Mansfield University

Institutional Review Board

Policies and Procedures

Table of Contents

Definitions and Abbreviations

CFR: The Code of Federal Regulations (CFR) is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. The CFR is divided into 50 titles which represent broad areas subject to Federal regulation. The Mansfield University IRB Guidebook refers to CFR sections at times, and provides links to the online location of the pertinent information. The main page for the CFR online may be located at http://www.access.gpo.gov/nara/cfr/cfr-table-search.html

Research means systematic investigation designed to develop or contribute to generalizable knowledge. Under this definition some demonstration, service and training projects may be considered to include research activities.

Human Subject is defined in 45CFR46 as a living individual about whom an investigator conducting research obtains (a) data through intervention or interaction with the individual or identifiable, private information. While the term "subject" has some negative connotations, it has been used in this document for purposes of consistency with federal regulations.

Private information includes information about behavior that typically occurs in a context in which an individual can expect that no research observation or recording is taking place and/or information which has been provided for specific purposes by an individual and which that individual can expect will not be made public, e.g., a medical record. If there are limitations on the degree to which privacy may be maintained, the limits of such protection will be made explicit during the informed consent process.

Minimal Risk means that the risks of harm anticipated in the proposed research are not greater in either probability or magnitude than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Informed consent means the knowing, legally effective consent of any individual or the individual's legally authorized representative. Such consent can be obtained only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate without coercion or undue influence. The nature of the information presented and the means of securing consent must be clearly understood by the potential subject. Informed consent is a process. A written informed consent documents this process but cannot serve as a substitute for it.

Legally Authorized Representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the research procedure(s). Any legally authorized representative who is not the parent, should indicate the decree number (that establishes the legal representation) on the consent form.

Review refers to the evaluation of a proposal by the Institutional Review Board consistent with the policies established by appropriate federal agencies and the Belmont Report. The review (and subsequent approval) are required before the study may be initiated.

The Belmont Report. On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, there-by creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations. It has become a seminal document in establishing principles for research with human subjects. It may be accessed on-line at http://www.dhhs.gov/ohrp/humansubjects/guidance/belmont.htm.

All systematic investigations involving human subjects that are performed to meet academic requirements (e.g., thesis, dissertation, etc.) or designed for public dissemination under the aegis of Mansfield University require Institutional Review Board (IRB) approval.

Statement of General Principles

Mansfield University is committed to the pursuit of excellence in teaching, research, and public service. Members of the University community, while upholding the highest standards of freedom of inquiry and communication, accept the responsibility this freedom entails: for competence, for objectivity, for consideration of the best interests of the University and society, and for the welfare of every participant in a project. The Institutional Review Board for the Protection of Human Subjects (IRB) is primarily concerned with the welfare and consideration of the best interests of all subjects participating in research, the University, and society.

The University gives assurance that it will comply with the Department of Health and Human Services (HHS) regulations for the Protection of Human Research Subjects (45 CFR 46, as amended). Thus, the following principles are affirmed and should be interpreted in the broad context provided by the code of medical and general ethics promulgated by the World Medical Association as the Declaration of Helsinki and by the Ethical Principles in the Conduct of Research with Human Participants of the American Psychological Association. Copies of all documents, including Mansfield University's Assurance of Compliance with HHS Regulations, are on file in the Grants Development Office.

1. Because participation of humans in research and training projects raises fundamental ethical and civil rights questions, no distinctions in the monitoring of projects will be drawn between funded and unfunded projects, sponsored and unsponsored projects, or among projects carried out by students, faculty, or other University employees, on-campus or off-campus. Furthermore, approval by an agency that will be used to obtain subjects is necessary to obtain final IRB approval for the project. Review by another IRB, however, does not replace that of the Mansfield University Board for studies conducted under the aegis of the University.

2. All activities involving humans as subjects must provide for the safety, health, and welfare of every individual. Rights, including the right of privacy, must not be infringed.

3. The direct or potential benefits to the subject, or the importance of the knowledge to be gained, must outweigh the inherent risks to the individual.

4. Participation in projects must be voluntary, and informed consent must be obtained from all subjects, unless this requirement is specifically waived by the IRB. Investigators may establish a process consistent with guidelines for the process of documenting informed consent (guidelines as stated in Section X, beginning on page 18). Methods that are in accordance with the requirements of 45 CFR 46.116 and 45 CFR 46.117 and are adequate and appropriate to the risks of the project must be used to obtain the subject's informed consent.

5. Consent should be obtained whenever appropriate from the participants themselves. If a subject is adjudicated to be not legally capable of giving informed consent, a legally authorized representative may do so. Any process by which informed consent is secured must consider the ability of the potential participant to comprehend the information and competently respond. Careful consideration shall be given to the representative's depth of interest and concern with the subject's rights and welfare. Informed consent must be secured for every project in which a person might participate.

6. An individual does not abdicate any rights by consenting to be a research subject. A subject has the right to withdraw from a research project at any time or can refuse to participate without loss of benefits to which the subject would otherwise be entitled. Further, a subject has the right to receive appropriate professional care, to enjoy privacy and confidentiality in the use of personal information and to be free from undue embarrassment, discomfort, anxiety, and/or harassment.

7. Safeguarding information about an individual that has been obtained in the course of an investigation is a primary obligation of the investigator. The faculty sponsor is always responsible for the monitoring of procedures. Such information shall not be communicated to others unless the following conditions are met:
    1. Explicit written permission for the release of identifying data is given by the individual. The consent form to release information must be independent of the Informed Consent Form and must specify the name(s) of the person(s) or agencies to whom the data will be released.
    2. Information about individuals may be discussed only for professional purposes and only with persons clearly involved in the project. Written and oral reports should present only data germane to the purposes of the project, and every effort should be made to avoid invasion of privacy.
    3. Provisions must also be made for the maintenance of confidentiality in the preservation and ultimate disposition of any data collected. Adequate security measures must be described to the IRB and carried out by the principal investigator until the records are destroyed. Information in the records which contain personal information that could permit another person to identify a subject should be destroyed as soon as possible in keeping with the long-range goals of the project and federal regulations requiring the maintenance of primary data for a period of three years.

8. Projects will be given initial and continuing review by the IRB as set forth in the description of Review Procedures and Criteria for Approval. All members of the University community involved in investigation and training are responsible for continual monitoring to assure compliance of their research with these principles.

9. No individual involved in the conduct and/or supervision of a specific project shall participate in IRB review of his/her project, except to provide information.

10. A second review may be required:
    - if six months has elapsed between IRB review and project initiation;
    - if natural or unforeseen circumstances warrant a change in procedure; or
    - if the principal investigator intends to change procedures after the proposed project has been approved by the IRB.

11. In all cases, the investigator should show practical regard for the Mansfield University community, recognizing that violations of the ethical and legal standards incorporated in this statement of principles (for example, concerning confidentiality, informed consent, and regard for the health, safety and welfare of all human subjects) could impugn the investigator's own name and the reputation of the University. Furthermore, the investigator should ensure that the research staff is reasonably protected from harm.

12. The investigator does not abdicate ethical and legal responsibility merely by complying with this protocol. It is always the responsibility of the investigator to obtain clearance from the IRB prior to the initiation of any research activity involving the use of human subjects. Failure to do so may result in personal restrictions on the research activities of such individuals, as well as potential endangerment of all federal funding to the University.

IRB Responsibilities

1. All research projects involving the use of human subjects must be submitted to the IRB for approval. If it is unclear whether the proposed research involves human subjects, the investigator should seek assistance from the IRB Chair or the Director of Grants Development. Applications shall be submitted to the office of the IRB Chair well in advance of the deadline for which the proposal is to be submitted (if being submitted to an external funding agency) or on which the research is to begin. If external funding is being sought, one copy of the complete proposal must be submitted along with the IRB application. Application forms may be obtained from the Grants Development Office and are available in the IRB web page. The IRB Chair will review the application material for procedural omissions prior to distribution to the full Committee for their review in advance of the next scheduled meeting.

2. The IRB will meet no less than once a semester with due regard for a thorough but speedy assessment of applications. The IRB meeting schedule will be distributed to college and departmental offices and is available on the IRB Web page. A copy of this schedule may be obtained upon request from the Grants Development Office. Therefore, to assure consideration of an application by the IRB, the principal investigator must initially submit two copies of a completed application to the IRB Chair no later than ten days prior to the next scheduled meeting. This will allow sufficient time for the screening process prior to the IRB meeting. **When the proposal contains copyrighted materials, the investigator is asked to send only one original set of these materials. The Board will share access to the one copy as needed.**

3. Departments may establish a special departmental committee to review applications prior to submission to the IRB. Although not a requirement, the IRB encourages this practice. If your department has such a committee, please complete this review before forwarding to the IRB. Departmental Review Form .

4. Responsibility for initial review resides within the individual departments in which research involving human subjects is being undertaken. Departments involved in human subjects research will identify a departmental research reviewer who is charged with the responsibility of determining whether proposed research should receive Departmental Review or IRB review. Each potential Departmental Reviewer will complete a training determined by the IRB Chair prior to becoming Departmental Reviewer.

5. When a student or faculty researcher wishes to undertake a research project, the researcher must complete two copies of the research review application. If the researcher believes the research is in an exempted category, the researcher must indicate which of the six exempted conditions the research meets and justify clearly why this research should be exempted. The research must provide a description of the research design, and assurances that the research poses no more than minimal risk to human subjects. (A definition of "minimal risk" follows below).

   > "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in

daily life or during the performance of routine physical or psychological examination or tests."

A discussion with members of the IRB, a departmental reviewer or the IRB chair is encouraged prior to applying for an exempted review. RESEARCHERS CANNOT, ON THEIR OWN, DECIDE THEIR RESEARCH IS EXEMPT FROM THE IRB PROCESS.

6. If the department research reviewer agrees that the research protocol meets one of the exempted conditions, s/he signs off on the application, collects the other necessary signatures, forwards a copy to the Chair of the IRB, and returns a signed copy to the researcher. Only after a signed copy of the research application is returned to the researcher may s/he begin the human subjects research.

7. If IRB Review is requested, the departmental reviewer determines that the application is complete, that IRB review is required, and forwards the two application copies to the IRB Chair.

8. The following represent sensitive situations that require special protections. Even if one or more of the six exempted conditions is met, research involving the following must be forwarded to the IRB for review:
    a) CHILDREN
    b) FETUSES OR HUMAN IN VITRO FERTILIZATION
    c) PRISONERS
    d) PREGNANT WOMEN
    e) AIDS/HIV STUDIES
    f) PERSONS WITH DISABILITIES OUTSIDE OF SCHOOL SETTINGS

9. If the research involves children in school settings or persons with disabilities in either school or institutional settings, the researcher must receive written permission from the school principal or institutional administrator prior to beginning the research (even when the research meets one of the six exempted conditions; see Exemptions page 16).

10. An expedited review procedure is possible for those applications that involve no more than minimal risk to subjects and also fall under one of the research categories eligible for expedited review or fall under the categories exempted by federal regulations. (See the list at Expedited Categories and Exempt Categories.) Final determination as to whether a specific project is eligible for expedited review can only be made by the IRB. For information as to whether or not your research project falls under either of these category definitions, contact the IRB Chair or the Director of Grants Development.

11. Final approval by the IRB shall require a majority vote by members present. If the IRB agrees that the proposed research protects human subjects in accordance with established standards, its conclusion shall constitute certification of approval. A letter of approval will be sent to the investigator. The faculty advisor will be copied on any correspondence sent to a student investigator.

12. In the case of a proposal being submitted to an external funding agency, certification of IRB approval of the protocol will be included in materials submitted to the external funding source. Documentation of IRB approval will be submitted in the form required by the agency.

Review Process

The following description of the IRB review process reflects the various ethical principles and regulatory requirements that each investigator should consider during the design phase of their project. In order to approve a research project involving human subjects, the IRB must assure itself that (1) the prospective subject population is appropriate in terms of characteristics and number, (2) the recruitment of subjects is free of coercion, (3) the experimental design of the study is sound, (4) any risks associated with the research project are minimized to the greatest extent possible, (5) the potential benefits are maximized to the greatest extent possible, (6) the risks to the subject are outweighed or balanced by the potential benefits, (7) the level of subject compensation (if any) is fair and non-coercive, (8) the degree to which confidentiality is maintained is acceptable, (9) the method used to obtain informed consent is ethically and legally acceptable, and (10) the investigator has the appropriate qualifications, experience and facilities to conduct the research.

The IRB review process is not particularly concerned with the nature of a research topic. Providing the rights and welfare of the subjects are adequately protected and the protocol will be conducted in full compliance with HHS regulations, it does not matter what the research topic is or how controversial it is perceived to be. However, after IRB review and approval is obtained, it is possible that a research project could require an additional level of review. As per 45 CFR 46:112, research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. Those officials cannot, however, approve any research project unless it is first approved by the IRB.

1. **Review of the Prospective Subject Population**
   The prospective subject population must be appropriate with respect to the nature and goals of the research. In addition, the investigator should be guided by the principles which lead to an equitable selection of subjects with regard to the potential risks and benefits of the research. The IRB, therefore, will examine carefully the characteristics of the subject population. Factors such as the required number of subjects, age range, sex, ethnic background, and health status will be considered. The utilization of any vulnerable classes of subjects such as sick persons, pregnant women, fetuses, prisoners, children, elderly persons, mentally disabled persons, and persons who are educationally or economically disadvantaged must be clearly justified. Although the use of vulnerable persons as subjects is not prohibited by any regulations or ethic codes, justification for involving vulnerable persons in research generally becomes more difficult as the degree of risk and vulnerability increases.

   Naturally, there are exceptions to the principle of "equitable selection of subjects." For instance, research involving the social consequences of a disease to which only one ethnic or racial group is susceptible would not require the application of this principle. Two examples are sickle cell anemia in the black population and Tay-Sachs Disease which affects Jewish people. (In cases of unequal access, a full explanation is required.)

2. **Review of Method(s) of Subject Recruitment**
   The IRB will review the method of prospective subject identification and recruitment in order to be assured it is ethically and legally acceptable. Advertisements used to recruit subjects are considered an extension of the recruitment and informed consent processes and, therefore, must be reviewed by the IRB.

3. **Review of Research Methods and Procedures**
   The IRB will review the experimental design in order to be assured that the potential risks to the subjects are minimized and the potential benefits maximized by using procedures consistent with sound research design. The IRB accepts the need for certain types of behavioral and social science studies to employ strategies that include either deception and/or the withholding of information. Employment of such strategies must, however, be fully justified. In general deception is not acceptable if, in the judgment of the IRB, the subject would have declined to participate had she/he been informed of the true purpose of the research. Studies which use deception and/or the withholding of information as part of their experimental design must include a post-study debriefing unless a waiver is granted by the IRB.

4. **Review of Potential Risks**
   A risk is a potential harm (injury) associated with the research that a reasonable person would be likely to consider significant in deciding whether or not to participate in the research. The concept of risk includes, but is not limited to, discomfort, burden, or inconvenience a subject may experience as a result of the research procedures. Underlying the consideration of risk, is the implicit moral guideline that all investigators have a duty not to harm their subjects and must minimize potential risk to the greatest extent possible.

   The five major types of risks are:
   - physical risk (e.g., pain, bruising and infection associated with venipuncture, muscle soreness and pain as a consequence of exercise testing, heart attack induced by maximal exercise test);
   - psychological risk (e.g., stress associated with psychological testing, stimulation of painful memories, feelings of guilt or discomfort precipitated by a sensitive survey);
   - social risk (e.g., invasion of privacy, loss of community standing);
   - legal risk (e.g., criminal prosecution or revocation of parole); and economic risk (e.g., loss of employment, loss of potential monetary gain).

     Both immediate and delayed risks of any procedure involving human subjects will be reviewed by the IRB. In addition, the estimated probability, severity, average duration, and reversibility of any potential harm will be considered according to available empirical data. Furthermore, since certain populations of vulnerable subjects may be at greater risk than others, the IRB will take into consideration the potential risk characterization of the subjects. Victims of child abuse or assault, for example, may be at increased risk in sociological or psychological studies. Children, the elderly, prisoners, the mentally disabled, and various ethnic groups may incur an increased level of risk in certain kinds of research projects.

Risk can also be classified as less than minimal, minimal, and greater than minimal. Federal regulations (45 CFR 46.102(i)) define minimal risk as, "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." The term "minimal risk" is used as a base or standard by which the risk associated with research is judged.

Examples of "less than minimal risk" procedures include collection of urine, collection of sweat, weighing, pulse measurement, blood pressure measurement, voice recordings, skin fold body composition measurements, and any standard psychological testing with no stress. In actuality, most "less than minimal risk" procedures are interventions that usually (but not always) have no known associated risk. For example, if an investigator were to take one blood pressure measurement using a sphygmometer, this would clearly be a "no known risk" procedure. If, however, the investigator's protocol requires monitoring of the subject's blood pressure every thirty minutes during a five-hour written exam given for Board certification, the associated risk would be at least "less than minimal" as opposed to "no known risk." This is because of the inconvenience and discomfort associated with multiple interventions. Since risk is such a relative concept, the IRB classification system does not distinguish between "no known risk" and "less than minimal risk" research except for the purpose of risk disclosure on the consent form.

Examples of "minimal risk" procedures include electrocardiography, collection of blood by venipuncture from healthy adults who are not pregnant, moderate exercise testing, administration of standard psychological tests with only a minor level of associated stress, and magnetic resonance imaging. Examples of "greater than minimal risk" procedures include radiology exams (x-ray, CT scan), maximal exercise testing, and stressful psychological testing, including asking sensitive or personal questions on a survey.

The IRB will review carefully the risk classification of the research which determines the type of IRB review and consent form format. Under certain circumstances, application of the minimal risk classification will be based upon a consideration of the risks inherent in each subject's life, thereby resulting in a relative standard of minimal risk. Thus, for example, the standard of minimal risk may be different when applied to a person with cancer or mental retardation versus a healthy person.

5. **Review of Potential Benefits**
   A benefit is a valued or desired outcome. Benefits associated with participation in research can be classified generally as those that accrue to the subject directly (e.g., acquisition by the subject of knowledge considered of value) and those that accrue to society (e.g., additions to the knowledge base). The IRB will review the anticipated benefits to both the subject and to others. In addition, the IRB will consider whether the benefits are maximized to the greatest extent possible through proper protocol design. Therefore, an underlying moral notion of "beneficence" should guide the investigator.

Financial or other forms of compensation are not considered a benefit to be derived from research participation. Although the subject may consider financial compensation a desirable outcome, this fact will not be used in the risk/benefit analysis.

6. **Risk/Benefit Analysis**
   Once the potential risks and benefits are identified, an ethical review of research requires an examination of the relationship of the risks to the benefits. Risks and benefits cannot be considered parallel constructs and, therefore, no formula is applicable. The various ethical codes and regulations, however, require a favorable balance between harm and benefit. To assist the investigator and the IRB in assessing the risk/benefit relationship the following principles are provided.

   In non-therapeutic research the potential risk to the subject must be outweighed or balanced by the potential benefit to the subject and/or by the potential benefit to society.

   In research where a standard therapy (not part of the research protocol) is employed solely for the benefit of the subject along with additional procedures performed solely for research purposes, the anticipated benefits of the therapy must not be used to justify exposing subjects to the risks associated with the research procedures. Such risks can only be justified in light of the potential benefits of the research procedures. Therefore, only the risks associated with the research procedures should be used in determining the risk/benefit ratio.

7. **Review of Subject Compensation**
   The IRB will review the amount of compensation (monetary as well as other forms) in order to be assured that it is not coercive and is equitable in distribution.

8. **Review of Confidentiality**
   The IRB will review the methods to be used to preserve confidentiality. If research data with subject identifiers will be made available to persons other than the listed investigators, sponsor or federal agency, the IRB will review the justification for sharing these data and determine acceptability.

9. **Review of Informed Consent**
   Although there are federal regulations requiring the subject or the subject's legally authorized representative to give consent prior to the subject's participation in an experiment, the principal reason for informing subjects about an experiment is that they have a moral right to know what is to be done to them and what risk this entails before they give their consent. Human beings are considered autonomous, and the requirement of informed consent is designed to uphold the ethical principal of "respect for persons." The use of human subjects is a privilege--a favor--granted to the researcher, rather than a right. An experiment is something that is done to the subject either primarily or solely for the purpose of advancing knowledge. Indeed, in non-therapeutic research the subject seldom receives any benefit. In order for consent to be ethically and legally valid, it must meet the requirements stated in Principle I of the Federal Regulations (45 CFR 46:116) which is based, in part, upon the Nuremberg Code. Principle I of the

Nuremberg Code states, "The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision." The legal documentation of informed consent is the consent form signed by both the subject and the investigator. The ethical and, indeed, legal validity of consent is, however, dependent upon the process of informed consent which requires the investigator to engage in dialogue or negotiation with the prospective subject. The consent form, therefore, should be used by the investigator as an instrument to guide the negotiations with the prospective subject. The informed consent form must embody the elements of informed consent contained in the HHS regulations as reflected in the IRB Guidelines. The IRB will review both the consent form and the process of informed consent to ensure its acceptability.

10. **Review of Investigator Qualifications**
    The IRB will review investigator qualifications and must be assured that a) the investigator has the appropriate qualifications and licensure to carry out the procedures involving human subjects with an acceptable degree of risk, and b) the investigator has adequate facilities and equipment to conduct the research with an acceptable degree of risk.

11. **Review of Monitoring Requirements**
    The IRB will determine whether or not a research project requires review more often than annually and will establish an appropriate monitoring procedure which may include observation of the consent process, observation of on-going research, and review of research records.

Procedures and Criteria for Approval

1. **Initial Approval**

   The principal investigator may be asked to meet with the IRB should it be apparent that clarification or modification of statements in the application are required. No individual involved in the conduct and/or supervision of the research project shall participate in its review, except to provide information to the IRB. The IRB may approve the project as is or may approve it with certain modifications required to meet federal standards. In the latter instance, the investigator will be informed by letter. The IRB approval letter will be sent upon written receipt of the modification. The faculty advisor will be copied on any correspondence sent to student investigators.

   If the IRB action is to disapprove the application, reasons for this negative decision will be provided in writing to the principal investigator or project director. If the researcher decides to modify the proposed research in such a way as to meet the objections of the IRB, the investigator may resubmit the modifications of the proposal for consideration at the next IRB meeting. If desired, the investigator may request a personal hearing at the next scheduled IRB meeting.

2. **Continuing Review and Submission of Annual Update**

   Complex and potentially dangerous projects will be reviewed at a frequency commensurate with the related risks. When initial approval of such a protocol is given, the IRB may indicate the need for re-evaluation of the project after a specified interval so that continued acceptance of the protocol is assured. Projects that are determined to be exempt will not require additional review. Non-exempt proposals are approved for a maximum period of one year only. For projects which continue beyond one year, it is the responsibility of the principal investigator to submit to the IRB an annual update. The first annual update is due twelve months following the date the proposal was approved and released. Upon receipt of the annual update the IRB will review and approve, if appropriate, continuation of the project for the next twelve month period. Investigators will receive one notification regarding the due date of an annual update. Failure to submit an update within 30 days following the due date will result in termination of IRB approval. Projects can be updated annually for a maximum approval period of five years. Continuation of projects beyond five years requires resubmission.

   If the IRB determines that a project requires review more often than annually, the investigator will be so notified. The IRB has the authority to directly observe ongoing research projects and the consent process as well as audit research records.

   When a project that has required continuing review is terminated/completed, the investigator must immediately notify the IRB in writing.

   Ongoing projects modified to include humans as subjects also must be submitted to the IRB for

review and approval prior to the use of human subjects. In the case of an externally funded project, the granting agency would be notified of the IRB action prior to the appropriation cycle for a budget period during which human subject involvement is proposed.

3. **Reporting Proposed Changes in a Research Protocol**

   Any proposed change in a protocol which affects the human subjects must be reviewed and approved by the IRB prior to the implementation except where an immediate change is necessary to eliminate a hazard to the subjects. Investigators should submit a Request for Change in Protocol and a revised consent form as required. Minor changes during the period for which approval is in force will be reviewed by an expedited review procedure.

   If a change in protocol is relatively minor and does not affect participants risk (e.g., change in investigator, change in the sequence of follow-up visits, clarification of question items) it is not necessary to have the subject sign a revised consent form or an addendum to the consent form. If, however, the change is not minor (e.g., addition of an intervention not addressed in the original consent form, disclosure of a previously unidentified risk, change to or inclusion of new question items asked of the participants) the investigator should have all new subjects sign a revised consent form and all currently enrolled subjects who are actively participating in the protocol sign an addendum to the consent form. If the change is considered significant (e.g., disclosure of a serious risk) the use of a witness is required.

4. **Submission of a Report of Injury**

   If a subject suffers an injury, the investigator must submit a Report of Injury to the IRB within 48 hours.

5. **Reporting Non-Compliance with IRB Guidelines**

   Any incident of non-compliance with IRB Guidelines should be reported immediately to the IRB. Non-compliance with IRB requirements is a violation of federal regulations for the protection of humans.

Exemptions

The basic premise of the human subjects review process is that all studies are subject to continuous review. However, some studies may require only an initial review and are EXEMPT from ongoing review. No study is totally exempt from review. The University has adopted six categories of research as exempt from continuing Institutional Review Board for the Protection of Human Subjects (IRB) review based upon Department of Health and Human Services (DHHS) regulations published in the Code of Federal Regulations, 45 CFR 46, March 8, 1983 and amended in the Federal Register on June 18, 1991. In order to establish an individual research project as exempt, an investigator must complete an IRB application. On the IRB application the investigator should indicate the number of the category under which an exemption is claimed. **Final determination as to whether a project is exempt rests with the IRB.**

If a research project is certified as exempt by the IRB, the investigator need not resubmit the project for continuing IRB review as long as there are no modifications in the exempted procedures. In other words, the use of the term "exempt" refers to the requirement for continuing IRB review but not to the general requirements for informed consent and protection of subjects. Thus, even if a project is determined to be exempt, the investigator still must inform potential subjects of the proposed procedures and their rights as subjects.

In accordance with DHHS regulations for the Protection of Human Subjects (45 CFR 46, as amended), the following categories of exemption have been adopted by Indiana University of Pennsylvania. The exempt categories do not, however, apply to research involving deception of subjects (i.e., where the researcher deceives the subject with regard to the purpose of the research and/or the results of the subject's actions in the study), sensitive behavioral research, or to research involving pregnant women, prisoners, mentally disabled people, and other subject populations determined to be vulnerable.

Exempt Categories

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (a) research on regular or special education instructional strategies, or (b) research on the effectiveness of or comparisons among instructional techniques, curricula, or classroom management methods.
   Educational research proposals are exempt providing **all** of the following conditions are met:
   1. All of the research is conducted in a commonly accepted educational setting (e.g., public school).
   2. The research involves normal educational practices (e.g., comparison of instructional techniques).
   3. The study procedures do not represent a significant deviation in time or effort requirements from those educational practices already existent at the study site.
   4. The study procedures involve no increase in the level of risk or discomfort associated with normal, routine educational practices.
   5. The study procedures do not involve sensitive subjects (e.g., sex education).
   6. Provisions are made to ensure the existence of a non-coercive environment for those students who choose not to participate.

7. The school or other institution grants written approval for the research to be conducted.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly, or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk for criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

   NOTE: Sensitive survey research is not exempt. A sensitive survey is one that deals with sensitive or highly personal aspects of the subject's behavior, life experiences or attitudes. Examples include chemical substance abuse, sexual activity or attitudes, sexual abuse, criminal behavior, sensitive demographic data, detailed health history, etc. The principal determination of sensitivity is whether or not the survey research presents a potential risk to the subject in terms of possible precipitation of a negative emotional reaction. An additional risk consideration is, of course, whether or not there is risk associated with a breach of confidentiality should one occur. With respect to potential psychological risk associated with a survey, the presence or absence of subject identifiers is not necessarily a consideration since the risk may be primarily associated with the sensitive nature of the survey as opposed to being dependent upon confidentiality. Subject identifiers do, however, become a factor when confidentiality is an issue.

   NOTE: When children are involved as subjects in research using survey or interview procedures, the research is not exempt.

   NOTE: When children are involved as subjects in research using observation techniques, the research is not exempt.

   NOTE: Observation research involving sensitive aspects of a subject's behavior is not exempt.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph 2 of this section, if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information is maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, assess, 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;

and/or (d) 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: (a) if wholesome foods without additives are consumed; or (b) 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.

Expedited Review

Department of Health and Human Services (DHHS) regulations (45 CFR 46, as amended) recognize that there are certain categories of research which involve procedures which pose no more than minimal risks to subjects and for which clear standards can be set. Accordingly, research projects which fall under one of the categories listed below will be reviewed by the Expedited Review Subcommittee, which will consist of the Institutional Review Board for the Protection of Human Subjects (IRB) Chair and/or one or more experienced IRB member/s selected by the Chair.

All members of the Expedited Review Subcommittee must agree that the protocol falls under one of the expedited categories. Any member may object to the application for expedited review or may have further questions that the investigator must answer. Similarly, each member has the option of referring the application to the IRB for full review.

If the application is approved by the Expedited Review Subcommittee, it will be reported to the IRB as a consent calendar item at the next convened meeting. The IRB is likely to approve the Expedited Review Subcommittee's action but has the option of requesting more information, requiring modification of the protocol, or disapproving the project.

Listed below are eleven categories subject to expedited review. Expedited review will be given only for research protocols that fall under one of these categories. These categories, as determined by the IRB, may not apply to pregnant women, children, prisoners, mentally disabled persons, and other classes of subjects considered vulnerable.

1. Minor modifications or additions to existing approved studies;
2. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects;
3. The study of existing data, documents, records, pathological specimens, or diagnostic specimens;
4. Voice recordings made for research purposes such as investigations of speech defects;
5. Moderate exercise by healthy volunteers;
6. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older who are in good health and not pregnant;
7. Collection (in a nondisfiguring manner) of hair, nail clippings, and deciduous teeth; and permanent teeth if patient care indicates a need for extraction;
8. Collection for analysis of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor;
9. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. (These procedures

include weighing, testing sensory acuity, electrocardiogram, electroencephalogram, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range, i.e. x-rays, microwaves.);

10. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; and
11. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

Informed Consent

Informed consent is a process. A written informed consent documents this process, but cannot serve as a substitute for it. No subject may be involved in research without the legally effective informed consent of the subject or the subject's legally authorized representative. This consent shall be sought under circumstances that provide sufficient opportunities for the subject to freely consider whether or not to participate. If the subject is a minor, written parental consent or legal guardian consent is required, and the investigator must obtain the assent of the child unless the child is incapable of giving assent.

The information given to the subject, or the subject's legally authorized representative, must be in simple, easily understood language. If the subject population is not English-speaking, the informed consent must be presented in whatever language is appropriate. If the person uses an alternative form of communication (e.g. Sign Language), the informed consent process must be designed to enable effective communication in the appropriate mode. (If a potential subject is illiterate, the investigator will be required to use a competent witness to verify voluntary informed consent.)

Written documentation of the consent process (e.g., a cover letter or cover sheet) is always required unless specifically waived by the IRB. The consent document should be signed by the subject or the subject's legally authorized representative unless this requirement is waived by the IRB.

In some types of projects, it may be important for information pertaining to consent to be provided verbally. In such an instance, a written summary (script) of what the potential subject will be told must be provided to the IRB for review and approval. Investigators should explain the rationale for not obtaining written informed consent in order that the IRB may approve such an exception.

No informed consent, whether oral or written, may waive or limit in appearance or in fact, the subject's legal rights, including any release of the institution or its agents from liability or negligence.

The following information must be a part of all written informed consent documents:

1. A statement that the project is research and an explanation of the scope, aims and purposes of the research, and the experimental procedures to be followed, including the expected duration of the subject's participation. This statement should include a description of any anticipated benefits the subject or others might reasonably expect.
2. Identification of the investigator, faculty sponsor (if relevant), as well as the name of any other sponsoring or funding source supporting the research. Mansfield University should be identified as the responsible institution or as one of the responsible institutions.
3. The following statement will be included in ALL written informed consents (including cover letters). It is suggested that this statement be inserted at the bottom margin of the form, letter or portion of the form that is to be retained by the subject.
   THIS PROJECT HAS BEEN APPROVED BY THE MANSFIELD UNIVERSITY OF PENNSYLVANIA INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS.

4. A description of any reasonable foreseeable risks or discomforts to the subject (including likely results if an experimental treatment should prove ineffective). If the risk potential is currently unknown or unmeasurable, a statement to that effect will be required.
5. A statement regarding the availability of compensation, medical treatment, or other services if injury occurs will be required for research which involves more than minimal risk. If compensation or medical treatment will be provided, information about how it may be obtained or where further information may be secured will be required.
6. A statement of any new information developed during the course of the research which may relate to the subject's willingness to continued participation will be provided. Related to this, an offer to answer any questions the subject (or the subject's representative) might have regarding the subject's rights shall be included. This statement should include the name, address and/or telephone number of the principal investigator as the contact point if questions or problems should occur.
7. A statement describing the method by which confidentiality of records identifying the subject will be maintained.
8. A statement that participation is voluntary and that refusal to participate or a subsequent decision to discontinue participation will not result in penalty or loss of benefits to which the subject is otherwise entitled. This statement should include a description of the consequences, if any, that accompany such a decision to withdraw and should explicitly state methods of withdrawal.
9. A copy of the informed consent shall be provided to the subject or the subject's legally authorized representative.

Federal law mandates that copies of all informed consents be retained for a minimum of three years after completion of the research. The principal investigator is responsible for the maintenance and retention of such records. If the principal investigator is a student, the faculty sponsor is responsible for the maintenance of these records. If the investigator leaves the institution within this three year period, all records must be forwarded to the Office of Grants Development.

APPENDIX A

Please see the IRB website at:

http://mansfield.edu/grants-development/institutional-review-board/