Exempt Applications

Effective Date: January 22, 2001
Original Approval Date: January 22, 2001
Revised Date: April 12, 2002
February 24, 2006, May, 2006, December 1, 2006

Approved By: Robert Hall, PhD
Associate Vice Chancellor, Research

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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 Health Sciences 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.

Any MU/HSTMVH activity meeting the following federal definitions requires review and approval by an MU IRB and is subject to all provisions of the institution-wide HRPP.

**Human Subjects Research:** Any activity that either (1) meets the DHHS definition of “research” that involves ‘humans subjects’ as defined by DHHS regulations or (2) any ‘clinical investigation’ of a ‘test article’ as defined by FDA regulations that involves human subjects as defined by FDA regulations.

**HHS Definitions**

*Research* – “a systematic investigation designed to develop or contribute to generalizable knowledge” [45 CFR 46.102(d)],

*Human Subject* “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information” *Intervention* includes both physical procedures by which data are gathered and manipulations of the participant or the participant’s environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable (i.e., the identity of the participant is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects [45 CFR 46.102(f)]

**FDA Definitions**

*Clinical Investigation*– “any experiment that involves a test article and one or more human subjects and that and that is one of the following: [21 CFR 50.3 (c)] [21CFR 56.3(c)]

i. subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the (FDA) act;

ii. not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit;

iii. the term does not include experiments that are subject to the provisions of 21 CFR 50.3(g).
Human Subject – “an individual who is or becomes a participant in research, either as a recipient of a test article or as a control. A subject may be either a healthy human or a patient” [21 CFR 56.102(e) – for FDA regulated drug, food or biologic research], or “A human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or who participates as a control. A subject may be in normal health or may have a medical condition or disease.” [21 CFR 812.3(p) – for FDA regulated device research]

Test article: any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product or any other article subject to regulation under the act or under sections 351 or 354-360F of the Public Health Service Act. [21 CFR 50.3(j)] [21 CFR 56.102(l)]

Some categories of research are difficult to discern as to whether they qualify as human subject research. The IRBs make available to the investigators worksheets to aid in the determination of whether an activity is human subjects’ research and the IRBs are also available to answer questions and guide the investigator in the determination.

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 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.

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.

For research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, 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.

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 an 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.

The exempt application and supporting documents will be submitted to the IRB administrative office for review. The HS IRB Chair or other IRB Member 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 (see exempt checklist), the IRB Chair or designee will determine the category of the exemption, document the determination and sign the application in the appropriate place indicating approval. The original approved application will be returned to the Principal Investigator for inclusion into the study file. 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.

On an annual basis the investigator must submit an Exempt Annual Update to keep the study open if so desired.

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 (attachment 5) of the approval of the project.

**Case Report Exception**

A single retrospective 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 retrospective 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." Therefore, the activity does not have to be reviewed by the HS IRB.

A completed Waiver of HIPAA Authorization or Authorization form must be submitted to the HS IRB, regardless of number of subjects, prior to accessing medical information to complete the case report.

Any prospective case reports or case reports of more than 3 individuals must still be submitted to the HS IRB Office on an exempt application request. Also, the HS IRB Office should be
contacted for additional guidance if there are any unique aspects to the case report or any questions as to whether an exempt request should be submitted.