

Activities Requiring Campus IRB Review
Policy Number 2876.41



Campus Institutional Review Board
University of Missouri-Columbia

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Approval Authority:

A handwritten signature in black ink, appearing to read 'Cheryl B. Li'.

Signed _____
IRB Chair

Date December 12, 2007

Institutional Approval:

A handwritten signature in black ink, appearing to read 'R. J. Hall'.

Signed _____
Associate Vice-Chancellor for Research

Date December 12, 2007

Activities Requiring Campus IRB Review

Policy Number 2876.41

1.0 Purpose

The purpose of this policy is to describe when specific research activities meet the DHHS and FDA definitions of human subject research requiring IRB review.

2.0 Scope

All activities involving human subjects in research, regardless of sponsorship, must be reviewed and approved by the Campus Institutional Review Board. No intervention or interaction with human subjects in research, including recruitment, may begin until the IRB has reviewed and approved the research protocol. Specific determinations of human subject research subject to IRB review fall under the jurisdiction of the Campus Institutional Review Board, and must be determined by the IRB.

3.0 Definitions:

Food and Drug Administration (FDA): The office responsible for implementing regulations governing the use of investigational drugs, biologics, devices and radiological procedures including radioactive drugs in clinical investigations with humans.

Research subject to regulation: Those research activities for which a federal department or agency has specific responsibility for regulating as a research activity. It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

DHHS Definitions:

“Research” as defined by DHHS regulations means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. [45 CFR 46.102(d)]

“Human Subject” as defined by DHHS regulations means 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. [45 CFR 46.102(f)]

“Intervention” as defined by DHHS regulations means both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. [45 CFR 46.102(f)]

“Interaction” as defined by DHHS regulations means communication or interpersonal contact between investigator and subject. [45 CFR 46.102(f)]

Office for Human Research Protections (OHRP): The office under the Department of Health and Human Services responsible for implementing DHHS regulations (45 CFR 46) governing biomedical and behavioral/social science research involving human subjects.

“Private information” as defined by DHHS regulations means 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 (for example, a medical record). [45 CFR 46.102(f)]

NOTE: Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order to be considered

Activities Requiring Campus IRB Review

Policy Number 2876.41

information to constitute research involving human subjects. This may include identifiable private information obtained from a primary subject about a third party.

“Identifiable information” as defined by DHHS means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

FDA Definitions:

“Research “ as defined by FDA regulations means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Federal Food, Drug, and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations. [21 CFR 50.3(c), 21 CFR 56.102(c)]

“Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act” means any use of a drug other than the use of an approved drug in the course of medical practice. [21 CFR 312.3(b)]

“Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act” means any activity that evaluates the safety or effectiveness of a medical device. [21 CFR 812.2(a)]

“Any activity in which results are being submitted to or held for inspection by FDA as part of an application for a research or marketing permit is considered to be FDA-regulated research. [21 CFR 50.3(c), 21 CFR 56.102(c)]”

“Human Subject” as defined by FDA regulations means an individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. [21 CFR 50.3(g), 21 CFR 56.102(e)] A human subject includes an individual on whose specimen a medical device is used. [21 CFR 812.3(p)]

4.0 Policy/Procedure

The Office of Research has the authority to govern the Human Research Protection Program (“HRPP”) and charges the Campus IRB to make the determination of whether an activity is exempt or subject to IRB Review. The Campus IRB has the authority to review activities meeting the DHHS definition of human subject research as defined by the HRPP and the FDA, and complies with its policies. The Campus IRB provides its investigators with written guidance and consultation to aid in the determination of whether an activity meets the definition of human subject research and is subject to IRB review. The Campus IRB is available to answer questions and guide researchers in determining whether their research activities are subject to IRB review.

The Campus IRB will make a determination of whether the activity is:

1. “Research” as defined by DHHS that involves “human subjects” as defined by DHHS.
2. “Research” as defined by FDA that involves “human subjects” as defined by FDA.
3. (1) AND (2)
4. Neither (1) nor (2)

Activities Requiring Campus IRB Review
Policy Number 2876.41

The Campus IRB must prospectively review any activity that either (1) meets the DHHS definition of “research” and involves “human subjects” as defined by DHHS (DHHS-regulated “Human Subject Research”) or (2) meets the FDA definition of “research” and involves “human subjects” as defined by FDA (FDA-regulated “Human Subject Research”).

“Research involving human subjects” means any activity that either:

- a) Meets the DHHS definition of “research” and involves “human subjects” as defined by DHHS (See below); or
- b) Meets the FDA definition of “research” and involves “human subjects” as defined by FDA (See below).

5.0 Process for Determining if Activities are Subject to IRB Review.

Research investigators may determine whether research to be conducted meets the federal definition for “research” or “human subject.” If an activity meets the definition of human subject AND research, it is classified as “human subject research” at the University of Missouri-Columbia. All activities meeting the federal definition of “human subject research” according to this policy require IRB review. If an investigator has a question about whether an activity is research involving human participants subject to IRB review, they SHALL contact the Campus IRB for a determination. The Campus IRB will take the following approach to make the determination:

A. When to ask:

Step 1 INQUIRY: Do my activities require review?

- The investigator should contact the Campus IRB if they have questions about whether an activity is research involving human participants subject to IRB review. The investigator may do this by either of the following:
 1. Email the Campus IRB Staff and describe the proposed activities. The Campus IRB may request an application be submitted to facilitate the determination. A written determination regarding the inquiry will be provided to the investigator.
 2. Telephone the Campus IRB Staff and describe the proposed activities. The Campus IRB may request an application be submitted to facilitate the determination. A written determination regarding the inquiry will be provided to the investigator.
- The Campus IRB staff will communicate directly with the investigator and request/review any written correspondence to facilitate the determination of whether the activities require IRB review. The written correspondence submitted to the IRB will be assigned to a reviewer/or designee in accordance with the Campus IRB Review Process Policy. See Policy.

NOTE: The Campus IRB MUST review any “research involving human subjects” that either:

- 1) Meets the DHHS definition of “research” and involves “human subjects” as defined by DHHS (See below); or
- 2) Meets the FDA definition of “research” and involves “human subjects” as defined by FDA (See below).

Activities Requiring Campus IRB Review

Policy Number 2876.41

B. What information to submit:

The Campus IRB may request information from the investigator in order to make a determination of whether an activity is research involving human participants subject to IRB review. The IRB may require an application be submitted to facilitate the determination.

Step 2 SUBMISSION REQUIREMENTS

If the Campus IRB requires an application submission, the investigator must complete the requisite submission process describing the proposed human subject research activities in compliance with the "Application Submission Process". See Policy for the information you must submit. If supplemental information is needed, the reviewer will request the information in writing.

C. Who has the authority to make a determination?

Step 3 REVIEW PROCESS:

The Campus IRB member or designee has the authority to make a determination of whether an activity is exempt or requires IRB review. The review determination will be made by the authority of the Campus IRB, IRB Chair, Compliance Officer, or designee in accordance with the Campus IRB policies. All determinations will be confirmed in accordance with the "Determining When an Activity is Human Subject Research" Checklist.

The member or designee will review the proposed activities, submitted information, and complete the "Determining When an Activity is Human Subject Research," "Determining when Human Subject Research activities are FDA Regulated", "Determining when Human Subject Research activities are VA Regulated" checklists to make a determination in accordance with its "Campus IRB Review Process" and "Application Submission Process" policies. See policies.

D. The criteria by which determinations are made.

Step 4 CRITERIA.

The Campus IRB will prospectively review proposed activities involving human subjects according to the criteria provided below. If the activities meet either of the following criteria, they are subject to IRB review:

The activities either:

1. Decision #1: Meet the DHHS definition of "research" and involves "human subjects" as defined by DHHS (DHHS-regulated "Human Subject Research") or
2. Decision #2: Meet the FDA definition of "research" and involves "human subjects" as defined by FDA (FDA-regulated "Human Subject Research"). All research that either meets the DHHS or FDA definitions of human subject research is subject to IRB review.
3. Decision #3 (Both Decision #1 and #2)
4. Decision #4 (Neither Decision 1 or 2)

Activities Requiring Campus IRB Review

Policy Number 2876.41

E. Documentation: The communication of such decisions to the person seeking a decision.

Step 5. DOCUMENTATION.

The Campus IRB will send written confirmation that the activity is human subjects research as defined by the University of Missouri-Columbia HRPP and indicate that the Campus IRB needs to review the research.

Decision #1: Written confirmation is sent to the investigator that the activities require IRB review.”

Decision #2: Written confirmation is sent to the investigator indicating the activities require IRB review by the Health Sciences IRB.

Decision #3: Written confirmation is sent to the investigator indicating the activities require IRB review by the Health Sciences IRB.

Decision #4 Written confirmation is sent to the investigator indicating the activities are not human subject research requiring IRB review as defined by the University of Missouri-Columbia HRPP.

Step 6 DOCUMENTATION:

The Campus IRB member or designee will document the decision in the eIRB database record.

- a. If the activities are human subject research, the reviewer’s checklists and comment field will be updated accordingly. The checklist will serve as the electronic signature. The reviewer may move the file into the appropriate “Stage” of eIRB to prompt the staff to communicate in writing that the activities are human subject research requiring IRB review. The investigator will be directed to complete an application to submit to the IRB. The investigator will receive written documentation of the determination of human subject research activities requiring IRB review. The investigator must comply with the “Application Submission Process Policy.” See Policy.
- b. If the activities are not human subject research, the reviewer’s checklists and comment field will be updated accordingly. The checklist will serve as the electronic signature. The reviewer may move the file into the appropriate “Stage” of eIRB to prompt the staff to communicate in writing that the activities are not human subject research requiring IRB review. The Campus IRB staff will submit written notification confirming the activities don’t meet the DHHS or FDA definition for human subject research that requires IRB review. The investigator will receive written documentation of the determination that the activities are not human subject research activities requiring IRB review.

NOTE: The Campus IRB review processes are conducted through an electronic paperless system. All checklists are designed to prompt the reviewer to make a determination and confirm documentation of that decision in the eIRB record.

The Campus Institutional Review Board DOES NOT have jurisdictional authority over the following human subject research activities, which must be reviewed by the Health Sciences IRB:

Activities Requiring Campus IRB Review

Policy Number 2876.41

FDA REGULATED ACTIVITIES: Human subject research activities involving products regulated by the Food and Drug Administration (FDA), or that fall under such requirements set forth in:

- 21 CFR 50 Protection of Human Subjects
- 21 CFR 56 Institutional Review Boards
- 21 CFR 312 Investigational New Drug Application
- 21 CFR 812 Investigational Device Exemptions

OR

VA REGULATED ACTIVITIES Human subject research activities that are under the jurisdiction of the Veteran's Administration or regulated by a Veteran Affairs Medical Center such as when:

- The researcher is employed at the VAMC or VA entity.
- The research is conducted at the VAMC or VA entity.
- The researcher(s) or activity(s) involve collaboration with the VAMC or VA entity.
- The researcher(s) intends to recruit subjects or access their data from the VAMC or VA entity.
- The research activities fall under the jurisdiction or auspices of any Veteran's Administration regulated entity, organization or agency.

NOTE: If the investigator has a question about whether their activities or FDA or VA regulated, they should contact either the Campus IRB or Health Sciences IRB for assistance.

6.0 Activities NOT SUBJECT to Campus IRB Review:

The Campus IRB has jurisdiction to review activities that meet the DHHS and FDA definition of Human Subject . If an activity does not meet the aforementioned definitions of human subject research requiring IRB review, it does NOT need to be submitted to the Campus IRB.

All activities that FAIL to meet the (3) prong test defining when the activity is reviewable, it is not human subject research and does NOT need to be submitted to the IRB.

Examples of activities NOT subject to IRB review because they do not meet the definition of "Human Subject Research" includes, but is not limited to:

1. Internal Classroom Activities. Many classroom activities are not subject to IRB review. These activities are conducted solely for pedagogical purposes and intended to contribute to the learning environment of the student. If such activities will be used for internal classroom purposes only, and are not conducted with the intent to develop or contribute to generalizable knowledge, it fails to meet the definition of human subject research and doesn't require IRB review.

*NOTE: A student should make sure the proposed activities have been approved by the instructor/or advisor and is not considered research activities subject to IRB review. See Below: STUDENT ACTIVITIES REQUIRING IRB REVIEW

2. Publicly Available Anonymous Datasets

Research involving the collection or study of anonymous existing data, documents, records, pathological specimens, or diagnostic specimens.

3. Anonymous Secondary Datasets: Data which contains no identifiers.

NOTE: If an investigator has a question about whether their activities are subject to IRB review, they should contact the Campus IRB office before initiation of recruitment activities.

Activities Requiring Campus IRB Review

Policy Number 2876.41

4. Journalistic Reporting: Newspaper reporting generally is not subject to IRB review when the activities are a fact-finding investigative process that is not designed to contribute to generalizable knowledge. Some journalistic activities may fall under the purview of the IRB when a research component meeting the definition of human subject research will be included in the activities. Students should contact the IRB if they have questions as to whether their activities are considered research subject to IRB review.

5. Information-gathering interviews: Where the interview questions focus on things, products, or policies rather than about people (or their thoughts regarding themselves or their experience with the product) the activity is not human subject's research. Example: canvassing librarians about inter-library loan policies or rising journal costs. If the question relates to an individual's experience or thoughts about the product, thing or policies it may be subject to IRB review. Contact the IRB if they have questions as to whether their activities are considered research subject to IRB review.

6. Research involving cadavers: When activities involve autopsy material or bio-specimens from deceased individuals it is not considered human subjects research subject to IRB review. (Note: If the research activities will provide private, health, or medical information about live relatives, IRB review may be required. Investigators should contact the Campus IRB for further information). (Example: Some archeological excavations.)

The Campus IRB's jurisdictional authority and activities are conducted in compliance with the "Campus Institutional Review Board Authority" policy. See Policy.

7.0 Activities Requiring Campus IRB Review

ALL ACTIVITIES INVOLVING HUMAN SUBJECT RESEARCH REQUIRE REVIEW BY THE IRB.

The University of Missouri-Columbia follows OHRP guidance which provides that it is the responsibility of the Institutional Review Board (IRB) or other designated institutional official(s), not the investigator, to determine whether research activities qualify for exemption. Institutions holding OPRR-approved Assurances generally require that all research involving human intervention/interaction or identifiable private information be subjected to independent verification of exempt status. The University of Missouri-Columbia requires Investigators to submit all activities meeting the definition of "human subject research" to the IRB for a review determination.

The Campus IRB is charged with making the determination of whether activities are "exempt" or can be waived in accordance with 45 CFR 46.101(b) or 45 CFR 46.101(i). Only the Campus IRB has the authority to determine which proposed research activities qualify as exempt from the requirement of Expedited or Full Board review. Research will be determined to be exempt ONLY when the sole involvement of human participants will be in one or more of the categories list in 45 CFR 46.101(B) (1-6). All determinations of exemption will be made in accordance with the "Campus IRB Review Process" policy. See policy.

EXAMPLES OF RESEARCH REQUIRING IRB REVIEW:

A. Student Classroom Projects That Require IRB review

It is important to note that NOT ALL classroom research activities are free of IRB oversight. Only activities not meeting the definition of "human subject research" are free of IRB review. The IRB must review exempt, expedited and full board human subject research activities to comply with OHRP regulations and Campus IRB policies. Students should check with their advisor or instructor for guidance in determining whether the activities involve human subjects or research. All human subject research is subject to IRB review. A student should contact the Campus IRB if they have questions about whether their activities meet the definition of human subject research and are subject to IRB review.

Activities Requiring Campus IRB Review

Policy Number 2876.41

Student research activities that meet the definition of human subject research designed to contribute to generalizable knowledge must be submitted to the IRB for review. Examples may include:

- (i) A Master thesis involving human subject research;
- (ii) Doctoral dissertations that involve human subject research;
- (iii) Undergraduate activities that involve human subject research;
- (iv) Any project or activity involving human subjects and research
- (v) Any project or activity involving human subjects and research, for which findings may be shared, published or otherwise disseminated with the intent of contributing to generalizable knowledge.

NOTE: If a student has a question of whether their activity is subject to IRB review, they should contact the Campus IRB Office before interacting with human subjects.

B. Additional human subject research activities subject to IRB review include, but are not limited to:

1. Internet Research

Online website(s) or venues that are set up for the purposes of collecting research data that will contribute to generalizable knowledge and contain identifiers which are recorded by the investigator in such a manner that subjects may be identified, directly or through identifiers linked to the subjects. These identifiers may include, but are not limited to, the IP address, email, zip code, paw print, or any other information that would regarding a particular topic. This may include the completion of questionnaires/surveys, personal data, etc.

NOTE: The Campus IRB reviews human subject research that is exempt. Online research of sources that 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 is considered human subject research subject to IRB review. The Campus IRB will review the proposed activities and make a determination regarding exempt status.

2. Pilot Studies

Activities involving only one individual or small groups of individual(s) may be subject to the same scrutiny as a full scale research project and subject to IRB review. Such activities will be reviewed on a case-by-case basis to determine if they meet the definition of “human subject research.” When the researcher intends to use the data derived from the pilot activity to be included in the full scale human subject research project design in order to contribute to generalizable knowledge it will be subject to IRB review.

NOTE: Pilot Studies conducted as a “Needs Based Assessment” or “Instrument Development” activity may not be subject to IRB review. The researcher should contact the IRB to determine if IRB review is required.

3. Journalism Research Projects:

Students, who will conduct either traditional scholarly research or a professional analysis examining areas related to the Journalism profession, which involves human subjects and is designed to contribute to generalizable knowledge, may be subject to IRB review.

NOTE: If a student has a question of whether their activity is subject to IRB review, they should contact the Campus IRB Office before interacting with human subjects.

Activities Requiring Campus IRB Review

Policy Number 2876.41

C. PUBLIC DATASETS INVOLVING INTERACTION WITH HUMAN SUBJECTS

1. Public Datasets

Publicly available datasets subject to IRB review involves a systematic investigation of 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., including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. These activities meet the definition of “human subject research” requiring IRB review. NOTE: These activities may be eligible for an exempt determination.

Examples:

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens whereby they are publicly accessible or the information is recorded by the investigator in such a manner that subjects can be identified, directly or through identifiers linked to the subjects.

D. RESEARCH INVOLVING CHILDREN

1. Research Involving Children

Research activities involving children are generally subject to IRB review. The only research activities involving children that may be categorized as exempt are those involving educational tests or observation of public behavior where the investigators do not participate in the activity being observed. To be exempt, these activities must also meet the condition that the data are recorded without individual identifiers, or the condition that disclosure of the recorded responses would not place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation. Otherwise, all the requirements of the human subjects’ regulations will apply.

8.0 Failure to Submit A Project for IRB Review

The implications of engaging in activities that qualify as human subject research subject to IRB review without obtaining prior review/approval by the Campus IRB are significant. Federal oversight agencies deem such research as serious noncompliance. All of the human subject research activities and IRB operations designated in the Federalwide Assurance Agreement (FWA), regardless of sponsorship, are guided by the ethical principles in “The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.”

Results from such studies may not be published or shared in compliance with the FWA unless IRB approval is granted. Conducting human subject research without prior IRB review is a violation of Campus IRB policy and its FWA. If an investigator conducts human subject research that is deemed noncompliant, the Campus IRB may prohibit the use of that data for publication purposes, or for course credit to satisfy academic requirements. All investigators conducting human subject research that is not in compliance with Campus IRB policies will be required to comply with the “Compliance Breach Policy.” See Policy.

If an Investigator begins a project that doesn’t initially require IRB review, but later finds that the data gathered could contribute to an existing knowledge base or that they wish to publish the results to contribute to generalizable knowledge, the Investigator should contact the IRB. The investigator may be required to submit a proposal to the IRB for review. The IRB has the right to determine if the data/results may be published or used to satisfy academic requirements.

Activities Requiring Campus IRB Review

Policy Number 2876.41

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