Standard Operating Procedures for the Institutional Review Board (IRB) Pertaining to Review of Research Involving Human Subjects

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Missouri State University (MSU) is dedicated to protecting the rights and welfare of human subjects recruited to participate in research conducted by MSU faculty, staff, and students. The MSU IRB Standard Operating Procedures (SOPs), in conjunction with the MSU IRB Policy, and Research Administration website, provide a central resource for researchers to find important information on required federal and state regulations and institutional policies governing these research activities.

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Title:

Research Involving Human Subjects (IRB) Policy
Op4.01-6

Policy Statement:

The protection of the rights and welfare of human subjects involved in research is part of Missouri State University's commitment to ethical conduct of research. Missouri State University will conduct matters related to research involving human subjects in compliance with federal and state laws and implementing regulations including, but not limited to, 45 CFR 46, also known as the Common Rule, and the Belmont Report.

Missouri State University will also assure that the University's faculty, staff, and students understand the importance of protecting the rights of human subjects involved in research and the University will implement practices to reduce risks associated with human subjects' involvement in research.

The President will establish an Institutional Review Board (IRB) that has the authority to develop and implement standard operating procedures (SOP) to assure research involving human subjects is compliant with this policy and applicable laws. Individual members of the IRB will be nominated and selected via the process outlined in Section A.1 of the SOPs. The President will also appoint an Institutional Official (IO) to have University system-wide responsibility for oversight of the implementation of this policy.

The functions of the IRB include, but are not limited to:

- Conduct initial and continuing review of research with human subjects and report the findings and actions to the investigator(s) in writing.
- Review and approve, require modifications in (to secure approval) or withhold approval of those components of activities related to human subjects involved in research.
- Determine which projects require more than an annual review and which projects require verification (from sources other than the investigators) that no material changes have occurred since the previous IRB review. Considerations used to make these determinations include the absolute risk to the subject, whether the risks outweigh the benefits, and prior conduct of the investigator(s) regarding the protection of human research subjects.
- Review proposed changes in research activities to insure that the protection of human research subjects is maintained.
- Investigate any actual or suspected adverse event or incident of noncompliance regarding research involving human subjects.
- Observe project activities at any point to ascertain whether human subject protections are implemented so as to reduce the likelihood of an adverse event or noncompliance.
- Make recommendations to the President, IO, or other designee regarding any aspect of the program related to the protection of human subjects involved in research.
- Suspend or terminate approval of research that is not being conducted in accordance with the requirements or that has been associated with unexpected serious harm to subjects.

All research conducted by Missouri State University students, staff, and/or faculty Missouri State University that involves human subjects must be reviewed by the IRB before implementation.

The University shall provide training for all personnel involved in research that involves human subjects. Persons are not permitted to be involved in projects involving human subjects until they have been certified as completing appropriate training.

Missouri State University Office of Research Administration will maintain all records necessary and file reports as required to be in compliance with applicable federal law and implementing regulations.

Missouri State University's IRB will develop and maintain SOPs described elsewhere to enable implementation of the University policy described above.

Reason or Purpose for Policy:

Missouri State University recognizes its responsibilities in conducting research programs involving human subjects. These responsibilities include protection of the rights and welfare of human subjects involved in research programs at Missouri State, the need to educate faculty, staff and students of the importance of human subjects' research protections, and compliance with applicable federal laws and implementing regulations.

Entities Affected by this Policy:

This policy is applicable to all Missouri State University faculty, staff, students, and visiting researchers and educators that will be involved with research involving human subjects.

Line of Authority:

Responsible Administrator and Office:

President, Office of the President

Contact Person in that Office:

Director of Research Administration

A. INTRODUCTION

Pursuant to 45 CFR 46, Missouri State University maintains an Institutional Review Board (IRB) and has created a policy and procedures to govern its actions. At Missouri State University, the IRB is charged with assuring the protection of the rights and welfare of human subjects involved in research. Therefore, the IRB is required to review all research involving human subjects prior to the conducting of any research. This manual has been developed to assist all members of the university community in complying with the stated policy and procedures of the institution regarding research involving human subjects.

A.1. General Distribution of Responsibility

Any undertaking in which a University faculty, staff member, or student investigates or collects information on living humans for research may be considered as "involving human subjects." It is the responsibility of each investigator to seek review by the IRB for any study involving human subjects prior to beginning the project.

The University's IRB is responsible for the review of research involving human subjects. The respective authorities and duties of the IRB are described in this procedural manual.

Members of the IRB are nominated by their respective colleges due to their expertise and ability to serve on the committee. The Institutional Official confirms college nominations. The IRB Chair is appointed by the Institutional Official and is responsible for the general conduct and operation of the IRB.

The Office of Research Administration (ORA) is responsible for coordinating and implementation of IRB policy and procedures. This includes the application review process, assisting in liaison with Federal agencies, regulations, record keeping and reporting, managing human subjects' research training, and assisting with assurance of compliance with federal regulations.

A.2. Abbreviations and Definitions Used in Policy and Procedures

Federal regulations and University policy use the following abbreviations:

CFR	Code of Federal Regulations
FDA	Food and Drug Administration
DHHS	Department of Health and Human Services
OHRP	Office for Human Research Protection
IRB	Institutional Review Board
PI	Principal Investigator
ORA	Office of Research Administration

Federal regulations and University policy define various terms in regard to protection of human research subjects. 45 CFR 46, also known as the Common Rule, is the body of regulations promulgated by DHHS. Most projects at the University fall under these regulations. 45 CFR 46 includes the following definitions:

A.2.1. Definitions Used by the Department of Health and Human Services

- *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the DHHS to whom authority has been delegated.

- *Department or Agency* means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

- *Research* means a systematic investigation—including research development, testing, and evaluation—designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purpose of the policy and procedures, whether or not they are supported or funded under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

- *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information.
  - *Intervention* includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes (e.g., cognitive experiment).

  - *Interaction* includes communication or interpersonal contact between investigator and human subject (e.g., a telephone interview).

  - *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 he or she can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator) in order for obtaining the information to constitute research involving human subjects.

- *Minimal risk* means that 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.

- *Vulnerable population* means children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons, individuals who are unable to give informed consent due to a physical or mental condition, or individuals whose circumstances may make them especially vulnerable to coercion (e.g., probationers).

- *Prisoner* means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. Prisoners receive additional protections under 45 CFR 46, Subpart C.

- *Child* means a person who has not yet attained the age of consent to treatments or procedures involved in the research, under the applicable laws of the jurisdiction in which the research will be conducted. Children receive additional protections under 45 CFR 46, Subpart D.

- *Parent* means a child's biological or adoptive parent.

- *Guardian* means an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

- *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

- *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.

- *Adverse effect* means an undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (*e.g*., subject becomes upset following completion of a depression questionnaire or subject experiences intestinal bleeding associated with aspirin therapy) that is directly or indirectly due to participation in a research study.

Some studies may fall under the regulations promulgated by the FDA (21 CFR 50). These will generally be studies that involve the testing of an investigational medication or a medical device. Refer to 21 CFR 50 for specific definitions regarding these studies. Some FDA definitions differ from the above DHHS definitions.

A.2.2. Definitions Used by Missouri State University

In addition to definitions promulgated by federal agencies, the University policy uses the following definitions:

1. *Principal Investigator* is the person who leads the project and is ultimately responsible for all aspects of it. On most projects, the term has the same meaning as "project director."

2. *College IRB Representative* is the member of a particular college who is a current member of the IRB and serves as the first reviewer on proposals submitted by the college (see the ORA website for a current listing of college representatives).

3. *Student project* means a study in which a student investigator (individually or as part of a group) gathers or analyzes information in a systematic manner, primarily for pedagogical purposes. It is not intended to contribute to generalizable knowledge and is not to be presented outside the class in which the research is being done or published/disseminated (including publication on the Internet) in any way, presented, archived, or compiled with similar research for later publishing or presentation. Research conducted for a senior project, master's thesis or seminar project does <u>not</u> fall under this definition.

4. *Institutional research* is a study that is designed to obtain information to assist in the administration of the University. Institutional research provides information for administrative planning, policy making, decision making, and includes examinations of institutional effectiveness. Institutional research is specifically defined as those data collection and interpretation efforts that: (a) will not be shared outside of the University environment; (b) will not be disseminated to other professionals; (c) presents no more than "minimal risk" (as defined by Federal regulation); (d) is not intended to produce "generalizable knowledge." (e) contains no identifiers in the data that might compromise an individual's confidentiality. Institutional efforts meeting this definition are not subject to the IRB policy and procedures.

5. *Training* refers to a process approved by the University, and required by federal regulations, to instruct investigators in the conduct of research involving human subjects.

A.2.3. General Principles

All of the University's human subject activities and all activities of the IRB are guided by the basic ethical principles that underlie the conduct of biomedical and behavioral research involving human subjects set forth in the report of the *National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, regardless of funding source. The three basic principles contained in The Belmont Report central to the ethics of research involving human subjects and guiding the IRB in assuring that the rights and welfare of subjects are protected include: respect for persons, beneficence and justice.

Respect for persons requires that potential subjects be given the opportunity to choose what will or will not happen to them and is the principle upon which obtaining informed consent and the consent process (including information, comprehension and voluntariness) is based. Respect for persons also provides additional protections for potentially vulnerable subjects.

Beneficence is exemplified in the expressions of "do no harm" and "maximize possible benefits and minimize possible harms", both on the individual investigator and societal levels, as they extend both to particular research projects and to the research enterprise as a whole, respectively.

Justice requires that there be fair procedures and outcomes in the selection of subjects, both individually (by offering potentially beneficial research to all who might benefit) and socially (based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons).

While not explicitly stated in the Belmont Report, an additional principle of **Scientific Integrity** also guides the IRB in its actions. This principle requires clarity around research processes sufficient to allow for an adequate evaluation of the impact the research may have on human subjects and right conduct on the part of those implementing the research to assure ethical behavior.

A.3. General Information on the IRB

Principal Investigators (PIs) are responsible for the preparation of applications and for the content therein. Applications are reviewed by (a) a faculty member's department head or designee, one IRB representative (in the case of an exempt application), or two IRB representatives (in the case of an expedited application), or by the entire board if deemed necessary by the initial IRB reviewer(s). If approved, the ORA will notify the PI of the IRB's decision. Approvals are for a one year period, unless a shorter interval is specified by the IRB.

Previously approved projects may be modified by the PI by submitting a new application cover sheet and a detailed description of the modifications/changes being made to the IRB Chair. If the Chair determines that the changes to the application significantly impact the risk/benefit ratio, he/she may require the PI to submit an entirely new application for review. If the risk/benefit ratio remains relatively unchanged, the IRB Chair can approve such changes without other review.

Reports of adverse events must be reported immediately via phone, email, or in person to the IRB Chair and to the ORA. A written report of the adverse event must then be submitted to the IRB Chair and ORA, within 5 working days after first awareness of the problem.

The IRB is responsible for the following activities:

- Conduct initial and continuing review of research with human subjects and report the findings and actions to the investigator(s) in writing.

- Review and approve, require modifications in (to secure approval) or withhold approval of those components of activities related to human subjects involved in research.
- Determine which projects require more than an annual review and which projects require verification (from sources other than the investigators) that no material changes have occurred since the previous IRB review. Considerations used to make these determinations include the absolute risk to the subject, whether the risks outweigh the benefits, and prior conduct of the investigator(s) regarding the protection of human research subjects.
- Review proposed changes in research activities to insure that the protection of human research subjects is maintained.
- Investigate any actual or suspected adverse event or incident of noncompliance regarding research involving human subjects.
- Observe project activities at any point to ascertain whether human subject protections are implemented so as to reduce the likelihood of an adverse event or noncompliance.
- Make recommendations to the President, IO, or other designee regarding any aspect of the program related to the protection of human subjects involved in research.
- Suspend or terminate approval of research that is not being conducted in accordance with the requirements or that has been associated with unexpected serious harm to subjects.

B. RESPONSIBILITIES AND ACTIONS OF THE INSTITUTIONAL REVIEW BOARD

B.1. Composition of the IRB and Appointment of Members

Federal regulations require that the IRB must be composed of at least five members (45 CFR 46.107). The University IRB shall be composed of at least eight (8) members. Representation will include members whose primary concerns are in scientific areas, such that social and behavioral sciences, education, business, and biomedical sciences are represented. The IRB should have at least one member whose primary concerns are in non-scientific areas and a community representative who is not otherwise affiliated with the University nor a member of the immediate family of a University employee. At least one member (or alternate) must be able to act as an advocate for "vulnerable populations", by virtue of experience and education. At least one member shall have expertise in both qualitative and quantitative research methods. In addition, the membership shall include men and women, as well as representation of racial and ethnic minority groups reflective of the composition of the University, when at all possible. All IRB members and alternates shall serve three-year terms and they may be reappointed for consecutive terms.

If a member goes on sabbatical or other leave for a semester, then an alternate will take his or her place from the college they represent. If a member or alternate leaves the University or goes on leave for one year or more, then the Institutional Official will appoint a replacement for the period of leave or for the remainder of the member or alternate's term, whichever is applicable.

The IRB Chair will be appointed by the Institutional Official. He or she will serve a three-year term with each year being a renewable contract between the individual and the Institutional Official, and he or she may be reappointed for consecutive terms. If the IRB Chair takes a sabbatical, other leave of absence, or leaves the University, the Institutional Official will appoint a replacement for the period of leave or for the remainder of the Chair's term.

B.2. Responsibilities and Actions of the IRB Chair

The Chair of the IRB is ultimately responsible for the conduct of the IRB. It is the responsibility of the Chair to coordinate all aspects of IRB functions, or to arrange for them to happen. This responsibility includes arranging for regular meetings, causing minutes to be kept, distributed, approved, and posted, arranging for appropriate

training for IRB members, consultations with PI's about current or prospective applications, and monitoring relevant federal guidelines and regulations.

B.3. Meetings and Quorums

A quorum is required to convene a meeting of the IRB. A quorum consists of at least a majority of members (or their alternates) present at the meeting, either in person or via a conference call. When members or alternates are associated with a project being reviewed, they are ineligible to vote on the project. However, the IRB may ask them to provide information about the project or they may excuse themselves from the meeting during the review. Potential conflicts of interest should be noted in the IRB meeting minutes. Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests), the IRB may not take further actions or votes until the quorum is restored. Alternate members of the IRB may be invited to each meeting and may participate in the discussion of agenda items, including reviews, although if they are not serving in a member's place, they are not be eligible to vote.

The Chair will convene meetings of the IRB for review of new applications, modification requests, continuation requests, suspension or termination of IRB approval, and IRB procedural and educational issues. The meeting schedule shall be posted on the IRB website.

B.4. Review of Research

In conducting the review of research, the IRB shall follow the regulations as stated in 45 CFR 46.109 and the University policy and procedures as described herein.

B.5. Approval of Research

In accordance with 45 CFR 46.111, the following criteria are to be met for a research project to be approved by the IRB:

- Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB considers only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB will not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research benefits that fall within the purview of its responsibility.

- Selection of subjects is equitable. In making this assessment the IRB takes into account the purposes of the research and the setting in which the research will be conducted and is particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

- Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with 45 CFR 46.116.

- Informed consent will be appropriately documented, in accordance with 45 CFR 46.117.

- The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

- There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Further, when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

B.6. Actions and Authority of the IRB

Action on any of the options listed below requires a majority vote of the quorum. Action to require revision of an application may be initiated by any reviewing IRB member upon initial review of an application if the IRB member determines that such revisions are (a) needed to determine the level of risk to subjects and/or (b) needed to complete an application.

B.6.1. Actions Regarding Approval of Applications

The IRB may reach any of the following determinations with respect to any proposed project, although generally these actions are restricted to those applications receiving full board review:

- Approve application as submitted.

- Approve pending changes. The IRB determines the changes that are required for approval and these are communicated in writing to the PI. The PI submits the changes to the IRB Chair. The Chair (or designated IRB member) may approve the application on behalf of the IRB if the changes meet the requirements described in the written communication with the PI.

- Require modifications and resubmission to the IRB.

- Request consultant review. At any point, the IRB Chair or the IRB may determine that someone not on the IRB with relevant expertise needs to be consulted to address research issues, as they relate to the protection of human research subjects. The consultant shall not be involved in the proposed project. In some cases, the identity of the consultant may need to remain confidential if there is any question that there could be problems should the PI know the identity of the consultant.

- Disapprove the application as submitted. When a project is disapproved, the PI may revise the proposal in accordance with IRB recommendations; discuss the project with the IRB Chair or respond in writing; or withdraw the proposal application.

B.6.2. Additional Actions and Authority of the IRB

- Consult with the ORA and Institutional Official concerning matters of development and implementation of policies and procedures regarding the protection of human subjects and the training of University employees and students regarding the conduct of research involving human subjects.

- Monitor projects having received a full board review for adherence to an approved protocol.

- Suspend or terminate approval of research that is not being conducted in accordance with Federal Regulations and University policy and procedures or that has been associated with unexpected serious

harm to subjects. Any suspension or termination of approval shall include a written statement of the reasons for the IRB's action and shall be reported promptly to the ORA, the PI's Department Head, and the funding agency (if applicable).

C. RESPONSIBILITIES AND ACTIONS OF THE OFFICE OF RESEARCH ADMINISTRATION (ORA)

C.1. Administrative Responsibilities of the ORA Pertinent to IRB Functions

The ORA is administratively responsible for the implementation of the assurance to the Secretary of Health and Human Services. Procedures and actions of the ORA with respect to implementation of the assurance include, but are not limited to the following:

- Assure that sufficient provisions have been made for staff and space needs in order to support the IRB's functions;
- Monitor changes in federal regulations and guidelines and propose to policies and procedures to the IRB;
- Oversee initial training and continuing instruction of IRB members, University administrators, and any other personnel for whom federal regulations and University policy requires training regarding humans subjects research;
- Provide that research covered by the regulations will be reviewed, approved, and subjected to continuing review by the IRB;
- Assure prompt reporting to the IRB, appropriate University officials, OHRP, and any sponsoring federal department or agency head of any unanticipated injuries or problems involving risks to subjects or others, any serious or continuing noncompliance with the regulations or requirements of the IRB, and any suspension or termination of IRB approval of research;
- Provide a statement of principles governing the institution in the discharging of its responsibilities in protection of the rights and welfare of human research subjects;
- Provide of a list of IRB members to DHHS, identified by the requirements contained in 45 CFR 46.103(b)(3); and
- Provide satisfactory written assurance to the Secretary of Health and Human Services that the institution will comply with the requirements as set forth in the applicable federal regulations.

C.2. Actions of the ORA upon Receipt of Notice of IRB Action from the Chair

For externally funded projects approved by the IRB, the ORA will complete any documentation required by the funding agency, and send the documentation to the proper agency.

C.3. Revisions of Policies and Procedures

The ORA, in consultation with the IRB and with their approval, may implement changes of policy and procedures for the review of research involving human subjects as may be consistent with currently applicable regulations, institutional requirements, and IRB experience. As changes occur in 45 CFR 46 and applicable portions of 21 CFR 50, they will be incorporated into University policy and procedures by reference, without requiring separate action by the ORA. When Federal agencies issues new or revised guidelines and regulations, the IRB Chair will consult with the IRB and draft a recommendation to the ORA regarding adoption. The ORA will maintain a current master copy of University policy, will provide a copy of any changes in University policy to all IRB members and alternates, and will update the IRB website. Additionally, the ORA shall determine the appropriate method of dissemination of policy and procedural changes to the University community.

D. RESPONSIBILITIES AND ACTIONS OF THE COMPLIANCE OFFICER

The Compliance Officer will be designated by the ORA. The following actions are the responsibility of the Compliance Officer:

- Retain the University's federalwide assurance, federal regulations, guidelines related to the involvement of human subjects, as well as the University's policies and procedures;
- Serve as an ex-officio member, without vote, on the IRB;
- Provide regulatory and ethical advice to PIs in preparation of application for research proposals involving human subjects and consent documents;
- Coordinate with grant and contract services regarding compliance with human subjects regulations and policy on externally funded projects;
- Arrange and oversee the training program for IRB members, IRB alternates, PIs, faculty, staff, and students on the ethical conduct of research involving human subjects;
- Educate members of the University community about changes to the IRB policy and procedures;
- Update the IRB website;
- Prepare and distribute meeting packets and agendas;
- Maintain records of IRB proceedings and decisions;
- Maintain filing system of submissions to the IRB;
- Maintain a log containing new applications, modification requests, adverse event reports, continuation requests, and completion reports;
- Assure that IRB records are being maintained appropriately and that records are accessible upon request, to authorized federal officials;
- Assure all cooperating research sites in federally supported research have appropriate OHRP-assurances and provide certification of IRB approval of proposed research to the appropriate federal department or agency;
- Report to the IRB, ORA, and Institutional Official any unanticipated injuries or problems involving risks to subjects or others, any serious or continuing noncompliance with the regulations or requirements of the IRB, and any suspension or termination of IRB approval of research; and
- Delegate responsibilities, as appropriate.

E. RESPONSIBILITIES AND RIGHTS OF THE PRINCIPAL INVESTIGATOR

E.1. Responsibilities

The PI has primary responsibility for all aspects of the protection of human subjects on a given project, including compliance with all Federal and University policies and procedures, and that all research associates involved in a PI's project also comply with said regulations, policies, procedures and guidelines.

E.2. Rights

- Applications shall be reviewed by the IRB in accordance with the ethical principles described in the Belmont Report, federal regulations, and University policy and procedures.
- When protocols are submitted, the IRB shall review the application as specified in the policy and procedures, barring any unforeseen and/or insurmountable problems.
- All decisions of the IRB shall be conveyed to the PI in writing (electronically or otherwise).
- The PI may consult with the IRB Chair or designee if he or she is unclear about the rationale for its decisions or if any questions arise at any time related to the application or approved protocol.

E.3. Responsibilities of the PI upon Leaving the University

When a PI plans to leave the University and continue the research activities at another institution, she or he must notify the IRB in writing. This will allow the IRB to close the active research file. The PI is responsible for obtaining IRB approval at the new institution. If the research project will continue at the University under another investigator, the PI must submit written notification of such changes, and the IRB will follow the review guidelines set forth in this policy.

E.3.1. Exporting Data

For the purposes of this policy, data exporting is defined as the extraction and/or compilation of data from a previously IRB-approved project. This exportation can either be when (a) the project Principal Investigator (PI), or their designee, leaves the employment of Missouri State University and wants to take the data with them for later use, or (b) when the project Principal Investigator deems it appropriate to provide the data to an individual or group that is not affiliated with Missouri State University. Under either of these conditions, the Principal Investigator, or their appropriately trained designee, may compile and prepare their data for transport elsewhere under the following conditions:

1. Only data pertaining to projects under the direction of the Principal Investigator may be mined for data
2. All data are to be thoroughly de-identified so that no participant's identity is revealed by any name, identification number, or demographic data sufficient to identify an individual
3. The PI receives approval to export data from their Department Head or Unit Head prior to extracting the data.
4. The Department/Unit Head will review all compiled data prior to final transportation
5. No original forms, surveys, samples, etc. shall leave the university; only the data therefrom shall be collected for transportation.

For more information, see *Guidance Regarding Methods for De-Identification* at http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/guidance.html

F. PROCESS FOR IRB REVIEW AND APPROVAL OF RESEARCH

F.1. Responsibilities

This section describes the three levels of IRB review for studies that involve human research subjects. These levels include "exempt," "expedited," and "full board review."

F.1.1. Exemption Certification Review

F.1.1.1. New Application

Research activities in which the involvement of human subjects constitutes no more than minimal risk and falls within one or more of the exempt categories described in 45 CFR 46.101 (see below) may be eligible for exemption certification. Research activities may be deemed exempt from this policy (but not from IRB review) if one of the following is true.

(1) Research is to be conducted in established or commonly accepted educational settings, involving normal educational practices, such as
   i. research on regular and special education instructional strategies, or
   ii. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involves 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.

(3) Research involves the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt 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.

(4) Research involves 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.

(5) Research and demonstration projects to be conducted by or subject to the approval of Official 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.

(6) 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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Only the IRB may certify that the proposed research meets the exemption criteria.

Review by only one IRB reviewer is necessary if the project is determined to be exempt by that reviewer. However, the IRB Chair, at his/her discretion, may provide a secondary review to assure project exemption. An IRB reviewer may take one of the following actions:

- Certify the research project as exempt and requiring no further IRB review, unless modifications are proposed which are outside the exemption categories. The PI is sent an exemption certification letter.

- Require additional information or modification(s). The IRB reviewer will contact the PI to request the required additional information or modification(s). If the IRB reviewer is satisfied that the protocol meets the exemption criteria, the research project is s as exempt and an exemption certification letter is sent to the PI.

- Deny exemption certification. If the protocol does not fall within one or more of the exemption categories, as deemed by the IRB reviewer, the application is considered for expedited or full review.

F.1.1.2. Modification Request

If a study is certified as exempt, the PI must request approval from the IRB Chair for any proposed modifications to the research project's protocol or informed consent or assent forms. The modifications must be approved by the IRB Chair prior to implementation.

F.1.2. Expedited Review

F.1.2.1. New Application

Research activities in which the involvement of human subjects involve no more than minimal risk and falls within one or more of the expedited review categories may be eligible for expedited review. Expedited reviews are for projects that do not meet the criteria for exempt status, and fall into one of the following categories:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
    a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
    b. Research on medical devices for which
        (i) an investigational device exemption application (21 CFR Part 812) is not required; or
        (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    a. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
    b. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be

collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
    a. hair and nail clippings in a nondisfiguring manner;
    b. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
    c. permanent teeth if routine patient care indicates a need for extraction;
    d. excreta and external secretions (including sweat);
    e. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
    f. placenta removed at delivery;
    g. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
    h. supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
    i. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
    j. sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device including studies of cleared medical devices for new indications.) are not generally eligible for expedited review. Examples:
    a. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
    b. weighing or testing sensory acuity;
    c. magnetic resonance imaging;
    d. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
    e. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:

a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
b. where no subjects have been enrolled and no additional risks have been identified; or
c. where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Only the IRB may decide whether the proposed research meets the expedited review criteria requirements.

At least two IRB members' reviews are necessary for a project to be determined expedited. Under the expedited review process, the IRB reviewers may take one of the following actions:

- Approve the research application and decide on the length of time the study is approved (one year or less); the PI is then sent a letter of approval.

- Require additional information or modifications. The IRB reviewer(s) will contact the PI to request the required additional information or modification(s). The reviewers may decide that one or both of them need to review the additional information or modifications. If the reviewers are satisfied that the protocol meets the IRB review criteria, the research project is approved for one year or less and a letter of approval is sent to the PI.

- Require a full review of the application. If the protocol does not fall within one or more of the expedited review categories, the reviewers have concerns about the rights and welfare of the subjects, or the additional information or modifications are extensive, the reviewers will forward the application for a full review. The PI will be notified in writing that a full review is required and will be informed of the reasons for this decision. Additionally, the PI may be asked to revise the application prior to distribution of the application to the full IRB.

F.1.2.2. Modification Request

The PI must request approval for any proposed modifications to the research project's protocol or informed consent or assent forms. The modifications must be approved by the IRB Chair prior to implementation. If the Chair determines that (a) proposed revisions modify subject risk significantly and/or (b) change the basic nature of the research project, the Chair will direct the PI to submit an entirely new application for consideration by the IRB.

F.1.2.3. Continuation Request

Research projects, which are approved under the expedited review process, will require continuation review at a specified interval, which will not exceed one year. If the PI fails to request a continuation or submit requested information, IRB approval will be terminated on the approval expiration date. All research activities, including data analysis, must cease, unless the IRB finds it is in the best interest of the individual subjects to continue participating in the research interventions or interactions.

F.1.2.4. Informing IRB Members of Expedited Reviews

At each regular IRB meeting, the IRB Chair will make available to the IRB a list of new research applications, modification requests, and continuation requests that have been submitted or approved through the expedited review process.

F.1.3. Full Board Review

F.1.3.1. New Application

Research activities involving human subjects in which there is more than minimal risk (which therefore does not fall within one or more of the exemption categories or expedited review categories), or involves certain vulnerable populations (e.g., prisoners) must undergo a full IRB review. The IRB college representative will recommend to the IRB Chair that a full board review is warranted. The PI is invited and encouraged to attend the meeting in which the application will be reviewed. If the PI is a student, the faculty sponsor and student must attend.

The PI is responsible for submitting the required materials to the IRB for a full board review 10 working days prior to a scheduled meeting. Submission of materials by the deadline does not guarantee the full review will be conducted at the next meeting. Reasons for delaying review until the next meeting may include an already full agenda or the protocol requires revisions prior to review. Therefore, the IRB recommends that the PI submit the materials as early as possible. If a majority of the IRB members deem it appropriate, they may waive this time period.

Under the full review process, the IRB will discuss issues pertinent to the wellbeing of potential research subjects, including issues of adequate informed consent, research designs and procedures adequate to provide safety and confidentiality, and risk/benefit ratios. The IRB may take one of the following three actions:

- Approve the research application and decide on the length of time the study is approved (one year or less from the date of the convened meeting at which the IRB reviewed and approved the proposal). The PI is sent a letter of approval.

- Require additional information or modifications. During the IRB meeting, the IRB members may ask the PI for additional information. If the PI does not have the additional information available at the meeting, the PI will forward this information, in writing, to the IRB Chair or designee, as soon as possible. Additionally, the IRB may require that modifications be made. At the conclusion of the review, the IRB will decide whether:
    - The IRB Chair or designee may review the additional information or modifications to ensure that they meet the IRB requirements and approve the application, if appropriate. If the additional information or modifications are not sufficient, the IRB Chair or designee may continue to work individually with the PI until the IRB requirements are met.
    - The IRB may require that the additional information or modifications be reviewed at the next IRB meeting. The PI would again need to be present at the meeting.

- Disapprove the research application. The PI is sent a letter describing the reasons the research application was not approved. The PI may revise the research application in accordance with IRB recommendations; discuss the reasons for disapproval with the IRB Chair or a designee; or withdraw the research application.

Projects that require full board review that are approved shall provide the IRB reports, at a timeframe determined by the IRB, about the progress of the project and about adherence to the approved project protocol. Additional information may be required by the IRB at the time the project is reviewed and approved, and shall be specified at that time.

F.1.3.2. Modification Request

The PI must request approval for any proposed modifications to the research project's protocol or informed consent or assent forms. The modifications must be approved by the IRB prior to implementation.

F.1.3.3. Continuation Request

Research projects are approved for a period of one year, unless a shorter interval is specified by the IRB. All projects that continue beyond the approved timeframe shall submit (a) an IRB application cover sheet indicating the PI, the project title, and that a continuation is requested, and (b) a brief statement about any changes or modifications to the protocol since originally approved. This should be certified by the PI and his/her department head, and submitted directly to the IRB Chair (or designee) for review. The IRB Chair, or designee, may approve the continuation. If modifications have been made since the original approval that either significantly change the project or significantly increase subject risk, then the IRB Chair (or designee) may inform the PI that submission of a completely new application is required. This application will then be reviewed as a new application (see section F1.1.1, F1.2.1, or F1.3.1). If modifications are approved, then the IRB Chair (or designee) will notify the PI of the approval.

If the PI fails to request a continuation or submit requested information, IRB approval will be terminated on the expiration date. All research activities, including data analysis, must cease unless the IRB finds it is in the best interest of the individual research subjects to continue participating in the research interventions or interactions. A notification letter will be sent to the PI and, if appropriate, the funding agency.

F.2. Length of IRB Approval

Typically, the IRB approves a research study or continuation request for up to one year. However, approval may be granted for less than one year in some circumstances, which may include, but are not limited to, high-risk protocols, projects involving unusual types of risk to subjects, projects involving vulnerable subjects (e.g., prisoners), and projects conducted by a PI who has previously failed to comply with IRB requirements.

F.3. Verification of Sources Other than the PI

Some projects may require verification from sources other than from the PI that no material changes have occurred since previous IRB review. The criteria for determining which studies may need outside verification include, but are not limited to: complex projects involving unusual levels or types of risk to subjects; projects conducted by PIs who previously failed to comply with 45 CFR 46 or the requirements of the IRB; and projects where concern about possible material changes occurring without IRB approval have been raised based on information provided in continuing review reports or from other sources.

F.4. Preparation of Public Use Data Files

Many funding agencies require or recommend that projects produce public use data files. If the PI knows that a public use data file will be created, he or she must indicate this in the initial application form. Once the project is completed, the PI shall submit the proposed public use data file to the IRB for inspection. The funding agency may provide guidance in creation of public use files. The PI should provide this information to the IRB when submitting the protocol to prepare a public use data file. If the PI does not initially plan to develop a public use data file, once the determination to develop a public use data file is made, he or she will need to submit a modification request to the IRB.

For the IRB to classify the file as a public use data file, one of the two following situations must apply:

- The data were anonymous when originally collected or data were collected from unknown persons.

- The data were collected from identified persons, but the file has been stripped of individual identifiers and any other information that may risk disclosure of any subject's identity.

When data have been collected from identified persons, the PI must consider the following elements in determining whether he or she has properly addressed the risk of disclosure of subjects' identity:

- All individual identifiers of each human research subject or any person named by any human research subject must be removed.

- All variables that can be surrogates for individual identifiers (e.g., street address of subject) must be removed.

- To remove the possibility of identification when a human research subject is in a small subgroup within the sample, it may be necessary to collapse or combine categories of a variable. For example, detailed breakdowns of religious denomination in a survey question, or medical procedure codes may need to be collapsed into fewer categories.

- Delete or mask, as described above, any variable that a secondary user may employ to identify any research subject. For example, the PI may need to assign a new subject ID to each individual if the original subject ID contained identifying information, such as letters from the last name or part of the date of birth.

- Use statistical methods to add random variation to variables that cannot otherwise be masked. For example, a data file may contain a combination of public and private information on a relatively small sample, perhaps demographic characteristics and salary of a public official, along with attitudinal information. The income variable may need to be altered so that it cannot be combined with the demographic characteristics to enable identifying the individual and thereby risking disclosure of private information. This option should be used only if other techniques do not work, because it may compromise the integrity of the data.

G. PROBLEMS INVOLVING RISK, ADVERSE EFFECTS, AND NONCOMPLIANCE

G.1. Guidelines for Defining Problems to be Reported

Unanticipated problems involving risks to subjects or others and adverse effects need to be reported to the IRB. Adverse effects may be directly or indirectly related to the research and may be expected or unexpected.

The following examples illustrate what needs to be reported:

Unanticipated problem involving risk to subjects: The laptop computer which has identifying information about research subjects is stolen.

Unanticipated problem involving risk to others: The research assistant involved in the project is inadvertently exposed to a low level of radiation.

Expected adverse effect: Subject A becomes upset when asked about feelings regarding prior sexual abuse. The subject is referred for counseling.

Unexpected adverse effect: Subject B becomes agitated and angry when asked general non-invasive questions about the appropriateness of corporal punishment of children. The subject is referred for counseling.

Reports of adverse events must be reported immediately via phone, email, or in person to the IRB Chair or to the Office of Research Administration. A written report of the adverse event must then be submitted to the IRB Chair and ORA, within 5 working days after first awareness of the problem.

G.2. Guidelines for Defining Noncompliance

Noncompliance includes, but is not limited to:

- Misuse or nonuse of approved informed consent procedures
- Failure to submit protocols in a timely manner
- Breaking confidentiality, unless required by law (e.g., child abuse)
- Unapproved subject recruitment activities
- Failure to secure confidential records in the required manner
- Failure to report problems involving physical or psychological injury to subjects or others
- Failure to report risks to subjects or others that exceed the protocol as approved
- Report from a subject of abuse by the PI or research staff
- Conducting research involving human subjects that has never been approved by the IRB
- Initiating changes to research protocols involving human subjects without prior IRB approval
- Continuing research activities beyond the IRB approved end date

Even though these types of events must be reported, the PI is encouraged to contact the IRB Chair and ORA if anything occurs that causes concern regarding the protection of human subjects.

G.3. Reporting of Problems or Noncompliance by the PI

The PI must contact the IRB Chair via phone and/or e-mail immediately following an incident of injury, increase in risk, unanticipated risk, other adverse effects experienced by subjects or others involved in research, or incident(s) of noncompliance. Additionally, the PI must submit a written report of the incident to the ORA, care of the IRB Chair, as soon as possible thereafter, but no later than 5 working days after first awareness of the

problem. If the incident is severe or increases the risk to subjects or others, the PI may be asked to suspend research activities pending further review by the IRB and/or ORA.

G.4. Investigation of Problems and Noncompliance

If any member of the IRB receives information about injuries to subjects, unanticipated problems involving risk to subjects or others, or serious noncompliance, through a source other than the PI or co-PI, he or she will immediately inform the IRB Chair and ORA. The IRB Chair may temporarily suspend IRB approval for a study, pending investigation by the ORA and further IRB review, after learning of the problem, adverse effect, or noncompliance.

A subcommittee of the IRB consisting of the IRB Chair, an IRB member or alternate who is the community representative, and another IRB member, who holds tenure and is outside the PI's department, will investigate the allegation of a problem involving risk to subjects or others, an adverse effect, or noncompliance. The IRB Chair will request an interview with the individual(s) alleging the problem, adverse effect, or noncompliance. The IRB Chair will share the results of this interview or written correspondence with the other members of the ad hoc committee, and they will decide how to proceed. The IRB Chair will notify the PI in writing within 5 working days that an allegation of problem, adverse effect, or noncompliance was received. Following the interview or upon receipt of a written allegation, the IRB Chair will request an interview with the PI and any other researchers involved, in order to assess the situation, require changes in the protocol, if necessary, and resolve the issues without further official action. The committee members will decide if both need to be present at the interview with the PI and other researchers involved. If the ad hoc committee members are not satisfied with the results of the initial interview with the PI, they may expand the investigation. The ad hoc committee members may interview the research staff and any other persons who have relevant information, including research subjects. The committee will produce written summaries to the interviewed parties for comments, and written comments received will be included in the record of the investigation.

The committee will prepare a report which includes a description of the investigative activities, how and from whom information was obtained about the problem(s), a list of those interviewed, a summary of records obtained, findings, basis of findings, and actions taken. Before the report is shared with the IRB, identifying information which may put the individual making the allegation at risk may be removed. The final report, which contains all identifying information, will be filled with confidential project records.

The PI's Department Head, other appropriate University administrative officials, OHRP (if applicable), and funding agency (if applicable) officials will be notified if problems are confirmed by the ad hoc committee.

G.5. Suspension or Termination of Approval of Research Activities

The IRB Chair may suspend a study at any point after receiving information regarding unacceptable and uncorrectable levels of risk or harm to the subjects or others or serious disregard on the part of the researcher to the policy and requirements of the IRB. The Chair will promptly notify the PI(s), as well as the ORA, in writing of this decision and the reason(s) for suspension of approval. The ORA will notify OHRP and funding agency (if applicable) of the suspension or termination of approval.

Furthermore, the IRB Chair will convene a meeting of the IRB to discuss the suspension of IRB approval and the IRB will decide whether:

1. IRB approval should be reinstated with or without modifications,
2. Suspension of IRB approval should be continued, or
3. IRB approval should be terminated. The PI will be informed, in writing, of the outcome of the IRB meeting.

G.6. Reporting of Problems or Noncompliance

The IRB Chair will keep the ORA informed of reports by PIs or others of unanticipated problems involving risk to subjects or others, adverse effects, serious or continuing noncompliance, and suspension or termination of IRB approval. The ORA will notify appropriate PIs Department Head, University administrative officials, OHRP (if applicable), and funding agency (if applicable) of unanticipated problems involving risk to subjects or others, unanticipated adverse effects, serious adverse effects that may have been expected, serious or continuing noncompliance, and the IRB suspension or termination of approval for research activities.

H. CONFLICTING INTERESTS

Several types of conflicting interests may arise in conducting research. Project personnel must report all such real or potential conflicts to the PI. The PI is responsible for making certain that no project personnel perform research tasks if there is likely to be a conflicting interest.

Conflicting interests apply to both funded and non-funded research. 45 CFR 46 does not directly address conflicts of interest, but the IRB is required to determine that information provided to potential and actual subjects regarding the research is objective and complete regarding the risks and benefits. It is also required to determine whether risks of the research have been properly addressed in the protocol. If conflicting interests exist, then such objectivity and handling of risks can be compromised.

Such potential conflicting interests include, but are not necessarily limited to those discussed below.

H.1. Financial Conflict of Interest

Federal policy covers Financial Conflicts of Interest in Research that is funded by DHHS, FDA, and NSF, among others. Disclosure of any such conflicts must be made in writing. The ORA has final responsibility to assure compliance with University policy and state and federal regulations regarding financial conflicts of interest.

H.2. Intellectual Property

All investigators must adhere to the University's policy regarding intellectual property claims (see the Policy Library and the *Faculty Handbook*).

H.3. Conflicts of Commitment

Conflicts of commitment arise when an investigator's time or other commitments to a project cannot be honored because of other existing commitments to the University. All investigators must avoid such conflicts that may arise due to the conduct of a research project.

H.4. Dual Relationships

Dual relationships exist whenever one role of the investigator calls into question his or her ability to be objective about fulfillment of another role. While such dual relationships may involve financial conflicts of interest, many do not.

The most common situations are likely to be those in which faculty recruit students for research projects. Faculty must not recruit students from their own classes, unless the IRB grants approval for doing so. See Section O of this policy for a more detailed discussion of students as research subjects.

I. COOPERATIVE RESEARCH

Cooperative research projects are those projects which involve more than one institution. The official relationship between the two institutions is not relevant. Each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with federal regulations and institutional policies. See 45 CFR 46.114 for more information.

PIs at Missouri State who are conducting research at another institution are required to abide by Missouri State requirements, as well as the requirements of the other institution. For studies funded by DHHS the PI is responsible for ensuring all data collection sites within the cooperative research protocol have an approved DHHS assurance (e.g., federalwide assurance), and each will review the research protocol separately.

When Missouri State is considered to be "engaged in research" (see OHRP guidance document "Engagement of Institutions in Research," January 26, 1999) but the PI is not associated with Missouri State (that is, for instance, when an outside group desires to collect data at Missouri State and has a local contact for doing so), the PI must submit the following for review by the IRB: an application cover sheet and completed protocol; a letter of support from the involved faculty member at Missouri State who will sponsor the project, and a letter of approval from the PI's IRB, unless the PI's institution does not have an IRB. If the PI's institution does not have an IRB, then they will be required to submit a full application to the IRB at Missouri State. The IRB will then complete the appropriate review process, based on the nature of the research project. Missouri State may choose to rely more heavily on the review of the PI's Institutional IRB. However, this does not relieve Missouri State's IRB from reviewing the project as outlined above, although an authorization agreement may facilitate projects.

When Missouri State is not "engaged in the research," the unaffiliated PI needs to obtain IRB approval at his or her institution and secure permission from any Missouri State official that may need to provide access to research subjects or data. The unaffiliated PI must follow all applicable Missouri State policies and procedures to conduct the study at Missouri State. Relevant policies and procedures may include, but are not limited to: Computers/Networks (Mass Email) policy and Advertising, Distribution, Solicitation and Facilities Usage policy.

I.1. Single IRB Approval

In situations in which faculty member is participating in a larger, multi-site research project, or where a faculty member is sponsoring a student who is a member of another University, AND where the research project in question has already been approved by another reputable IRB, the Missouri State University IRB may grant a "single IRB approval" to such a project conducted at Missouri State. Separate application forms for such projects are available through the Office of Research Administration website and require a simplified application which includes a copy of the IRB approval letter from the other involved institution. This application is then submitted to the Chair of the Missouri State University IRB for review and disposition.

J. INFORMED CONSENT

J.1. Informed Consent Requirements

Informed consent is an ongoing process, not just a form that is signed. Informed consent assures that potential subjects understand the nature of the research project and can make an informed, voluntary decision about participating or not participating. The language used to present the information needs to be appropriate for the targeted subject population. Researchers should keep in mind that (a) individuals should be provided with enough information about a study and what it requires of them to be able to make a truly informed choice, and (b) individuals have the right to participate or not participate in a study and those who decide to participate may withdraw their consent from the study at any time for any reason, without incurring negative consequences.

The process of obtaining informed consent must comply with the requirements of 45 CFR 46.116. Documentation of informed consent must comply with 45 CFR 46.117. The PI is responsible for ensuring that informed consent is obtained in writing from the subject or the subject's legally authorized representative (e.g., parent or legal guardian), is understandable to the subject (or representative), is obtained in circumstances that are not coercive and that offer the subject (or representative) sufficient opportunity to decide whether he or she will participate. If any subjects are members of vulnerable populations, 45 CFR 46 Subpart B, Subpart C, and Subpart D describe additional informed consent requirements.

The informed consent process and documents in research studies that involve health information may need to include statements that meet the requirements of Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The informed consent form may not include exculpatory language in which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the PI, sponsor, or institution (or its agents) from liability for negligence.

The IRB may approve a consent procedure which does not include some or all of the elements of informed consent as noted above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

1. the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
    a. public benefit or service programs;
    b. procedures for obtaining benefits or services under those programs;
    c. possible changes in or alternatives to those programs or procedures; or
    d. possible changes in methods or levels of payment for benefits or services under those programs;
2. the research could not practicably be carried out without the waiver or alteration.

The IRB may waive the requirement for a signed informed consent form if the following requirements are met:

1. the research involves no more than minimal risk to the subjects;
2. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. the research could not practicably be carried out without the waiver or alteration; and
4. whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Informed consent procedures must be delineated in the procedures portion of the application to the IRB. Any waivers to the procedure or documentation must be requested, as well (as per stipulations noted above). For studies in which the documentation of informed consent is waived, a letter of invitation to participate, which includes the elements of informed consent, may be appropriate.

J.2. Alterations to the Informed Consent Procedure

Federal regulations on informed consent do allow for modifications in the consent procedures and, under certain circumstances, informed consent may be waived entirely if the research meets certain conditions (as noted above) [see 45 CFR 46.116(c)(d)]. Note that such modifications and waivers are not allowed under FDA regulations. See 45 CFR 46.116(c)(d).

J.3. Alterations in the Documentation of Informed Consent

Typically, informed consent must be documented through the use of a written informed consent form that has been approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy

should be given to the individual signing the form. However, documentation of informed consent may be waived in some circumstances. See 45 CFR 46.117(c) and the above exceptions for more information.

J.4. Research Involving Children

Research projects involving children as subjects typically require the written permission of one or both parents [see 45 CFR 46.408(b)] or guardian in accordance with the informed consent procedures delineated in the informed consent requirements (Section J.1). In addition to parental or guardian permission for a child to participate in a research study, the assent of the child must be solicited, assuming the child is capable of providing assent. To make this judgment, the IRB will consider the age, maturity, and psychological state of the targeted child population. Even if the children are capable of providing assent, the IRB may waive the assent requirement when consent requirements are waived (see CFR 46.116).

Typically, parental or guardian permission must be documented. However, a PI may request a waiver of the documentation of informed consent based on 45 CFR 46.117(c) (see above noted exceptions for more details). Additionally, the IRB may determine that parental or guardian permission is not a reasonable requirement to protect subjects (e.g., neglected or abused children) and it may waive the consent requirements, provided that an appropriate mechanism for protecting the children who participate as subjects in the research is substituted and the waiver is not inconsistent with federal, state, or local law [45 CFR 46.408(c)]. If a PI requests a waiver, they must present compelling evidence for such a waiver.

K. PROTECTION OF CONFIDENTIAL INFORMATION

The PI is responsible for ensuring the privacy and confidentiality of all personally identifiable information from research subjects, except as required by law (e.g., child abuse) or allowed with written permission of the research subject. This information may be contained in either electronic or hard copy formats. When appropriate, the informed consent document should outline those conditions under which data are not considered confidential (e.g., child abuse). Data collection and storage, and safeguards to ensure confidentiality must be delineated by the PI in the procedures portion of the application to the IRB.

K.1. University Access to Confidential Records

The University has the right of access to the supporting records for all research at the University or supported by University-sponsored funds, provided such access to the records shall be for reasonable cause, at reasonable times, and after reasonable notice. The University's right of access to the data shall continue regardless of the location of the responsible investigator. Information or data that would violate the confidentiality of sources or subjects involved in the research should not be disclosed. Extramural sponsors providing support for research at the University may also have the right to review the data and records resulting from that extramural support. Co-investigators and trainees who are an integral part of a research project have the right to review all records and data which are part of that project.

K.2. Other Regulations Related to Privacy, Confidentiality, and Consent

In addition to 45 CFR 46 and FDA regulations (21 CFR 50), other federal regulations may apply to research involving human subjects.

K.2.1. Privacy Rule under the Health Insurance Portability and Accountability Act of 1996 (HIPAA)

The Privacy Rule, a Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996, regulates the way covered entities handle individually identifiable health information known as protected health information (PHI). The Privacy Rule itself applies only to covered entities, not to research itself; however, the Privacy Rule may affect researchers because it establishes the conditions under which covered entities can use or disclose PHI for research. Missouri State is a hybrid entity, which means that some units are covered under HIPAA, while other units are not. The Privacy Rule does not directly regulate researchers who are engaged in research within units that are not part of the covered entities, even though they may gather, generate, access, and share personal health information. The Privacy Rule is in 45 CFR Part 160 and Subparts A and E of Part 164. PIs planning to engage in physical or medical health related research that is covered under the Privacy Rule are advised to begin consultation with the covered entity early in the research design process.

K.2.2. Family Education Rights and Privacy Act (FERPA)

The Family Education Rights and Privacy Act (FERPA) is a federal law (20 U.S.C. § 1232g; 34 CFR Part 99) that applies to educational agencies and institutions that receive federal funds under any program administered by the Secretary of Education. FERPA gives parents certain rights with respect to their children's education records. These rights transfer to the student when he or she reaches age 18 or attends a postsecondary school. Students to whom the rights have been transferred are "eligible students." Generally, schools must have written permission from the parent or eligible student before releasing any identifiable information from a student's education record. The consent must specify the records that may be disclosed, state the purpose of the disclosure, and identify the party to whom the disclosure may be made. FERPA does, however, allow schools to disclose records to organization(s) conducting studies for, or on behalf of the school, in order to develop, validate, or administer predictive tests; administer student aid programs; or improve instruction. Additionally, schools may disclose, without consent, "directory" information, unless specifically directed by parents or eligible students not

to disclose directory information about them. PIs are encouraged to consult with the school early in the research design process regarding the need to obtain consent for educational records.

K.2.3. Protection of Pupil Rights Amendment

The Protection of Pupil Rights Amendment (PPRA) is a federal regulation (20 U.S.C. § 1232g; 34 CFR Part 99) that was amended by Congress in 2001 by the No Child Left Behind Act regulates survey research in schools. Schools and contractors must obtain prior written parental consent before minor students are required to participate in any U.S. Department of Education funded survey, analysis, or evaluation that reveals information concerning the following: political affiliations or beliefs of the student or the student's parent; mental and psychological problems of the student or the student's family; sex behavior or attitudes; illegal, anti-social, self-incriminating, or demeaning behavior; critical appraisals of other individuals with whom respondents have close family relationships; legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers; religious practices, affiliations, or beliefs of the student or student's parent; or income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program). Additionally, local educational agencies or institutions that receive funds under any program administered by the U.S. Department of Education are required to develop and adopt policies concerning parents' rights to inspect, upon request, any survey created by a third party before the survey is administered or distributed by a school to students and provide parents the opportunity to ask that their child not participate. PIs are encouraged to consult with the school early in the research design process regarding how PPRA may impact the research protocol.

L. INTERNET RESEARCH

Research using the Internet has unique characteristics that are not directly addressed by the Federal regulations. Currently, the Internet is used primarily for two research activities – recruitment of subjects and survey administration. Most human subjects protection issues that arise in conducting research activities on the Internet concern privacy/confidentiality and true informed consent. The ability to consent is difficult to ascertain over the Internet. Generally, this ability is related to age, but may be relevant to other vulnerable populations (e.g., decision ally impaired, incarcerated). Also, email-based activities are far less secure than website-based activities. Software exists to enhance the privacy of both types of activities. The University strongly recommends that researchers work with a vendor that specializes in Internet-based research to minimize risks in these areas.

Internet-based studies may not include minors as subjects unless the IRB waives written parental permission and informed consent.

Whether the purpose is recruitment, survey administration, or some other purpose, Internet-based materials must include the following items, to the extent applicable. These items are to be included in addition to all information that is normally required for informed consent:

1. addresses of the investigator and IRB Chair;
2. no claim about the superiority, safety, or effectiveness of procedures, interventions, devices, or any other materials used in research;
3. a description of the process for completing the on-line research activity;
4. information on subsequent contacts that will be made if the individual agrees to participate;
5. no promise of anonymity and why;
6. information regarding procedures for protection of information that the subject provides over the Internet;
7. a statement that there will be no future email contacts or an opt-out message that permits individuals to have their names removed from any future mailings. If future contacts are planned, the information must state the number and frequency of such contacts;
8. instructions to delete the email message that originated the contact

After reading information about the study, the individual must be required click a button either to indicate his or her wish to continue or to leave the site and opt out of participation. After clicking the button, the subject will be taken via a link to the study task. If the individual opts out, clicking the button will exit the site.

Generally, Internet-based surveys do not require written documentation of consent. If the IRB does require such documentation, the following additional procedures must be used:

1. The “agree to participate” button must contain a message, or there must be a separate statement right above the button, that indicates that clicking the button means the subject has read the statement, printed a copy for his or her files, and agrees to participate in the study or be considered for recruitment for the study and accepts that personal information will be electronically supplied to the researcher to document his or her participation (such as name, e-mail name, and date).

2. There must be a mechanism by which information is returned to the researcher that identifies the person who is participating. This documentation must be kept by the researcher for at least three years beyond the end of the study.

The following apply to all types of study materials:

1. Individuals must be able to easily print a readable copy of information about the study and the informed consent documentation (if required) for their own records.

2. The printed version of all information must carry the approval date and the date approval expires for the study as determined by the IRB.

3. The IRB must be able to access the document on-line before approval will be given.

M. HUMAN SUBJECTS PROTECTION IN FIELD RESEARCH

Field research typically involves observation of and interaction with individuals and groups in their own environment, often over long periods of time. It also includes other types of generally qualitative activities that fall under the definition of research, such as interview conducted for historical or biographical research and archival research on identifiable living individuals. Interviews by journalists conducted solely for the purpose of writing an article in a newspaper, magazine, or other media outlet are not considered research and do not require IRB review.

It may not be possible to specify in an informed consent statement the detailed description of the research protocol, as the research itself may involve interactions between the researcher and subjects that evolve over time. Likewise, differences in language, culture, or the nature of the subjects or topic may preclude the use of a written informed consent document. If appropriate justification is given, the IRB may waive the requirement for some or all of the informed consent requirements or the requirement to obtain signed informed consent in certain situations; 45 CFR 46.116(c) and (d) describes the circumstances in which waiver is possible. The investigator should request such a waiver from the IRB if he or she determines that it is appropriate. The IRB will make the final determination. In addition, the sensitive nature of some field research may make it advisable for the investigator to consider obtaining a Certificate of Confidentiality.

Investigators conducting field research should consider guidelines developed by a relevant professional association, such as the American Anthropological Association, the American Historical Association, or the American Sociological Association, when designing their protocols.

N. OTHER STUDIES INVOLVING HUMAN SUBJECTS

This section sets out policy for conducting other types of studies that include human subjects, but do not meet the Federal definition of research.

N.1. Student Projects

Generally both graduate and undergraduate student research involving human subjects is either in the form of class projects or independent directed research projects. The type of review required is determined by whether the research projects are intended to contribute to generalizable knowledge. Student projects involving human subjects that fall into the following categories always require IRB review and approval or exemption certification, as described in previous sections of this policy.

- Thesis and dissertation
- Projects undertaken with the intent of presenting findings at a conference (including Missouri State or other University-affiliated undergraduate or graduate research presentation venues)
- Projects undertaken with the intent of publication, including publication on the Internet.

Many courses include projects that are designed to train students in research methods such as anonymous surveys, oral histories, field work in cultural anthropology, clinical interns practicing diagnosis, and program evaluations conducted in connection with a student internship. Many independent directed research projects may have these same goals. While these projects do not normally require IRB review, they are subject to and require faculty oversight.

Class projects and independent directed research projects not designed to contribute to generalizable knowledge do not require IRB review unless the proposed research places the subjects at more than minimal risk, usually evidenced by one or more of the following:

- Subjects are members of a vulnerable population (as defined in University policy).
- The study asks identifiable subjects about illegal activities (e.g., underage drinking), which may place the data at risk of subpoena.
- The study places identifiable subjects at risk of a breach of confidentiality that may lead to criminal or civil liability, or damage the subject's financial standing, employability, or reputation [45 CFR 46.109(b)(3)].
- The study places subjects at more than minimal risk due to psychologically sensitive subject matter (e.g., interviews covering traumatic events).

N.1.2. Sponsor Responsibilities in Student Projects

All student projects must have a University faculty/staff sponsor. For class projects, this is usually the instructor. The instructor should supervise the student researcher sufficiently to assure the protection of human research subjects in accordance with ethical standards of the relevant discipline.

All faculty members or staff who supervises any type of student project using human subjects must be trained in accordance with University policy, as do the students involved in the research and any student assistants involved in these projects.

The instructor is responsible for determining whether the proposed study is designed to contribute to generalizable knowledge and is subject to IRB review. If so, the instructor (i.e., faculty sponsor) must assist the student in preparing the application for review. If in doubt, instructors are always welcome to contact an IRB representative for consultation.

Even though IRB review may not be required for some student projects, these projects must communicate applicable elements of informed consent (e.g., institutional affiliation of researcher, risk, benefit, voluntary participation, permission to withdraw, etc.) and include appropriate anonymity and confidentiality protections. The sponsoring instructor is both ethically and legally responsible for the protection of subjects.

Before conducting research, students must be taught about the ethics of conducting research with human subjects. Instruction should, at a minimum, include information on the purpose of the IRB, the informed consent process, and the principles set forth in the *Belmont Report*. The instructor may require the student to complete the training program(s) offered by Missouri State and required of other researchers. The IRB advocates that departments use this training program in research methods courses as the mechanism to insure that students have been properly instructed in the protection of human research subjects.

The instructor must investigate any problem reported by the student. If any harm to a subject has occurred, the instructor must report in writing to the IRB immediately and have the student cease research activities until a decision is made regarding continuation of the project.

N.1.3. Student Research Responsibilities

Students must conduct only the activities approved by the instructor. Activities must be conducted in accordance with the principles set forth in the *Belmont Report* and University Policies and Procedures.

Students must report to the instructor any problems that arise regarding human subjects.

N.2. Institutional Research

Data collected or studies conducted for purposes of providing information to the University, any unit within the University, or any other organization (e.g., accrediting agency), with the purpose of addressing issues deemed important to University operations is considered to be institutional research. Studies of this nature do not require IRB review. If information collected is intended for further or wider dissemination within the University or to other organizations, for publication (including Internet), or involves more than minimal risk, it requires IRB review.

When IRB review is not required, institutional research projects or other activities must still communicate applicable elements of informed consent (e.g., purpose, risk, benefit, voluntary participation, permission to withdraw) and include appropriate anonymity and confidentiality protections.

N.3. Other Projects

The primary types of projects included in this category are program evaluations, policy analyses, or quality assurance studies conducted for the purpose of providing information only to the organization studied. Such studies do not require IRB review if they involve no more than minimal risk as defined in Federal regulations and University policy and do not involve vulnerable populations. Any such project conducted with the intent of further dissemination of results meets the definition of research according to federal and University policy and requires IRB review.

When IRB review is not required, such projects must still communicate applicable elements of informed consent and include appropriate anonymity or confidentiality protections.

N.4. Publicly Available Data

Many private organizations and public agencies make individual level data available to the public. Such files fall outside the federal regulations for the protection of human subjects, once they have been classified as public use data files. Not all publicly available data, however, has been classified as public use.

To classify files as public use, producers and suppliers of such files are responsible for having the data reviewed by the appropriate IRB before making them available to the public. Information to this effect should be indicated on the documentation supplied with the file.

PIs do not need to obtain IRB approval to use public use data files nor do they need to seek IRB review of the exemption status of the data. Where applicable, such information has already been reviewed for the protection of human subjects and the files produced have been certified not to violate confidentiality.

If University PI plans to obtain individually identifiable data (from the sponsor of the public use data file or any other source) and merge with the public use data file, the University investigator must seek IRB approval.

If the public use status cannot be ascertained from the documentation supplied with the file, the University PI must contact the supplier to ascertain the public use status of the data. If this status cannot be ascertained and provided to the PI in writing or if the data are not classifiable as "public use," then the University PI must submit an application for IRB review. For example, this situation may occur when an investigator receives permission from a PI at another University to use data produced from a research project that is ongoing.

In addition to data files, any published hard copy or electronic documents (including web pages) available to the public that contain individual data (whether identifiable or not identifiable) fall outside federal regulations for the protection of human subjects. PIs do not need to obtain IRB approval to use such information nor do they need to seek IRB review of the exemption status of the data.

O. TRAINING

O.1. Who Must be Trained?

The University's assurance with the OHRP requires certification for all IRB members and alternates, and all individuals affiliated with the University (faculty, students, and staff) who conduct research involving human subjects. This assurance also requires that the University provide continuing education on research with human subjects.

The training requirements discussed herein cover all funded and non-funded projects that include human subjects. Research involving human subjects refers to those project in which, "… 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)
This policy covers all proposed and ongoing projects submitted to the IRB for approval, regardless of the level of review required (i.e., full, expedited, exempt).

O.2. When Training Must Occur

Training of all University-affiliated individuals (faculty, students and staff) must be completed before the project or renewal is approved. In addition, funding agencies may require completion of training before funds are approved or released, and may have training requirements that exceed the University's. The PI is responsible for adhering to both Missouri State's and the funding agency's training policies.

Initial certification is valid for three years. All investigators and current research staff/students trained must renew certification every three years while working with human subjects. All IRB members and alternates must complete the certification when first appointed to the IRB; furthermore, they must participate in continuing education through IRB meeting activities.

Researchers may be recertified at any time within their three year certification period before the expiration of certification. Recertification of all investigators and research students/staff must occur before the IRB can renew approval of a project.

P. STUDENTS AS RESEARCH SUBJECTS

Students are often used as subjects in research studies, by University student, faculty, and staff researchers as well as researchers from other universities and organizations. Because of their unique position, University policy addresses several issues pertaining to the use of students in research projects.

P.1. Types of Activities Covered by this Section

Some course work involves research-type activities that serve an entirely pedagogical purpose. For example, professors may have students administer surveys or psychological instruments to each other in class so that they can practice interviewing techniques. These activities are NOT considered research (as defined by Federal regulations or this policy), and do not require IRB review. Projects in which students include other students in studies that are not designed for use beyond a course are not considered research as defined by federal regulations or this policy (i.e., results are not shared outside the classroom and data do not contribute to "generalizeable knowledge")(e.g., administering an anonymous survey to students in the dining hall regarding food service, the data from which is only used in the pertinent class). These studies may, however, require review and approval by other parts of the University administration. It is the investigator's/course instructor's responsibility to determine what policies and regulations apply to their situation.

Research involving normal educational practices typically falls under an exempt review category under 45 CFR 46.101(b)(1) and must be submitted to the IRB for exemption certification. Informed consent procedures must be followed. In many such cases, students cannot opt out of participation in the intervention, because the intervention may be the pedagogical techniques routinely used in the class. In such studies, the instructor should provide information on the research at the beginning of the course. This information should offer the student the option to refuse to have his or her information (e.g., grades) included in the study. If the study is conducted at another school (e.g., student teaching assignment), informed consent must be obtained in accordance with the rules of that school, as well. In these studies, the informed consent must include a contact person to address questions regarding the study who it not the instructor or graduate assistant assigned to the course.

Research that is exempt under 45 CFR 46.101(b)(2) and (3) and all non-exempt research must follow the recruitment and protection policies set forth in this section.

P.2. Recruitment of Students for Research Studies

This section discusses three distinct groups of students – a PI's current students, other University students, and students at other schools who are subjects in University studies.

University policy regarding protection of human subjects must be followed with all students, whether they are University students or students at another school. Additional protections are required when the potential research subjects are a PI's current students. A PI's current students include those at University or at any other location(s) where the person teaches under the auspices of the University (e.g., student teaching, prison-based courses).

The University does not normally allow students to participate in a research study conducted by a PI from whom they are currently taking classes except under the exemption categories [45 CFR 46.101(b)(1)]. This practice is used to minimize any possible explicit or implicit coercion, and maximize the possibility of having true informed consent, without duress. If the nature of the study or other circumstances makes it impossible to conduct the study without using one's own students, the IRB may consider exceptions on an individual basis.

The preferred method is to have data collected by an independent third party (e.g., colleague in own or other department), in such a way that the instructor does not know the identity of the subjects and does not have

access to identifiable data until final course grades have been assigned and entered. If data are collected in the classroom, the instructor shall not be present. The third party cannot be a graduate assistant assigned to the course, but may be a graduate assistant who works on the study. This method should be used wherever feasible, even if the information from the students is anonymous (e.g., anonymous self-administered survey).

The University discourages situations that allow a student to enter the faculty researcher's class while that student is participating in the faculty member's research project. While this may not be avoidable (e.g., due to scheduling of courses in a student's major), special care must be taken to follow the rules discussed above.

P.3. Awarding Credit for Participation in Research Studies

Researchers may award course credit or extra credit for participation in research if and only if another opportunity to earn the same amount of credit is available to students who decline to participate. The amount of work required to receive the credit must be similar to that required for participation in the study. For example, if the study consists of completion of an approximately 30-minute survey, then the extra credit for non-subjects should require a task that takes about the same length of time.

The informed consent process must explicitly state how much extra credit is to be awarded and at what point. Informed consent must indicate how or whether extra credit will be awarded if the student withdraws from the study before completion. The University generally favors awarding extra credit if a student withdraws, unless the withdrawal is immediate (e.g., before the intervention or experiment begins) or unless there is ample evidence of bad faith on the part of the student. If the student disputes awarding of credit in an approved study, he or she may appeal to the department head, whose decision is final. If the department has a different policy regarding handling of disputes over the awarding of credit for research project participation, then the University's policy takes precedence.