ‘Data Analysis Application” and be reviewed by expedited procedure.

E. 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 research cannot involve prisoners. The research is not FDA regulated. 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.

F. 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.

The research does not involve prisoners.

Submission and Review Process

The Exempt Application and supporting documents will be submitted to the IRB administrative office for review. The IRB Chair or other designee will review the application and supporting documents to determine if it meets the criteria set forth in 46.101(b). If the application meets the criteria for an exempted application, the IRB Chair or designee will determine the category of the exemption.

Exempt research will be evaluated to determine if it fulfills MU's ethical standards. The research must involve no more than minimal risk. Also included in this evaluation, if applicable, is review for:

1. Selection of participants is equitable
2. If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data
3. If there are interactions with participants, it may be determined that a consent process is necessary that will disclose such information as:
    a. That the activity involves research
    b. A description of the procedures
    c. That participation is voluntary
    d. Name and contact information for the researcher
    e. There are adequate provisions to maintain the privacy interests of participants

All approved documents are found in eCompliance document storage.

The project number, the title and the Principal Investigator's name will be included in the information attachments to the agenda and minutes of the next board meeting.

Continuing Review

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.

Exempt Amendments

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.

Research Activities Determined not to be Exempt

If the application does not meet criteria for an exempted project, the Principal Investigator will be contacted that approval was not granted for the exemption of the project. The notification will indicate either that the project did not meet requirements for human subjects research, or what modification are necessary to allow the research to be exempt, or to request the investigator submit a full board/expedited application.

Project Approval

The Principal Investigator will be notified in writing of the approval of the project.

Case Report Exception

A case report of 3 or less individuals is not interpreted to meet the definition of research as this small number does not contribute to "generalizable knowledge". A single case report is a medical/educational activity that does not meet the DHHS definition of "research", which is: "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." The activity is not reviewed by the IRB for research, but is reviewed by the IRB which also serves as the privacy board, for compliance with HIPAA.

A completed Case Report Form must be submitted for review and approval, regardless of number of subjects, prior to accessing medical information to complete the case report. Investigators have the option of requesting to obtain HIPAA authorization from the subject or to request a waiver of HIPAA authorization. The waiver of authorization will be reviewed and approved by a board member. The authorization will be acknowledged. The investigator will be notified in writing once approval is granted.

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