Exempt Applications

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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.

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 ‘human 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)],

*Systematic Investigation:* A "systematic investigation" is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question.

*Generalizable Knowledge:* Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program (e.g., publications or presentations.) However, research results do not have to be published or presented to qualify the experiment or data gathering as research. The intent to contribute to "generalizable (scholarly) knowledge" makes an experiment or data collection research, regardless of publication.

*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)]

*Minimal Risk* “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

**FDA Definitions**

Clinical Investigation- “any experiment that involves a test article and one or more human subjects 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 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 ‘Retrospective Chart Review Form’ 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
   f. This information will be stamped as part of the approved project

All approved documents will be found in the e-irb system. 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 Exempt Annual Update to keep the study open if so desired.

**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 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 IRB.

A completed Waiver of HIPAA Authorization or Authorization form must be submitted to the 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 IRB Office for expedited review. The 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.