

MISSOURI BAPTIST UNIVERSITY

Institutional Review Board (IRB)

**GUIDELINES FOR INVESTIGATORS
IN PREPARATION OF
HUMAN SUBJECT RESEARCH PROTOCOLS
FOR IRB REVIEW**

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I. INTRODUCTION

Missouri Baptist University has established an Institutional Review Boards (IRB) to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of Missouri Baptist University. Research projects involving human subjects require review and approval by the MBU IRB. An IRB is an ethics committee composed of scientists and non-scientists who serve as advocates for human subjects research. The IRB is charged with the responsibility of reviewing and overseeing human subjects research conducted under the aegis of Missouri Baptist University.

All faculty and students at Missouri Baptist University conducting research involving human subjects as defined in [45 CFR 46.102](#) must submit their research protocol to an Institutional Review Board (IRB) for review prior to commencing the project.

II. DEFINITIONS

In order to assist investigators in deciding whether a planned activity constitutes research involving human subjects, the following federal definitions of research and human subjects are provided:

- **Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. A research project generally is described in a protocol that sets forth explicit objectives and formal procedures designed to reach those objectives. The protocol may include therapeutic and other activities intended to benefit the subjects, as well as procedures to evaluate such activities. Research objectives range from understanding normal and abnormal physiological, psychological, or social phenomena, to evaluating diagnostic, therapeutic, or preventive interventions and variations in services and practices. The activities or procedures involved in research may be invasive or noninvasive and may include surgical interventions, removal of body tissues or fluids, administration or application of chemical substances, randomization of subjects, modification of diet or daily routine, strenuous physical exertion, alteration of environment, observation, administration of questionnaires or tests, review of records, etc. “Research” does not generally include activities that defined practice activities in public health, medicine, psychology, and social work such as routine outbreak investigations and disease monitoring) and studies for purposes of internal management (program evaluation, quality assurance, quality improvement, fiscal or program audits, marketing studies or contracted-for services. Journalism or political polls are generally excluded unless these activities have the clear intent include of contribute to generalizable knowledge (Ryan, Brady, Cooke, Height, Jonsen, King, Lebacqz, Louisell, Seldin, Stellar, & Turtle (1979).
- **Human subject** 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.

- **Further Defining Human Subjects**

A human subject is defined by Federal Regulations as “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.” (45 CFR 46.102(f)(1),(2))

Living individual – The specimen(s)/data/information must be collected from live subjects. Cadavers, autopsy specimens or specimens/ information from subjects now deceased is not human subjects.

“About whom” – a human subject research project requires the data received from the living individual to be about the person.

Intervention includes physical procedures, manipulations of the subject, or manipulations of the subject's environment for research purposes. **Interaction** includes communication between the investigator and the subject. This includes face-to-face, mail, and phone interaction as well as other modes of communication.

Identifiable private information “includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place,” (such as a public restroom) “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 health care record).” (45 CFR 46.102(f)(2))

“Identifiable” means the information contains one or more data elements that can be combined with other reasonably available information to identify an individual (e.g. Social Security #).

In other words, research involving human subjects is any activity which has the intent of securing information from humans for the purpose of advancing generalizable knowledge. Such activity may or may not differ in a significant way from customary practice.

III. Composition of the Missouri Baptist University IRB

The Missouri Baptist University Institution Review Board currently has 6 members, representing various components of the Missouri Baptist University campus. Initial membership consists of:

Chairman: Van Vaughn, Counseling/Education (Three years)
Ex Officio: Clark Triplett, Dean of the Graduate School
Jerry Deese, Chair of Natural Sciences Division (Three Years)
Mark Englehardt, Site Coordinator, Troy/Wentzville, Education (Two Years)
Janet Puhls, Chair of Social and Behavioral Science Division (Two year)
Thomas Smith, Director of Athletics (One Year)

Terms of service will be for 3 years with one new members rotating in on the first year, and two new members in years two and three. The Dean of the Graduate School will always be the Ex Officio.

IV. IDENTIFYING HUMAN RESEARCH STUDIES

Not all studies that may have the characteristics of human subjects research meet the regulatory definition. Only those that do require IRB review. There are three categories to be considered:

- studies that are human subjects research
- studies that may be considered human subjects research (gray area)
- studies that do not qualify as human subjects research

Observational studies of public behavior (including television and internet chat rooms) do **not** involve human subjects as defined when there is no intervention or interaction with the subjects and the behavior is not private. Also, studies based on data collected for non-research purposes may **not** constitute human subjects research if individuals are not identifiable (e.g. data such as service statistics, school attendance data, crime statistics, or election returns).

Studies based on data that are individually identifiable but are also publicly available may **not** constitute human subjects research. However, the term “publicly available” is intended to refer to record sets that are truly readily available to the broad public, such as census data, or federal health, labor, or educational statistics. An investigator should **not** assume information qualifies as “publicly available” merely because it has been posted on an electronic website and can be accessed without authorization.

- **Examples Of Activities That Are Not Human Subjects Research**

Activities that fit any of the categories below do not need IRB review.

1. **Data collection** for internal departmental, school, or other University administrative purposes. Examples: teaching evaluations, customer service surveys.
2. **Service surveys** issued or completed by University personnel for the intent and purposes of improving services and programs of the University or for developing new services or programs for students, employees, or alumni, as long as the privacy of the subjects is protected, the confidentiality of individual responses are maintained, and survey participation is voluntary. This would include surveys by professional societies or University consortia. *Note: If at a future date, an opportunity arose to contribute previously collected identifiable or coded survey data to a new study producing generalizable knowledge, IRB review may be required before the data could be released to the new project.*
3. **Information-gathering interviews** (through interviews, surveys, etc.) where questions focus on things, products, or policies rather than people or their thoughts. Example: asking company officers to provide data about company facts (such as number of employees) or to provide copies of company policies. *Note: If the study involves collecting the officers’ opinions of company policies (e.g. in your opinion, is the policy effective?), then the study will need IRB review.*
4. **Course-related activities** designed specifically for educational or teaching purposes, where data is collected from and about human subjects as part of a class exercise or assignment, but are **not** intended for use outside of the classroom. Example: instruction on research methods and techniques. *Note: The IRB is only required to review studies that meet the Federal definitions of research and human subject⁴, or “engaged in research”.*
5. **Biography or oral history** involving a living individual that is not generalizable beyond that individual.
6. **Activities involving cadavers**, autopsy material or bio-specimens from now deceased individuals. *Note: Some research activities in this category, such as genetic studies providing private or medical information about live relatives, may need IRB review. The MBU IRB also acts as a Privacy Board, and may require a “Notification of Decedent Research” form which is located on the MBU IRB website under HIPAA. Please contact the IRB for further information.*
7. **Innovative therapies** except when they involve "research" as defined by the above criteria.

(An innovative clinical practice is an intervention designed solely to enhance the well being of an individual patient or client. The purpose of an innovative clinical practice is to provide diagnosis, preventative treatment, or therapy to particular individuals.) *Note: When innovative therapies differ significantly from routine practice it should be viewed and treated as such with appropriate safeguards in place to protect the rights and welfare of the patients.*

8. **Quality improvement** projects are generally **not** considered research unless there is a clear intent to contribute to generalizable knowledge **and** use the data derived from the project to improve or alter the quality of care or the efficiency of an institutional practice. Any individual who is unsure whether or not a proposed quality improvement project should be classified as research should contact the IRB for guidance. If the data are re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, an application must be submitted to the IRB.
 9. **Case histories** which are published and/or presented at national or regional meetings are **not** considered research if the case is limited to a description of the clinical features and/or outcome of a single patient and do not contribute to generalizable knowledge. MBU IRB policy states that 2 cases may be studied before submitting to the IRB.
 10. **Publicly available data** do **not** require IRB review. Examples: census data, labor statistics. *Note: Investigators should contact the IRB if they are uncertain as to whether the data qualifies as “publicly available”.*
 11. **Coded private information or biological specimens** that were **not** collected for the currently proposed projects do not need IRB review as long as the investigator cannot link the coded data/specimens back to individual subjects. If the data/specimen provider has access to the identity of the subjects (e.g. subjects’ names, addresses, etc.), the investigator must enter into an agreement with the data/specimen provider that states under no circumstances will the identity of the subjects be released to the investigator. *Note: Investigators are not allowed to make this determination. These projects require verification from the IRB.*
- (<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>)
12. Some examples of **Non-Engagement in Research** include: when an institution’s employees or agents act as consultants on research but at no time obtain, receive, or possess identifiable private information; perform commercial services for the investigators (e.g. noncollaborative services meriting neither professional recognition nor publication privileges); or simply inform prospective subjects about the availability of research, but at no time obtain consent or act as authoritative representative of the investigator(s). *Note: The examples above are not an all inclusive listing.*
- (<http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm>)

V. EXAMPLES OF STUDIES THAT ARE HUMAN SUBJECTS RESEARCH

1. Studies that involve human subjects for testing new devices, products, drugs, or materials.
2. Studies that collect data through intervention or interaction with individuals. Examples of this type of research include drug trials, internet surveys about alcohol consumption, studies that involve deception, research involving risky behaviors or attitudes, and open-ended interviews with minors that contribute to generalizable knowledge.
3. Studies using private information that can be readily linked to individuals, even if the information was not collected specifically for the study in question.

4. Studies that use bodily materials such as cells, blood, urine, tissues, organs, hair, or nail clippings, even if one did not collect these materials for the study. However, such research may be considered exempt or not human subjects research if the materials/data are coded and the investigator does not have access to the coding systems. Guidance on research involving coded private information or biological specimens is available on the web at:
<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>)
5. Studies that produce generalizable knowledge about categories or classes of subjects from individually identifiable information.
6. Studies that use human beings to evaluate environmental alterations. For example, making changes to a living or working space (e.g. changing the temperature).

If an investigator is unsure of whether his/her proposal constitutes “human subjects research”, they should contact the MBU IRB. The IRB staff, Chair and/or designee will determine if the study is human subjects research. If a study does not qualify as human subjects research, the IRB can issue a written notification (email or letter) stating that the project does not require IRB review or approval. *Note: Faculty advisors, or publications may require a determination letter from the IRB.*

In assuring compliance with the Missouri Baptist University ethical practices, the University requires that, prior to initiation, all research projects involving humans as subjects or human material be reviewed and approved by the IRB. (Note: Subjects of research can include faculty members, staff employees, regardless of source of funding and location of the study, to such research conducted by faculty, staff, and students of the University. Whenever an investigator is uncertain as to whether the study falls under IRB jurisdiction, an informal letter (or e-mail) describing the proposed activities can be sent to the IRB. The IRB will then send a response to the investigator advising whether or not the research activity constitutes human subjects research. This process benefits both the investigator and Missouri Baptist University. Research that will involve human subjects should not be initiated until the IRB review process has been completed and approval has been provided. The investigator should always err on the side of caution and communicate openly with the IRB.

VI. SUBMISSION TO THE IRB

The first question a researcher should consider with respect to IRB review is whether the research project fits the definition of human subjects research. In light of the mission to protect human subjects, and the potential regulatory consequences of not obtaining IRB review and approval, the investigator should choose to err on the side of caution and consult the IRB when he/she is uncertain whether the study is human subjects research or not.

RESOURCES

- United States Department of Health & Human Services: Office for Human Research Protections (OHRP)
<http://www.hhs.gov/ohrp/>
- US HHS Office of Human Research Protections (OHRP) Decision chart to assist in determining whether a project is human subjects research. www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm select: *Chart 1: Is an Activity Research Involving Human Subjects?*
- US HHS Office for Human Research Protections (OHRP) Engagement of Institutions in Research
<http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm>
- United States Food and Drug Administration

<http://www.fda.gov/>

- Federal Policy for the Protection of Human Subjects (Common Rule)

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

- Guidance on Research Involving Coded Private Information or Biological Specimens

<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>

- The Belmont Report <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>

The Institutional Review Board, established by Missouri Baptist University, serves to assure that research on human subjects is planned and carried out in accordance with certain ethical principles and federal regulations. Website links to the ethical codes are included in Section VI of this document.

VII. IRB TRAINING AND EDUCATION

In accordance with federal requirements and guidelines and Missouri Baptist University Institutional Review Board Standard Operating Procedures, education on the use of human subjects in research is mandatory at Missouri Baptist University. All faculty, staff, students, and collaborating researchers who are involved in the use of human subjects in research must complete the course of instruction offered by the National Cancer Institute entitled “Human Participant Protections Education for Research Teams”. Investigators affiliated with Missouri Baptist University and investigators that are collaborating on a project at Missouri Baptist University must complete all required modules, regardless of where the research is being conducted. Co-investigators who are not affiliated with Missouri Baptist University may provide a copy of their training certificate from their institution with the MBU IRB application.

Investigators can register to take the course on line at

<http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>

VIII. REVIEW MECHANISM

A. Exempt Review of Protocols: Research activities in which the *only* involvement of human subjects will be in one or more of the categories listed under [45CFR46.101 \(b\)](#) qualify as exempt. Such research may include observation; survey or interview procedures; research conducted in commonly acceptable educational settings, involving instructional techniques, curricula, educational tests (cognitive, diagnostic, aptitude, achievement); the use of existing data (for more than two subjects), records, pathological or diagnostic specimens, wherein the subjects cannot be identified or linked with the data; and research involving taste and food quality testing and consumer acceptance studies.

Even if a study may qualify as exempt, researchers must complete and submit a Request for Exempt Review Application to the IRB office. The determination of exemption may only be made by the IRB, not the researcher. Exempt studies do not require continued IRB monitoring. However, any changes made to exempt research must be submitted on a Change in Protocol form and approved by the appropriate IRB. Also, the investigator should notify the IRB upon completion of their exempt research.

The investigator must submit the IRB Exemption Form and Protocol, including the consent form(s), where appropriate, to the appropriate IRB Office. After the IRB receives the complete submission, and the IRB Chairperson or IRB Member Designee concludes that the research falls within the parameters for exempt research, other aspects of human

subject protection will be reviewed (e.g. risk-benefit ratio, informed consent requirements) and a determination made for approval. If the IRB reviewer deems it necessary for the protocol be reviewed by the full IRB (e.g. the protocol is more than minimal risk), the protocol will be reviewed at the next convened IRB meeting. A determination of “disapproved” cannot be made by an IRB Chair or Designee without full board review.

- B. Full Board Review of Protocols:** All research activities that do not meet the criteria for exempt review must be reviewed by the appropriate IRB at a convened IRB meeting.

The board will meet _____

In approving research, which proposes the inclusion of human subjects, the IRB must determine that:

- (1) the risks to subjects are minimized by using procedures which are consistent with sound research design and do not unnecessarily expose subjects to risk; and
- (2) the risks to the subject are outweighed by the potential benefit to the subject and by the importance of the knowledge to be gained; and
- (3) the rights and welfare of the subject are protected by using adequate and appropriate methods to obtain informed consent.

In order to enhance the review process, the IRB relies on all members of the University community with sufficient information to review proposals in assuring that experimental protocols are properly designed and in seeking advice as to whether the state of the science justifies the use of human subjects at the particular time. This occurs when expertise is known to be available with an individual, when other reviewers are unavailable or overloaded or for other reasons determined by the Chairperson of either IRB. The University extends this policy to seeking outside review by consultants when necessary. Comments or appropriate distillations of comments will be supplied to an investigator for consideration in strengthening the proposal.

The investigator will be notified promptly by letter of the IRB’s action on each proposal. The investigator must respond in writing within 60 days from the date of the action letter. If there is no response within 60 days, the IRB office will administratively withdraw the proposal from further consideration.

IX. TYPES OF IRB ACTIONS

- A. Full Approval:** If the proposal is fully approved, the investigator will be notified by letter. Instructions will be provided in the letter concerning further reporting requirements. Continuing progress reports as well as immediate reports of unanticipated or serious adverse events are required on all IRB-monitored human research projects.
- B. Contingent Approval:** If the proposal is contingently approved, the Board will set specific conditions under which a protocol can be approved. Studies which are contingently approved require additional information or minor revision. When the

convened IRB stipulates specific revisions requiring simple concurrence by the investigator may the IRB Chair or another IRB member designated by the Chair subsequently approve the revised research protocol and/or consent form on behalf of the IRB under expedited review procedure. Contingently approved studies do not, usually, require further discussion by the full IRB. Investigators will be notified by letter when proposals are contingently approved.

- C. **Deferred:** Investigators will be notified by letter when proposals are deferred. Only when the convened IRB requests substantive clarifications or modifications regarding the protocol or informed consent documents that are directly relevant to the determinations required by the IRB under 45 CFR 46.111, IRB approval of the proposed research will be deferred. Deferred proposals require significant revision and re-submittal for full IRB review. Investigators must submit the proposal by the usual deadlines.
- D. **Tabled:** Investigators will be notified by letter when proposals are tabled. Tabled proposals are unable to be reviewed due to the omission of required documentation to make any determination concerning the research. Investigators must resubmit a complete proposal for full board review by the usual deadlines.
- E. **Disapproval:** Disapproval is a rare action, necessary only when the research risks outweigh the benefits to study participants; the conduct of the protocol is not adequately justified in the subject population; or other, significant problems exist, specific to the protocol. The decision to disapprove only takes place at a convened IRB meeting.
- F. **Suspension or termination:** The IRB has the authority to suspend or terminate human research that is not being conducted in accordance with the IRB's decisions, conditions, and requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, the appropriate institutional officials and government agency.

X. IRB REPORTING REQUIREMENTS

- A. **New Protocols:** Proposed research projects, which will involve the use of human beings as subjects, should be reviewed by the IRB and approved before the protocol is initiated.
- B. **Changes in Approved Protocols:** Should there be a change in an approved protocol, it should be brought directly, before implementation, to the attention of the IRB Office. A Change in Protocol Form should be used.
- C. **Continuing Review and Study of Notice Completion:** At the end of the IRB-approved project period (usually a year), a continuing review report must be submitted for review and for continuance of approval to be provided. Non-exempt research cannot go on without continued approval. Investigators will be reminded at least two months in advance of the required information and timing for continuing review. The required information includes a progress report describing the number of subjects studied, a description of any unanticipated or serious adverse events, and other information as directed by the IRB. A final report must be submitted at the completion of the project.

- D. Serious Adverse Events and Unanticipated Problems:** Research investigators are responsible for reporting promptly to the IRB any unanticipated problems which may involve risks to the human subjects or others, or any serious adverse events events, such as deaths, which are the result of participation in the research. The IRB should be notified in writing within three days of any life threatening adverse event, subject death (whether related to the study or not), or legal action taken as a result of a subject's participation on a study. Serious Adverse Events and Unanticipated problems should be reported in writing to the IRB within ten days.
- E. Noncompliance:** Members of the University community (i.e. faculty, staff, and students) have the responsibility for reporting promptly to the IRB any serious or continuing noncompliance with the University's human research review requirements and/or determinations made by the IRB.

If any investigator suspects research misconduct, he/she can report such misconduct anonymously on the MBU Confidential Hotline at 877-525-5669

- F. Rehearings:** Any investigator dissatisfied with the IRB's decisions, conditions, or requirements is entitled to a rehearing at a subsequent IRB meeting at which time the investigator should be present for purposes of questioning and further discussion.

XI. ETHICAL PRINCIPLES AND GUIDELINES

- A. Title 45 Code of Federal Regulations Part 46 - Protection of Human Subjects
<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>
- B. The Belmont Report
<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm>
- C. The Declaration of Helsinki
<http://www.med.umich.edu/irbmed/ethics/Helsinki/HelsinkiDeclaration.html>
- D. The Nuremberg Code
<http://www.med.umich.edu/irbmed/ethics/Nuremberg/NurembergCode.html>
- E. Ethical Principles of Psychologists and Code of Conduct
<http://www.apa.org/ethics/code.html>
- F. Title 21 Code of Federal Regulations Part 50 – Protection of Human Subjects
<http://www.fda.gov/oc/ohrt/irbs/appendixb.html>

- G. Title 21 Code of Federal Regulations Part 56 – Institutional Review Boards
<http://www.fda.gov/oc/ohrt/irbs/appendixc.html>
- H. Title 21 Code of Federal Regulations Part 312 – Investigational New Drug Application
<http://frwebgate4.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=2736656842+1+0+0&WAISaction=retrieve>

XII. IRB FORMS AND GUIDANCE

Various MBU forms will be listed and hyperlinked here

References

Ryan, K. N., Brady, J.V., Cooke, R. E., Height, D. I., Jonsen, A. R., King, P., Lebacqz, K., Louisell, D. W., Seldin, D. W., Stellar, E., Turtle, R. H.(1979). The Belmont report ethical principles and guidelines for the protection of human subjects of research. Washington, DC: The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research The National Institute of Health