

IRB HANDBOOK

**REGULATIONS GOVERNING THE USE OF
HUMAN SUBJECTS IN RESEARCH AT
MOREHEAD STATE UNIVERSITY**

Respect for Persons

Justice

Beneficence *

**DEVELOPED BY THE INSTITUTIONAL REVIEW BOARD (IRB)
FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH**

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Please Note: The regulations in this handbook apply to all human subject research. Before conducting any human subject research, the IRB must receive and approve a completed protocol application. The researcher/principal investigator may not conduct any part or parts of the human subject research until he/she receives written approval from the IRB.

* Source: The Belmont Report

Revised: September 2008

Basic Ethical Foundations

The Cover Page illustrates the three basic principles of ethics particularly relevant to the protection of human subjects in biomedical and behavioral research. They are:

1. Respect for Persons. Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

An autonomous person is an individual capable of deliberation about personal goals and acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.

However, not every human being is capable of self-determination. The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

2. Justice. Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are (1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, and (5) to each person according to merit.

3. Beneficence. Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.

The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.

Source: Office for Human Research Protections (OHRP)
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This Handbook was Compiled by the Members of the
Institutional Review Board (IRB)
for the Protection of Human Subjects in Research
Based upon Federal Regulations as Set Forth in Publications of the
Office for Human Research Protections (OHRP)

**The Morehead State University (MSU)
Institutional Review Board (IRB) for the Protection of Human Subjects in Research
Mission Statement**

The MSU IRB mission is to support the conduct of good research ethics by safeguarding human subjects and their rights and making a determination whether human subjects in research will be placed at risk.

2008 - 2009

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PREFACE

Morehead State University (MSU) has a commitment to fulfill its ethical and moral responsibility to human subjects of research conducted under the auspices of the institution. Therefore, MSU has established an Institutional Review Board (IRB) to review research protocols so that human subjects are protected and the research is in compliance with federal regulations. The IRB was established according to federal regulations to promote the rights and guard the emotional and physical well-being of human subjects in research, and in doing so, it is also the aim of the IRB to foster research and to assist researchers engaged in research. This handbook is published as an aid to researchers (MSU faculty, staff, students or external researchers) who wish to pursue research involving human subjects as participants in research.

The IRB does not judge the merits of research protocols but rather reviews each proposed research protocol to ensure that the rights and welfare of the human subjects are protected according to the regulations. Approval from the IRB thus provides assurance that the project as outlined is in compliance with federal regulations. A decision to not approve a protocol is *rarely* final. The IRB will work with researchers to arrive at revisions (usually minor) that will ensure compliance and protect the human subjects, researchers, and the University. The IRB may require additional safeguards not specified in the federal regulations, if necessary. The IRB takes seriously the responsibility of monitoring ongoing research involving human subjects.

The handbook is arranged with the researcher's needs in mind. The handbook describes the IRB and outlines criteria by which protocols will be judged to be in compliance or not in compliance and guides the researcher through the process of submitting a protocol. **Appendix A** contains a list of Tips on Informed Consent from The Office of Human Research Protections. **Appendix B** provides a copy of the specific regulations dealing with the protection of human subjects to be found in the Code of Federal Regulations so the researcher may consult them directly. **Appendix C** provides copies of the Belmont Report, the Nuremberg Code, and the Declaration of Helsinki, which are the ethical principles dealing with human subjects. **Appendix D** contains the forms to be used at various stages of the process. **Appendix E** provides a copy of PAC-32, Misconduct in Research.

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INTRODUCTION

Morehead State University has a commitment to fulfill its ethical and moral responsibility to human subjects of research at the institution. Institutions engaged in research involving human subjects supported by a department or agency to which the Federal Policy applies must establish an IRB to review and approve the research. Morehead State University has an Institutional Review Board (IRB) for the Protection of Human Subjects in Research according to the Code of Federal Regulations, 45 CFR 46, Protection of Human Subjects. Specific references to these regulations are identified throughout the handbook to assist the researchers in reviewing the Federal Policy for the Protection of Human Subjects (see **Appendix B**). MSU has adopted the regulations, as well as the *ethical principles outlined in the Belmont Report, the Nuremburg Code, and the Declaration of Helsinki* (see **Appendix C**). The regulations apply to all research involving human subjects, whether funded by an external or internal source or not funded.

Whenever a researcher (MSU faculty, staff, students or external researchers) engages in a research project at MSU that involves human subjects as participants, or when MSU faculty, staff, or students engage in research at another institution, MSU must guarantee that the researcher will comply with federal policies safeguarding human subjects in research. Federal regulations require that the proposed research be reviewed and approved by an IRB and remain subject to continuing review by the IRB (see Protocol Application, **Appendix D**). In particular, federal funds administered by a department or agency may not be expended for research involving human subjects until the research has been reviewed and approved by the IRB. Moreover, the head of a federal department or agency may terminate or suspend support for any project if an institution fails to comply with this policy.

To be in compliance, the IRB must review proposed and ongoing research and provide the appropriate federal department or agency head with the following:

1. a statement of principles governing MSU in the discharge of its responsibilities for protecting the rights and welfare of human subjects in research conducted at or sponsored by the institution;
2. a list of IRB members identified by name, earned degrees, and representative capacity;
3. written procedures which the IRB will follow:
 - a. for conducting initial and continuing reviews of research;
 - b. for reporting its findings and actions to the researcher and the Institutional Official;
 - c. for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that changes in research already approved may not be initiated without IRB review and approval; and
 - d. for ensuring prompt reporting to the IRB, Institutional Official, and the appropriate federal department or agency head of any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB, or any suspension or termination of IRB approval.

If research is undertaken without the intention of involving human subjects, but researchers later propose to involve human subjects, the revised research project must be reviewed and approved by the IRB before the project proceeds, prior to involvement of human subjects and/or participants.

ROLE OF THE AUTHORIZED INSTITUTIONAL OFFICIAL

Morehead State University must designate an official representative responsible for the oversight of research and IRB functions in accordance with federal regulations. The President appoints the official who has the legal authority to act and speak for the institution, and can ensure that the University will effectively fulfill its research oversight function. The President has appointed the Associate Provost for Research and Sponsored Programs as the Morehead State University Institutional Official who has oversight of research and IRB functions. As the person responsible for oversight and functions and according to the OHRP IRB Guidebook, the Institutional Official appoints the chair of the IRB to assure the protection of the rights and welfare not only of research subjects, but also the institution itself, and, if necessary, recommends dismissal of members to the President. Selection of appropriate personnel will assure the protection of the rights and welfare of research subjects and the University itself.

INSTITUTIONAL OFFICIAL RESPONSIBILITIES AND AUTHORITY

In fulfilling the federal requirements, the President of Morehead State University has appointed the Associate Provost for Research and Sponsored Programs as the Institutional Official.

- The Institutional Official is legally authorized to represent Morehead State University relating to the IRB and human subject research at the University.
- The Institutional Official is the University's contact person with the Office for Human Research Protections (OHRP) and has full responsibility for ensuring compliance with federal and University regulations.
- The Institutional Official has oversight of research and IRB functions.
- The Institutional Official has oversight of IRB activities. The Institutional Official has access to open and closed session minutes.
- The Institutional Official recommends membership of IRB members to the President and, if necessary, recommends to the President dismissal of IRB members for cause.
- The Institutional Official appoints the chair of the IRB.
- The Institutional Official reports any suspension or termination of IRB approval to the appropriate federal agency when research is funded thusly.
- The Institutional Official is the person responsible for dealing with issues of noncompliance of research that involves the use of human subjects: 1) without an approved protocol during the research, or 2) with an approved protocol.
- The Institutional Official is authorized to attend all meetings, both open and closed session.

ROLE OF THE ASSOCIATE PROVOST FOR RESEARCH AND SPONSORED PROGRAMS

The Associate Provost for Research and Sponsored Programs, Institutional Official, has the responsibility for providing administrative support of the IRB. The Director, Research Integrity and Compliance is responsible for managing IRB administrative support. The Associate Provost is authorized to attend all meetings, both open and closed session, and has access to open and closed session minutes. The Associate Provost designates the staff member to serve as the Office of Research and Sponsored Programs nonvoting representative on the IRB. The Associate Provost assesses the services provided by the IRB as part of the Office of Research and Sponsored Programs Assessment Survey. Results of the IRB portion of the survey will be shared with the Institutional Official and the committee members by the Associate Provost on an annual basis. The administrative support responsibilities include:

- receiving all protocols;
- preparing and distributing the agenda and review materials to the IRB members;
- recording the minutes of IRB meetings;
- maintaining the IRB database and records; and
- preparing and forwarding review notifications.

ROLE OF THE IRB

The IRB reviews and approves, requires modifications in, or disapproves research protocols annually or more frequently dependent upon the risks to subjects and whenever changes occur in the protocol or procedures. This process protects the rights and welfare of human subjects by requiring equitable selection of subjects, obtaining informed consent, minimizing risks, and ensuring privacy and confidentiality. The IRB must be notified of any unanticipated problems involving risks to subjects or others, including physical or psychological injury to subjects, improper disclosure of private information, economic loss, or other potentially harmful occurrences.

ROLE OF THE IRB CHAIR

One of the most important actions to be taken in establishing an IRB is selecting the individual who will function as chair. The IRB chairperson should be a highly respected individual from within or outside the institution, fully capable of managing the IRB and the matters brought before it with fairness and impartiality. The task of making the IRB a respected part of the institutional community will fall primarily on the shoulders of this individual. The IRB must be fair and impartial, immune to pressure either by the institution's administration, the researchers whose protocols are brought before it, or other professional and nonprofessional sources. Source: The Institutional Review Board Guidebook, 1993.

- The Institutional Official appoints the chair of the IRB.
- The IRB chair serves a one-year term, but can be reappointed.
- The IRB chair presides over convened meetings.
- The IRB chair works with researchers to facilitate the protocol review process.
- The IRB chair will plan, develop, and conduct training workshops for researchers annually.
- The IRB chair works with designated RSP staff to facilitate services and resources provided to the IRB.

ROLE OF THE IRB VICE CHAIR

- The IRB vice chair is elected by the committee from the membership.
- The IRB vice chair serves a one-year term.
- The IRB vice chair presides over convened meetings in the absence of the chair.
- The IRB vice chair works with researchers to facilitate the protocol review process.
- The IRB vice chair assists the chair in planning, developing, and conducting training workshops for researchers annually.
- The IRB vice chair works with designated RSP staff to facilitate services and resources provided to the IRB.

IRB MEMBERSHIP

The Institutional Official recommends membership to the President who appoints the members for a three-year term of service.

The IRB must have at least five members, with varying backgrounds to promote complete and adequate review of research activities involving human subjects commonly conducted by the institution. The IRB must be sufficiently qualified through the experience and expertise of its members and the diversity of their backgrounds, including considerations of their racial and cultural heritage, gender, and their sensitivity to issues such as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

- The IRB includes at least one member whose primary concerns are in scientific areas, at least one member whose primary concerns are in nonscientific areas, and at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
- The IRB does not consist entirely of men or entirely of women and appointments are not made exclusively on the basis of gender.
- The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote.
- An IRB member does not participate in the review of any project in which he/she has a conflicting interest, except to provide information requested by the IRB.

Composition of the IRB where prisoners are involved: In addition to satisfying the above requirements, an IRB shall also meet the following specific requirements:

- A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.
- At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research protocol is reviewed by more than one Board only one Board need satisfy this requirement.
- The prisoner representative does vote on the research protocol that involves prisoners as subjects.

Members can be dismissed from the IRB for cause, which includes but is not limited to the following:

1. not attending three consecutive meetings;
2. not successfully completing IRB Member Training; or
3. disciplinary actions outlined in PAc-22.

IRB AUTHORITY

- The IRB has the authority to approve, require modifications in, or disapprove all research protocols involving human subjects.
- The IRB has the authority to suspend or terminate approval of a protocol that is not being conducted in accordance with the ethical principles, federal regulations, or IRB requirements or that has been associated with unexpected serious harm to human subjects. Investigation of noncompliance of research involving human subjects will be conducted by the Institutional Official (see **Noncompliance Section**).

IRB RESPONSIBILITY

The IRB responsibilities are:

- to conduct review of research protocols involving human subjects;
- to determine which research protocols require continuing review more often than annually, based on the level of risk;
- to determine which research protocols require verification from sources other than the researchers that no material changes have occurred since previous IRB review, including specific criteria used to make these determinations, e.g., randomly selected protocols, complex protocols involving unusual levels or types of risk to subjects; protocols conducted by researchers who previously have failed to comply with OHRP regulations or the requirements of the IRB, and protocols where concern about possible material changes occurring without

IRB approval have been raised based upon information provided in continuing review reports or from other sources;

- to immediately notify the researcher, Institutional Official, dean, and department chair of any suspension or termination of IRB approval;
- to immediately notify the Institutional Official of any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB;
- to approve, require modifications in, or disapprove research protocols by a majority vote (quorum – majority of the IRB members are present including one nonscientific member). If the quorum fails during a meeting due to member recusal, absence of a nonscientist, or early departure, no further actions or votes will be taken by the IRB;
- to conduct training workshops to acquaint researchers with the regulations and to assist researchers with the preparation of protocols;
- to meet as necessary during the academic year to review protocols requiring convened meetings (full board review) and/or other IRB business requiring convened meetings. For full board reviews, the committee will designate a quorum for convened meetings during the summer. The protocol due date for summer review will be the Friday before each summer session begins. Exempt and Expedited review will be conducted throughout the year.
- to conduct continuing review of approved research protocols at intervals appropriate to the degree of risk, but not less than once per year, for protocols which are subject to continuing review;
- to determine if a research protocol is exempt from federal and IRB regulations; and
- to report evidence of noncompliance of an approved protocol to the Institutional Official (see **Noncompliance Section**).

RESEARCHER RESPONSIBILITY

MSU researchers (faculty, staff, and students) who conduct research involving human subjects at MSU or other institutions and/or external researchers who conduct research at MSU must obtain written approval from the IRB prior to involving human subjects in the research and/or making changes to a previously approved protocol.

The researcher is responsible for assessing possible risks to human subjects involved in the research and of taking appropriate steps to minimize those risks wherever possible.

- The researcher is required to submit a protocol application that describes the proposed use of human subjects in research and receive IRB approval prior to involving the human subjects in research (see Protocol Application, **Appendix D**).
- The researcher is responsible for protecting the rights and welfare of human subjects.
- The researcher is responsible for complying with all applicable ethical principles, federal regulations, and IRB requirements.
- The researcher is responsible for conducting the research according to the IRB approved protocol.
- The researcher is responsible for reporting any changes in previously approved protocols to the IRB and receiving approval prior to implementation of the changes.
- The researcher is responsible for obtaining annual continuing review and approval for multi-year projects, or more frequently as determined by the IRB.
- The researcher is responsible for immediately providing a written report to the IRB of any unanticipated injuries or problems involving risks to human subjects or any serious or continuing noncompliance with this policy or the requirements or determination of the IRB.
- Research involving human subjects conducted by students is always under the supervision of a faculty or staff member.

- The researcher is responsible for obtaining required IRB training, including completing online training modules and attaching documentation of a Course Completion Record to all submitted protocols (see Requirements for Training Section).
- The researcher is responsible for maintaining all protocol records including, but not limited to, approved protocol application and all amendments/modifications, approved informed consent documents, approved instruments, IRB notifications, and other relevant documents for three years after the research project has been completed.
- The researcher, when acting as a consultant, is required to retain copies of IRB notifications from originating institution(s) of all collaborative research for the purpose of analyzing data in which data collection has been completed, when appropriate. These records must be retained for three years after the research project has been completed.

REQUIREMENTS FOR TRAINING

IRB Members

The federal regulations require that an “IRB shall be sufficiently qualified through the experience and expertise of its members...” All members shall receive in service IRB member training upon appointment. *Each IRB member is required to successfully complete online IRB Member Training and provide a Course Completion Record to the IRB Administrative Secretary for recordkeeping purposes prior to reviewing protocols.* The Institutional Official will be notified by the IRB of each member’s successful training. Failure to successfully complete the online training will result in dismissal from the committee by the President.

Researchers

All researchers (MSU faculty, staff, students, and/or external researchers) are required to successfully complete the appropriate (or required) online training modules of the Collaborative IRB Training Initiative (CITI) <http://www.citiprogram.org/> Course in the Protection of Human Subjects Research and attach a Course Completion Record to the protocol application. All researchers are required to complete the basic modules before submitting their protocol application and if the research involves the use of special populations such as children/minors, prisoners, the collection of data in schools, additional modules appropriate to the research also must be completed and Course Completion Records must be documented with the protocol application. CITI Training Completion Records are valid for three years; (i.e. the IRB considers the training documentation to expire after three years) however, after a three year period, the researcher must complete the CITI Refresher course before submitting any new protocol application. The IRB will only review protocol applications accompanied by CITI Course Completion Records.

IRB RECORDS

The IRB prepares and/or maintains documentation of IRB activities, including the following:

- copies of all research protocol documents reviewed and approved, change of status, annual continuing review, injury to subjects, and final reports submitted by researchers;
- minutes of IRB meetings that are sufficient in detail to show attendance at the meetings; actions taken by the IRB; the vote on the actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and the resolution;
- records of notifications for protocol and annual continuing review;
- copies of all correspondence between the IRB and researchers;
- copies of all written procedures for the IRB; and
- copies of statements of significant new findings provided to subjects.

The records required shall be retained for at least three (3) years, and records relating to research which is conducted shall be retained for at least three (3) years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the appropriate Federal Department or Agency at reasonable times and in a reasonable manner.

MSU'S IRB REVIEWS ALL RESEARCH INVOLVING HUMAN SUBJECTS

Definitions, 46.102

- **Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (see IRB Definition Section). Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.
- **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains:
 - data through intervention or interaction with the individual, or
 - identifiable private information.
- **Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the human subject or the subject's environment that are performed for research purposes. **Interaction** includes communication or interpersonal contact between investigator and subject. **Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, 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 or associated with the information) in order for obtaining the information to constitute research involving human subjects.
- **IRB** means an Institutional Review Board established in accord with and for the purposes expressed in this policy.
- **IRB approval** means the determination of the IRB that the research protocol has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.
- **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.

The definition of minimal risk for research involving prisoners differs somewhat from that given for noninstitutionalized adults. [See 45 CFR 46.303(d) and IRB Guidebook Chapter 6, Section E, "Prisoners."]
- **Children** are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.
- **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.
- **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.
- **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 which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

In addition to the above, the IRB provides the following definitions:

- **Affiliated Individual** – faculty, staff, or students whose research has been, is, or will be listed in a Tenure, Promotion, PBSI portfolio, or will use MSU's name on a publication or presentation.
- **Aggregate Data** are individual records that have been grouped or combined in a way so that an individual respondent cannot be identified. This means that all unique identifiers, including such items as an address, name, social security number (or other code number), date of birth, death or marriage, for example, have been purged from the data set and that individual records have been grouped together in a manner which further precludes the identification of an individual. In some cases, information such as age, sex, race or religion could be used to identify an individual that has been grouped or aggregated. Precautions must be taken to avoid this situation.
- **Anonymous** means no one, anywhere, ever can identify individual subjects.
- **Archival Data** is any data considered to be previously collected, or existing data. This can mean closed records, secondary data sets (already collected and in the public domain), historical information, and other information that would preclude identifying an individual in any way (by name, social security number, ethnicity, etc.) and evaluated in aggregate form.
- **Associated Individual** – faculty, staff, or students who, during the conduct of research, make use of Morehead State University facilities, equipment, supplies, personnel, students, or grounds.
- **Benefit** – a valued or desired outcome; an advantage.
- **Certificates of Confidentiality** are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research subjects in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to subjects. Any research project that collects personally identifiable, sensitive information and that has been approved by an IRB is eligible for a Certificate. Federal funding is not a prerequisite for a Certificate. For more information, see the NIH Certificates of Confidentiality Kiosk (<http://grants1.nih.gov/grants/policy/coc/>).
- **Comparison of Teaching Methods or Course Content** in two or more sections of a faculty member's course is not considered research involving human subjects when the comparison is made between test grades or scores (no identifiers) in order to improve a faculty member's teaching methods or course design and will not be used for publication or presentation; in such cases, course comparisons do not come under the purview of the IRB.

- ➔ **Confidentiality** – methods used to ensure that information obtained by researchers about their subjects is not improperly divulged.
- ➔ **Contribute to Generalizable Knowledge** – investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings.
- ➔ **Debriefing** - providing subjects previously undisclosed information about the research project following completion of their participation in research. (Note that this usage, which occurs within the behavioral sciences, departs from standard English, in which debriefing is obtaining rather than imparting information.)
- ➔ **Evaluation Component of an Internal or External Grant** usually includes formative and summative components and is conducted for the purpose of measuring the accomplishment of program activity objectives and the effectiveness of the program in achieving the program goals. A grant evaluation provides a comparison of what was to what is, documents performance outcomes, and assesses the impact of the program or project. A final report that summarizes the success of the program is required by the funding source. The evaluation component is not research, as defined in the federal regulations (research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge), and does not come under the purview of the IRB.
- ➔ **External IRB Approval Required for Research Conducted at Other Institutions** - researchers who are conducting research in conjunction with another university or IRB need concurrent approval from both institutions (Morehead State University's IRB and the other participating IRB). However, concurrent approval may be waived (at the discretion of MSU's IRB per federal regulation 46.114 [cooperative research with other institutions]) if the researcher can provide to the MSU IRB a documented approved protocol and notification of approval by the other IRB. The IRB requests the information in order to determine if MSU approval can be waived and the other institution's approval can be accepted.
- ➔ **Informed Consent** - a person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence [Federal Policy §116; 21 CFR 50.20 and 50.25].
- ➔ **Instructors or others** who are not directly associated with the research, but nonetheless have certain rights and must be safeguarded; for example, an instructor of a class whose students will be asked to participate in a research project. The researcher must obtain the instructor's permission to conduct the research in the class. The instructor has the right to refuse to allow the research to be conducted in the class. The researcher must include safeguards that will be used to protect the rights of the instructor against reprimands by the institution.
- ➔ **Privacy** – having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.
- ➔ **Protocol** - the formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.
- ➔ **Research Grant or Research Component of an Internal or External Grant** that involves research, as defined by the federal regulations (research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge), and human subjects, as defined by the federal regulations (human subject means a living individual about whom an investigator [whether professional or student] conducting research obtains (1) data through intervention or interaction with the

individual, or (2) identifiable private information), must be reviewed and approval received from the IRB prior to the involvement of the human subjects.

- ➔ **Research Project Collaboration with MSU Researcher/Consultant for the Purpose of Analyzing Data (Data Collection Complete):** Research whereby the data collection has been completed prior to the collaboration with an MSU affiliate or associate researcher. MSU researcher/consultant should retain a copy(s) of the notification of IRB approval from the originating institution(s) when appropriate. (See **Researcher Responsibilities Section**).
- ➔ **Risk** - the probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk." (See also: *Minimal Risk*.)
- ➔ **Self-Assessment Surveys** distributed by academic and/or administrative units or faculty at the University that are for the *sole purpose of assessing services or instruction or course-curriculum* provided by the units or faculty and will only be used by the academic and/or administrative units or faculty for internal purposes (e.g., institutional research – improving services or instruction or course-curriculum, workshop evaluations, alumni evaluations) are not considered research and do not come under the purview of the IRB. However, if the data collected from the *self-assessment surveys will be disseminated through external publication or presentation*, then the activity is considered research and must be reviewed and approved by the IRB prior to the data collection.
- ➔ **Sensitive** describes data of so personal a nature that the potential of harm to subjects is more than minimal, such as sexual behavior or criminal activity.
- ➔ **Systematic Investigation** is an activity that involves a prospective research plan which incorporates data collection, both quantitative and qualitative, and data analysis to answer a research question.
- ➔ **Voluntary** - free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.

IRB REVIEW

Activities that meet the definition of *research* and involve *human subjects* must be reviewed and approved by the IRB prior to any involvement of human subjects in the research project. There are three types of protocol submission and review:

1. exempt;
2. expedited; and
3. full board.

EXEMPT REVIEW

The IRB determines whether research protocols involving human subjects qualify for an exemption from the federal regulations. This decision is never made by the researcher. Even though the research may qualify as exempt from federal regulations, the committee still has a responsibility to decide whether the protocol represents ethical research. It should be noted that research involving special populations who are not legally able to provide consent for participation, such as research using children, prisoners, and the cognitively impaired, typically will not qualify for exemption.

Exempt Research is Defined by the Federal Regulations as:

Unless otherwise required by Federal Department or Agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are **exempt** from this policy¹:

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

¹ Institutions with HHS-approved assurances on file will abide by provisions of Title 45 CFR part 46 subparts A-D. Some of the other departments and agencies have incorporated all provisions of Title 45 CFR Part 46 into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, subpart C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Initial Review of Protocols:

Exempt protocol applications (see Protocol Application, **Appendix D – Request For Exemption From Federal Regulations**) can be submitted to the IRB at any time during the year. The protocols are reviewed by the chair or a member designated by the chair. If the reviewer approves the application as exempt, a written notification will be forwarded to the researcher. Results of the exempt review will be presented to the committee at a regularly scheduled meeting by the chair.

Requesting Exemption:

Certain research involving human subjects may be considered exempt by the Office for Human Research Protections (OHRP). However, each institution must determine if federal regulations are met and institutions may require additional safeguards. It is important to remember that at MSU the IRB determines if a research project is exempt. The decision is not made by researchers.

Researchers who submit a request for exemption, whose research is determined not to qualify for exempt status, will have the protocol returned to them so they may prepare an application for expedited or full board review.

Use of Questionnaires at MSU:

Most of the research that is conducted at MSU is questionnaire research. The MSU IRB carefully reviews each questionnaire to determine potential risks to human subjects. Therefore, no questionnaire is exempt by virtue of being “just” a questionnaire. Each questionnaire submitted to the MSU IRB is evaluated with regard to the subject’s potential experience of participating in the research and completing the questionnaire. Each questionnaire, survey or other paper-pencil method must be reviewed by the MSU IRB.

EXPEDITED REVIEW

The IRB determines whether research protocols involving human subjects qualify for expedited review according to the federal regulations. This decision is never made by the researcher.

An IRB may use the expedited review procedure to review either or both of the following:

- (1) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,
- (2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

The MSU IRB will consider changes as minor that do not increase the level of risk or change the level of privacy or confidentiality approved in the original protocol. Types of minor changes may include, but are not limited to: additional questions on an instrument or changes to the consent document for clarification purposes.

Expedited Review Procedure² is Defined by the Federal Regulations (OHRP Guidance, 1998):

Applicability:

- (A) Research activities that:
 - (1) present no more than minimal risk to human subjects, and
 - (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. *Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.*
- (B) The categories in this list apply regardless of the age of subjects, except as noted.
- (C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- (D) The expedited review procedure may not be used for classified research involving human subjects.
- (E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review – expedited or convened – utilized by the IRB.
- (F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research 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 children³ 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 are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

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.
- ² An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.
- ³ Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).

Initial Review of Protocols:

Expedited protocol applications (see Protocol Application, **Appendix D – Expedited or Full Board Review**) can be submitted to the IRB at any time during the year. The Expedited protocol applications are reviewed by the chair or a member designated by the chair. The reviewer can exercise all authorities of the IRB except disapproval. The researcher will receive written notification of the findings. Results of the expedited review will be presented to the committee at a regularly scheduled meeting by the chair. If the protocol is incomplete, it will be returned to the researcher for revision and resubmission. If the reviewer is unable to make a determination, the protocol will be forwarded to the full committee for review.

FULL BOARD REVIEW

Full Board Review is Defined as:

Research that does not meet the criteria for exempt or expedited review must be submitted to the full board for review at a convened meeting. The IRB meets monthly or more frequently if necessary during the academic year to review protocols requiring convened meetings (full board review). The committee will designate a quorum for a convened meeting once during Summer I and once during Summer II. The protocol due date for summer review will be the Friday before each summer session begins. Protocol applications, ten (10) copies, received will be date stamped, assigned a protocol number, recorded in the IRB database, and forwarded to IRB members one week prior to the scheduled meeting. Once the protocol has been reviewed, a notification of the IRB's decision (approve, require modifications to approve, or disapprove with a statement of the reasons) will be forwarded to the researcher.

Initial Review of Protocols:

Full board protocol applications (see Protocol Application, **Appendix D – Expedited or Full Board Review**) must be submitted according to the published deadline dates. The Full board protocol applications are delivered to the members at least one week prior to the scheduled meeting. The protocol will be approved if the majority of the quorum present vote for approval. The members may require modifications in (to secure approval), or disapprove the research activities. A written notification of the IRB findings will be forwarded to the researcher.

IRB REVIEW OF RESEARCH

IRB Review of Research is Defined by the Federal Regulations as:

- (a) The IRB reviews and has authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.
- (b) The IRB requires that information given to subjects as part of informed consent is in accordance with 46.116. The IRB may require that information, in addition to that specifically mentioned in 46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.
- (c) The IRB requires documentation of informed consent or may waive documentation in accordance with 46.117.
- (d) The IRB notifies investigators and the institution in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
- (e) The IRB conducts continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

CRITERIA FOR IRB APPROVAL

Criteria for IRB Approval of Research is Defined by the Federal Regulations as:

- (a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:
 - (1) 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.
 - (2) 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 should consider 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 should 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 risks that fall within the purview of its responsibility.
 - (3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be 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.

- (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 46.116.
 - (5) Informed consent will be appropriately documented, in accordance with, and to the extent required by 46.117.
 - (6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
 - (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- (b) 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, economically or educationally disadvantaged persons, or MSU students, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

REVIEW BY INSTITUTION

Review by Institution is Defined by the Federal Regulations as:

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

GENERAL REQUIREMENTS FOR INFORMED CONSENT

Informed consent, a person's voluntary agreement based on adequate knowledge and understanding of relevant information to participate in research or to undergo a diagnostic, therapeutic, or preventative procedure, is generally a required component of research. As such, researchers should plan and describe their procedures for obtaining and documenting informed consent to the IRB in order to gain approval for their research.

Researchers bear the burden of providing relevant information about the research to potential subjects, including the nature and aim of the research, the subject's role in the project, and possible risks to the subject's physical, psychological, or emotional well-being.

If a full understanding of the nature or aim of the research on the part of human subjects would somehow invalidate results and human subjects must therefore be misled, the researcher must, whenever possible, explain the true nature and aim of the research to subjects *after the fact*. This obligation placed upon the researcher helps to ensure that appropriate care will be taken throughout the research to protect human subjects and their rights and to ensure their respectful treatment.

The investigator must make it clear to prospective subjects that they are free to refuse to participate or to withdraw from involvement at any time. Prospective subjects must be given sufficient time to consider whether or not to participate and must not be subjected to any form of coercion or undue influence. Information given to a prospective human subject shall be in language understandable to the subject. No informed consent, whether oral or written, may include any exculpatory language through which the subject waives or appears to waive any legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

It should be noted that, although the process of informed consent may involve a participant documenting his/her agreement to participate by signing a form, this documentation is only one part of the informed consent process and does not substitute for the other steps.

When research involves the use of special populations who are not legally able to provide informed consent, such as children, prisoners, or the cognitively impaired, the researcher bears the burden of not only informing the subjects of the research, but also their guardians. In such cases, it is

necessary to obtain parental/guardian permission for participation and it also may be necessary to obtain assent of the subject, and a description of both processes (and documentation procedures) must be approved by the IRB. For more information see a full description below (pages 18 & 19).

General Requirements for Informed Consent are Defined by the Federal Regulations as:

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy, unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language, through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

In the process of informed consent, some basic types of information should be shared with potential subjects. Researchers may use the following checklist as a guideline:

- _____ a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- _____ a description of any reasonably foreseeable risks or discomforts to the subject;
- _____ a description of any benefits to the subject or to others which may reasonably be expected from the research (MSU IRB: or a statement that no benefits are to be expected);
- _____ a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- _____ a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- _____ for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- _____ an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
- _____ a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

When appropriate, the following types of information should also be included

- _____ a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- _____ anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

- _____ any additional costs to the subject that may result from participation in the research;
- _____ the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- _____ a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- _____ the approximate number of subjects involved in the study.

For some tips on conducting informed consent procedures, see Appendix A

The approval by the IRB of a waiver of signed informed consent does not relieve the obligation of the researcher to obtain informed consent. The IRB may approve a full waiver of informed consent. Researchers must complete **Part B** to request a waiver of informed consent or signed informed consent. The IRB will determine in each case whether the justification meets the federal criteria for a waiver of informed consent or signed informed consent.

- ***Requirements for permission by parents or guardians and for assent by children:***

- In addition to the determinations required under other applicable sections, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with 46.116.
- In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by 46.116, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under 46.404 or 46.405. Where research is covered by 46.406 and 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
- In addition to the provisions for waiver contained in 46.116, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

- Permission by parents or guardians shall be documented in accordance with and to the extent required by 46.117.
- When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective (46.116(d)(e)).

Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

DOCUMENTATION OF INFORMED CONSENT

Documentation of Informed Consent is Defined by the Federal Regulations as:

- *Except as provided in the paragraph "An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects..." of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.*
- *Except as provided in paragraph "An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects..." of this section, the consent form may be either of the following:*
 - a written consent document that embodies the elements of informed consent required by 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator should give either the subject or the representative adequate opportunity to read it before it is signed; or
 - a short form written consent document stating that the elements of informed consent required by 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the *IRB shall approve a written summary* of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, *the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary.* A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.
- *An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either:*
 - that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

OR

 - that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

THE CONSENT FORM

Informed consent must be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.

Informed consent may be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. The consent form may be read to the subject or the subject's legally authorized representative, but the subject or representative must be given adequate opportunity to read it before it is signed. A copy of the consent form must be given to the person signing the form.

The consent form must include all of the required elements of informed consent detailed in 45 CFR 46.116 and must be in language understandable to the subject. The consent form should be written at no more than the 8th grade reading level and all technical terms or jargon should be explained in ordinary language.

The IRB recommends the use of the second person writing style in the informed consent to communicate to prospective subjects that there is a choice to be made. Use of first person may be interpreted as coercive.

The investigator must develop a consent form that includes the basic elements of informed consent. The subject or the subject's guardian must be given adequate opportunity to read the form before signing it. The written consent form shall state that the subject has agreed to participate in the research project. The written consent form may *either* provide the subject with the basic information required by the federal government as outlined above, *or* it may simply state that this information has been presented orally. If this information is presented orally and not in writing, the investigator must have a witness to the oral presentation.

Investigators need to be aware that many college students are under age and that in addition to an underage subject's consent an investigator must obtain the consent of a parent or guardian to the minor's participation in the research.

WAIVING OF INFORMED CONSENT

The IRB may approve a consent procedure which does not include or which alters some or all of the elements of informed consent set forth in this section provided that the IRB finds and documents that:

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; and
3. the research could not practically be carried out without the waiver or alteration.

WAIVING OF SIGNED INFORMED CONSENT

The IRB may waive the requirement for the researcher to obtain a signed consent form for some or all subjects if it finds either:

1. the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. [In this case, each subject will be asked whether he or she wants documentation linking him or her with the research, and the subject's wishes will govern.]; or
2. that the research presents no more than minimal risk to subjects and involves no procedures for which written consent is normally required outside of the research context.

Researchers must complete **Part B** to request a waiver of informed consent or signed informed consent if submitting an Expedited/Full Board Review protocol, or provide the appropriate information in the consent portion of the Application for Exemption.

For other exceptional circumstances under which the IRB may waive the requirement to obtain and document informed consent, see Sections 46.116 and 46.117 of the Code of Federal Regulations in **Appendix B**, and Part B in **Appendix D**.

UNDERAGE SUBJECTS AND SPECIALIZED POPULATIONS UNDER STUDY

Federal regulations require that IRBs give special consideration to protecting the welfare of particularly vulnerable subjects, such as children and minors (persons under 18 years of age), prisoners, pregnant women, mentally disabled persons, terminally ill patients, minorities, elderly persons, economically or educationally disadvantaged persons, and so-called "normal" volunteers such as students and employees. Researchers need to take additional special precautions when involving such special classes of subjects.

The primary concern regarding the participation of such specialized populations in research is whether the subjects have a real choice regarding their participation in research, or whether their situation prohibits the exercise of free choice. IRBs should safeguard the consent process (and, indeed, the entire research relationship) to ensure open and free communication between the researcher and the prospective subject.

Consent documents must be written in language easily understandable to subjects; the possibility of illiteracy should be accounted for, as should the need for communicating in foreign languages. The involvement of representatives from the target population(s) may also be pertinent to IRB review. When children or minors are involved in research, the regulations require the assent of the child or minor along with the permission of the parent(s). Additionally, research involving persons whose autonomy is compromised by disability or restraints on their personal freedom should bear some direct relationship to their condition or circumstances. All human subjects research conducted in a foreign country in which American researchers are involved, and which would be subject to the federal regulations if it were conducted wholly within the United States, must comply with the federal regulations for the protection of human subjects in all material respects.

The researcher should also remember that any study in which women of childbearing potential are possible subjects may inadvertently include pregnant women. For information about additional protections of fetuses or pregnant women involved in research see Subpart B of the Code of Federal Regulations in **Appendix B**.

For information about additional protections of prisoners involved in research see Subpart C of the Code of Federal Regulations in **Appendix B**.

For information about additional protections of children or minors involved in research see Subpart D of the Code of Federal Regulations in **Appendix B**.

STUDENTS

Students as Subjects of Research

There are special concerns regarding the involvement of normal (i.e., healthy) persons who volunteer to participate in research. Volunteers for whom no therapeutic benefit can result from participation in research should be exposed to risks that are minimized to the greatest extent possible. Normal volunteers, such as students and employees, should generally be recruited through announcements or advertisements, rather than through individual solicitations. Personal solicitations increase the likelihood that participation will be the result of undue influence. Researchers should also consider that students may be under age and may thus fall into two special classes as *normal and underage* subjects. Instructors (and/or supervisors or employers, if applicable) should not collect data from their own students (and/or supervisees or employees, if applicable); however, a research assistant may be utilized to do so.

Students as Conductors of Research

Students are often required to conduct research as part of the course work for a class, for an independent study project, or as part of a postgraduate degree. When that research involves human subjects, the research may be subject to IRB review. The concern here is not for the students in the

class or conducting independent research projects, but for the *subjects* of the research, who may or may not themselves be students.

Student research involving human subjects, conducted to satisfy the requirements of regular courses, independent studies, or graduate degree programs, is subject to IRB review if intended by the student researcher or by supervising faculty for publication or other public presentation, including theses. Research protocols so subject must be reviewed and approved by supervising faculty before being submitted to the IRB. Faculty supervising such research are expected to be familiar with IRB protocol requirements. *If, however, these activities are intended solely for the practice and experience of the student researchers, and will not be published or otherwise presented, an IRB approval will not be necessary.* Faculty are cautioned, however, to have student researchers follow good research practices in obtaining informed consent from subjects of research and maintaining confidentiality. Both undergraduate and graduate students conducting independent research projects will need to have their IRB protocols thoroughly reviewed and approved by their supervising faculty member *before* they are submitted to the IRB committee. Morehead State University is potentially liable for any activities conducted under its auspices.

For further information about the above classes of subjects and other specialized populations see Chapter Six: Special Classes of Subjects in the OHRP Protecting Human Research Subjects Institutional Review Board Guidebook (available on the Web at http://www.hhs.gov/ohrp/irb/irb_guidebook.htm) and on the MSU IRB Web page at <http://www.moreheadstate.edu/rgc/secure/index.aspx?id=6943>.

TIMING OF SUBMISSION AND REVIEW

When submitting materials and writing the abstract for an IRB protocol, the researcher should keep in mind the purpose for the review. The IRB is charged with safeguarding the rights and safety of research subjects and needs sufficient information to complete the review. Hence, the IRB needs to have answers to the following questions:

- How are subjects to be selected?
- What will be the role of the subjects? This includes informing the IRB what information subjects will be given and when.
- What are the circumstances of all interaction between the researcher(s) or people working for the researcher(s) and the subjects?
- Who else might be affected by the research?

These details should be clear in the abstract and materials submitted with the protocol application. Note that in some cases, this level of detail may well be more than that required in a detailed grant application. Finally, keep in mind that the IRB needs to document these details. Hence, if a researcher describes needed details in a conversation with an IRB member, the detail needs to be provided in writing to the IRB as part of the protocol application documentation.

Research involving human subjects, as defined in the Code of Federal Regulations and **Appendix B**, must be approved by the IRB whether internal or external funding is requested or funding will not be requested. However, timing of protocol submissions varies somewhat depending on the source of funding. Researchers should make certain to indicate whether a protocol is for internal or external funding. Researchers usually can expect a review response within four weeks from the date of a protocol submission for full board review. Protocols that involve special populations (e.g., prisoners) or require general counsel review may require a longer review time. The IRB accepts protocol applications at any time; however, the IRB forwards notification of specific protocol due dates for full board review each month by email. Exempt and expedited protocols can be submitted throughout the year, including summer as needed. Committee meeting dates are in conjunction with the protocol due dates.

INTERNAL FUNDING

Protocols for University-funded research must be submitted well in advance of proposal deadlines so that certification of IRB approval can be *included* with the proposal. Protocols for MSU Faculty Research and Creative Productions Grants and Summer Research and Creative Production Fellowships must be submitted according to the specific protocol due dates forwarded by email each month in order to receive IRB approval before the proposal deadlines.

EXTERNAL FUNDING

Some federal departments or agencies require IRB approval prior to submission of grant proposals while others do not. Follow proposal guidelines carefully or call the MSU Office of Research and Sponsored Programs if the timing of IRB approval for a specific external department or agency is unclear. Researchers should make certain to indicate that the protocol is for external funding.

MISCONDUCT IN RESEARCH

Misconduct in research does not come under the purview of the IRB. *All written allegations of misconduct in research are to be forwarded directly to the Provost and Executive Vice President by faculty and staff members according to PAC-32 and will be handled by the Provost and Executive Vice President according to PAC-32. PAC-32 can be viewed at <http://www.moreheadstate.edu/hr/policies/index.aspx?id=3822>.*

NONCOMPLIANCE OF RESEARCH INVOLVING HUMAN SUBJECTS WITH FEDERAL AND UNIVERSITY REGULATIONS

The IRB exists first and foremost to protect the rights and welfare of human subjects in research. Unapproved research involving human subjects or research that deviates from the approved protocol, places the human subjects at risk. All written allegations of noncompliance of research involving human subjects are viewed as serious by the Institutional Official and the IRB. *Written allegations must be made in good faith by persons with direct knowledge of the allegation.* To ensure that human subject research is conducted according to an approved protocol that is in compliance with federal regulations and ethical principles, any issue of noncompliance of research involving human subjects will be handled according to the procedures outlined in this section.

Noncompliance of Research Involving Human Subjects *Without an Approved Protocol*

The Institutional Official is the person responsible for dealing with issues of noncompliance of research projects that involve the use of human subjects *without an approved protocol* during the research project.

- Written allegations of noncompliance of research involving human subjects are to be forwarded directly to the Institutional Official by the person with direct knowledge of the allegations.
- The Institutional Official is responsible for investigating the allegations including determining the seriousness of the allegation, meeting with and informing the researcher, stopping the research during the investigation, and conducting the investigation in a timely manner.
- The researcher will provide a written response to the allegations.
- Once the response is received, the Institutional Official will complete the investigation and may consult with General Counsel.

- Based upon the results of the investigation, the Institutional Official may administer sanctions that may include suspension of all approved and future research projects that involve human subjects for a period of time, confiscation of all data collected, and a written assurance from the researcher that no data collected without an approved protocol will be used.
- If on going, the research will be halted immediately.
- If the outcome of the investigation is determined to be an error of omission by the researcher, the researcher will complete IRB training and provide assurance that no data collected without an approved protocol will be used.

Noncompliance of Research Involving Human Subjects *With an Approved Protocol*

The Institutional Official has oversight of research and IRB functions, thus the Institutional Official is the person responsible for dealing with issues of noncompliance of research involving human subjects including conducting investigations and administering sanctions, if appropriate.

- Written allegations of noncompliance of research involving human subjects for an approved protocol are forwarded directly to the chair who will convene the IRB to discuss the allegation.
- The IRB will determine *by quorum vote* if the noncompliance of research involving human subjects is serious or not serious and if the approval of the research protocol should be suspended or terminated. (45 CFR 46.113)
- The Chair of the IRB shall forward to the Institutional Official the written allegation of noncompliance of research involving human subjects and provide the IRB's determination of the seriousness of the violation and the IRB's decision to suspend or terminate. (45 CFR 46.113)
- The Institutional Official will inform the researcher of the allegation and the IRB's decision regarding the issue.
- The researcher will provide the Institutional Official with a written response to the allegation and corrective action to be in compliance with federal and University regulations, if appropriate.
- Once the response is received, the Institutional Official will complete the investigation.
- The Institutional Official will notify the researcher and the IRB regarding the outcome of the investigation.
- Any data collected that has been associated with a violation of noncompliance of research involving human subjects must not be used by the researcher.
- The researcher will be required to forward all data to the Institutional Official along with a written certification that the data will never be used.
- The Institutional Official will provide the data and certification to the IRB for the permanent file.
- The Institutional Official may administer sanctions that may include suspension of all approved and future research projects that involve human subjects for a period of time.

Some examples of noncompliance of research involving human subjects with federal and IRB regulations include, but are not limited to:

- failure to obtain IRB approval for a research project that involves human subjects;
- failure to obtain IRB approval for changes in a previously approved protocol;
- misuse or nonuse of the informed consent document;
- failure to respond to an IRB request for additional information to continue review of a proposed protocol;
- failure to submit for IRB approval continuing review for projects with durations of more than one year; and
- failure to conduct the research project according to the approved protocol.

PREPARATION OF FULL BOARD PROTOCOLS

Incomplete protocols will not be reviewed by IRB members but will be returned to the researcher with a memo that requests additional information. Once this information is received, the review will continue. Ten (10) collated and stapled sets of the following items must be sent to the IRB, 901 Ginger Hall:

1. **Completed application, including an abstract, informed consent script and letter, all instruments, and recruiting materials,** required for initial submission (see **Appendix D**) with all necessary signatures.
2. *NOTE that research involving fetuses, human in vitro fertilization, or pregnant women, women or minorities, children and minors, cognitively impaired persons, prisoners, traumatized and comatose patients, terminally ill patients, elderly/aged persons, or other special classes of subjects; research involving normal volunteers such as students and employees; and international research require additional information and procedures, perhaps including review by other committees (e.g., an Ethical Advisory Board). [See Subparts B, C, and D of the Protection of Human Subjects in Appendix B; or consult Chapter Six: Special Classes of Subjects in the [QHRP Protecting Human Research Subjects Institutional Review Board Guidebook](http://ohrp.osophs.dhhs.gov/irb/irb_guidebook.htm) (available on the Web at http://ohrp.osophs.dhhs.gov/irb/irb_guidebook.htm and on the IRB's web page at <http://www.moreheadstate.edu/rgc/secure/index.aspx?id=6943>).]* Protocols in these areas of research must be initiated well in advance of proposal deadlines (if IRB approval must accompany the proposal) and must be carefully coordinated with the IRB.

FULL BOARD PROTOCOL REVIEW PROCESS

Keeping in mind the time frame outlined under "Timing of Submission and Review," each complete protocol will be reviewed as follows:

1. complete protocols will be hand delivered to individual IRB members soon after they are received by the IRB;
2. the IRB will read the protocols and, based on criteria outlined in this handbook and forms in Appendix D, will decide whether the protocol "conforms in all respects to established policies and institutional assurances and does not place humans at risk;"
3. the IRB will meet to discuss the protocols. The chair of the IRB will notify the researcher in writing of the IRB's vote to approve, require modifications in, or disapprove the protocol. If the protocol cannot be approved in its present form, this notice will express the concerns of the IRB and will inform the researcher of the specific changes required to secure approval of the protocol; and
4. revisions of any kind, whether recommended by the IRB or initiated by the researcher, *must* be reviewed and approved by the IRB. Once the revised protocol is received, the protocol will be returned to the IRB members. Final approval will be granted if a majority of IRB members accepts the revised protocol.
5. for exempt and expedited protocols, see the appropriate sections for the review process.

REPORTS REQUIRED BY THE IRB

A number of progress reports are required after the original protocol approval.

The IRB is required to conduct continuing review of research covered by the policy described in this handbook and **Appendix B**.

Researchers whose protocols are approved through expedited or full board procedures, whose duration is more than one year must participate in continued review as determined by the IRB. To fulfill a requirement for continuing review researchers must submit **Part H** to the IRB yearly or more frequently if required by the board. Failure of the IRB to enforce submission of follow-up reports could seriously compromise future attempts by MSU faculty to secure external funding; therefore, any researcher who chooses not to submit follow-up reports will not be allowed to submit new protocols

for review until all follow-up reports for previous protocols which are due or past due have been received and approved.

Additionally, if *any* revisions are made to an approved project or if any unforeseen risks arise during an investigation, the researcher must submit **Part H** to the IRB with an attached memorandum fully explaining the nature of the change or unforeseen risk. Examples of changes that must be submitted to the IRB include, but are not limited to, changes in procedures, measures/instruments, researchers (PIs) or key personnel, changes in risks, adverse reactions from subjects, date extensions, etc.

Finally, upon completion or termination of an approved expedited or full board project, researchers must again submit **Part H**.

When **Part H** is submitted to the IRB for any reason, the IRB Chair will review the submission. If minor changes or date extensions are requested, the Chair may approve the submission; however, if substantial changes or changes in risk level are being requested, or adverse reactions are being reported, the submission may be forwarded to the full board for consideration.

APPENDIX A

TIPS ON INFORMED CONSENT FROM THE OFFICE OF HUMAN RESEARCH PROTECTIONS

The process of obtaining informed consent must comply with the requirements of 45 CFR 46.116. The documentation of informed consent must comply with 45 CFR 46.117. The following comments may help in the development of an approach and proposed language by investigators for obtaining consent and its approval by IRBs.

- **Informed consent is a process, not just a form.** Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language" (i.e., understandable to the people being asked to participate). The written presentation of information is used to document the basis for consent and for the subjects' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.
- **Use of the first person** (e.g., "I understand that...") can be interpreted as suggestive, may be relied upon as a substitute for sufficient factual information, and can constitute coercive influence over a subject. Use of scientific jargon and legalese is not appropriate. Think of the document primarily as a teaching tool not as a legal instrument.
- **Describe the overall experience that will be encountered.** Explain the research activity, how it is experimental (e.g., a new drug, extra tests, separate research records, or nonstandard means of management, such as flipping a coin for random assignment or other design issues). Inform the human subjects of the reasonably foreseeable harms, discomforts, inconvenience and risks that are associated with the research activity. If additional risks are identified during the course of the research, the consent process and documentation will require revisions to inform subjects as they are recontacted or newly contacted.
- **Describe the benefits that subjects may reasonably expect to encounter.** There may be none other than a sense of helping the public at large. If payment is given to defray the incurred expense for participation, it must not be coercive in amount or method of distribution.
- **Describe any alternatives to participating in the research project.** For example, in drug studies the medication(s) may be available through their family doctor or clinic without the need to volunteer for the research activity.
- **The regulations insist that the subjects be told the extent to which their personally identifiable private information will be held in confidence.** For example, some studies require disclosure of information to other parties. Some studies inherently are in need of a Certificate of Confidentiality (see reference under Definitions) which protects the investigator from involuntary release (e.g., subpoena) of the names or other identifying characteristics of research subjects. The IRB will determine the level of adequate requirements for confidentiality in light of its mandate to ensure minimization of risk and determination that the residual risks warrant involvement of subjects.
- **If research-related injury (i.e., physical, psychological, social, financial, or otherwise) is possible in research that is more than minimal risk [see 45 CFR 46.102(g)], an explanation must be given of whatever voluntary compensation and treatment will be provided.** Note that the regulations do not limit injury to "physical injury." This is a common misinterpretation.
- **The regulations prohibit waiving or appearing to waive any legal rights of subjects.** Therefore, for example, consent language must be carefully selected that deals with what the institution is voluntarily willing to do under circumstances, such as providing for compensation beyond the provision of immediate or therapeutic intervention in response to a research-related injury. In short, subjects should not be given the impression that they have agreed to and are without recourse to seek satisfaction beyond the institution's voluntarily chosen limits.
- **The regulations provide for the identification of contact persons who would be knowledgeable to answer questions of subjects about the research, rights as a**

research subject, and research-related injuries. These three areas must be explicitly stated and addressed in the consent process and documentation. Furthermore, a single person is not likely to be appropriate to answer questions in all areas. This is because of potential conflicts of interest or the appearance of such. Questions about the research are frequently best answered by the investigator(s). However, questions about the rights of research subjects or research-related injuries (where applicable) may best be referred to those not on the research team. These questions could be addressed to the IRB, an ombudsman, an ethics committee, or other informed administrative body. Therefore, each consent document can be expected to have at least two names with local telephone numbers for contacts to answer questions in these specified areas.

- **The statement regarding voluntary participation and the right to withdraw at any time can be taken almost verbatim from the regulations (45 CFR 46.116(a)(8)).** It is important not to overlook the need to point out that no penalty or loss of benefits will occur as a result of both not participating or withdrawing at any time. It is equally important to alert potential subjects to any foreseeable consequences to them should they unilaterally withdraw while dependent on some intervention to maintain normal function.
- Don't forget to ensure provision for appropriate **additional requirements** which concern consent. Some of these requirements can be found in sections 46.116(b), 46.205(a)(2), 46.207(b), 46.208(b), 46.209(d), 46.305(a)(5-6), 46.408(c), and 46.409(b). The IRB may impose additional requirements that are not specifically listed in the regulations to ensure that adequate information is presented in accordance with institutional policy and local law.

APPENDIX B

Code of Federal Regulations
TITLE 45 PUBLIC WELFARE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
PART 46 PROTECTION OF HUMAN SUBJECTS
Revised June 23, 2005
Effective June 23, 2005

Subpart A -- Basic HHS Policy for Protection of Human Research Subjects

Sec.

- [46.101](#) To what does this policy apply?
- [46.102](#) Definitions.
- [46.103](#) Assuring compliance with this policy--research conducted or supported by any Federal Department or Agency.
- [46.104-](#)
[46.106](#) [Reserved]
- [46.107](#) IRB membership.
- [46.108](#) IRB functions and operations.
- [46.109](#) IRB review of research.
- [46.110](#) Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
- [46.111](#) Criteria for IRB approval of research.
- [46.112](#) Review by institution.
- [46.113](#) Suspension or termination of IRB approval of research.
- [46.114](#) Cooperative research.
- [46.115](#) IRB records.
- [46.116](#) General requirements for informed consent.
- [46.117](#) Documentation of informed consent.
- [46.118](#) Applications and proposals lacking definite plans for involvement of human subjects.
- [46.119](#) Research undertaken without the intention of involving human subjects.
- [46.120](#) Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
- [46.121](#) [Reserved]
- [46.122](#) Use of Federal funds.
- [46.123](#) Early termination of research support: Evaluation of applications and proposals.
- [46.124](#) Conditions.

Subpart B -- Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

Sec.

- [46.201](#) To what do these regulations apply?
- [46.202](#) Definitions.
- [46.203](#) Duties of IRBs in connection with research involving pregnant women, fetuses, and neonates.
- [46.204](#) Research involving pregnant women or fetuses.
- [46.205](#) Research involving neonates.
- [46.206](#) Research involving, after delivery, the placenta, the dead fetus or fetal material.
- [46.207](#) Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

Subpart C -- Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Sec.

- [46.301](#) Applicability.
- [46.302](#) Purpose.
- [46.303](#) Definitions.
- [46.304](#) Composition of Institutional Review Boards where prisoners are involved.

[46.305](#) Additional duties of the Institutional Review Boards where prisoners are involved.
[46.306](#) Permitted research involving prisoners.

Subpart D -- Additional Protections for Children Involved as Subjects in Research

Sec.

[46.401](#) To what do these regulations apply?
[46.402](#) Definitions.
[46.403](#) IRB duties.
[46.404](#) Research not involving greater than minimal risk.
[46.405](#) Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.
[46.406](#) Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
[46.407](#) Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.
[46.408](#) Requirements for permission by parents or guardians and for assent by children.
[46.409](#) Wards.

Authority: 5 U.S.C. 301; 42 U.S.C. 289(a).

Editorial Note: The Department of Health and Human Services issued a notice of waiver regarding the requirements set forth in part 46, relating to protection of human subjects, as they pertain to demonstration projects, approved under section 1115 of the Social Security Act, which test the use of cost-sharing, such as deductibles, copayment and coinsurance, in the Medicaid program. For further information see 47 FR 9208, Mar. 4, 1982.

Note: As revised, Subpart A of the HHS regulations incorporates the Federal Policy for the Protection of Human Subjects (56 FR 28003). Subpart D of the HHS regulations has been amended at Section 46.401(b) to reference the revised Subpart A.

The Federal Policy for the Protection of Human Subjects is also codified at

7 CFR Part 1c	Department of Agriculture
10 CFR Part 745	Department of Energy
14 CFR Part 1230	National Aeronautics and Space Administration
15 CFR Part 27	Department of Commerce
16 CFR Part 1028	Consumer Product Safety Commission
22 CFR Part 225	International Development Cooperation Agency, Agency for International Development
24 CFR Part 60	Department of Housing and Urban Development
28 CFR Part 46	Department of Justice
32 CFR Part 219	Department of Defense
34 CFR Part 97	Department of Education
38 CFR Part 16	Department of Veterans Affairs
40 CFR Part 26	Environmental Protection Agency
45 CFR Part 690	National Science Foundation
49 CFR Part 11	Department of Transportation

Subpart A Basic HHS Policy for Protection of Human Research Subjects

Authority: 5 U.S.C. 301; 42 U.S.C. 289(a); 42 U.S.C. 300v-1(b).

Source: 56 FR 28003, June 18, 1991; 70 FR 36325, June 23, 2005.

§46.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable

to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

- (1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in [§46.102\(e\)](#), must comply with all sections of this policy.
 - (2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in [§46.102\(e\)](#) must be reviewed and approved, in compliance with [§46.101](#), [§46.102](#), and [§46.107 through §46.117](#) of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.
- (b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:
- (1) Research 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 involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
 - (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 (b)(2) of this section, 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 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, 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.
- (c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.

- (d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.
- (e) Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.
- (f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.
- (g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.
- (h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the FEDERAL REGISTER or will be otherwise published as provided in department or agency procedures.
- (i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes or research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Human Research Protections, Department of Health and Human Services (HHS), or any successor office, and shall also publish them in the FEDERAL REGISTER or in such other manner as provided in Department or Agency procedures.¹

¹ Institutions with HHS-approved assurances on file will abide by provisions of Title 45 CFR part 46 subparts A-D. Some of the other departments and agencies have incorporated all provisions of Title 45 CFR Part 46 into their policies and procedures as well. However, the exemptions at 45 CFR **46.101(b)** do not apply to research involving prisoners, subpart C. The exemption at 45 CFR **46.101(b)(2)**, for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, [subpart D](#), except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

[56 FR 38012, 28022, June 18, 1991; 56 FR 29756, June 28, 1991; 70 FR 36325, June 23, 2005]

§46.102 Definitions.

- (a) *Department or agency head* 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.
- (b) *Institution* means any public or private entity or agency (including federal, state, and other agencies).
- (c) *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 procedure(s) involved in the research.
- (d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or

supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

- (e) *Research subject to regulation*, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).
- (f) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains
 - (1) Data through intervention or interaction with the individual, or
 - (2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, 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 or associated with the information) in order for obtaining the information to constitute research involving human subjects.

- (g) *IRB* means an institutional review board established in accord with and for the purposes expressed in this policy.
- (h) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.
- (i) *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.
- (j) *Certification* means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

§46.103 Assuring compliance with this policy -- research conducted or supported by any Federal Department or Agency.

- (a) Each institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Human Research Protections, HHS, or any successor office, and approved for federalwide use by that office. When the existence of an HHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Human Research Protections, HHS, or any successor office.

- (b) Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the department or agency head that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:
- (1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to Federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to department- or agency-supported or regulated research and need not be applicable to any research exempted or waived under [§46.101 \(b\) or \(i\)](#).
 - (2) Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.
 - (3) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the department or agency head, unless in accord with [§46.103\(a\)](#) of this policy, the existence of an HHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Human Research Protections, HHS, or any successor office.
 - (4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.
 - (5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval.
- (c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the department or agency head prescribes.
- (d) The Department or Agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the department or agency and such experts or consultants engaged for this purpose as the department or agency head determines to be appropriate. The department or agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.
- (e) On the basis of this evaluation, the department or agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The department or agency

head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

- (f) Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived under [§46.101 \(b\) or \(i\)](#). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by [§46.103](#) of this Policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Under no condition shall research covered by [§46.103](#) of the Policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution. (Approved by the Office of Management and Budget under control number 0990-0260.)

[56 FR 38012, 28022, June 18, 1991; 56 FR 29756, June 28, 1991; 70 FR 36325, June 23, 2005]

§§46.104--46.106 [Reserved]

§46.107 IRB membership.

- (a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.
- (b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.
- (c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
- (d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
- (e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
- (f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§46.108 IRB functions and operations.

In order to fulfill the requirements of this policy each IRB shall:

- (a) Follow written procedures in the same detail as described in [§46.103\(b\)\(4\)](#) and to the extent required by [§46.103\(b\)\(5\)](#).
- (b) Except when an expedited review procedure is used (see [§46.110](#)), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting

§46.109 IRB review of research.

- (a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.
- (b) An IRB shall require that information given to subjects as part of informed consent is in accordance with [§46.116](#). The IRB may require that information, in addition to that specifically mentioned in [§46.116](#), be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.
- (c) An IRB shall require documentation of informed consent or may waive documentation in accordance with [§46.117](#).
- (d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
- (e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research. (Approved by the Office of Management and Budget under control number 0990-0260.)

§46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

- (a) The Secretary, HHS, has established, and published as a Notice in the FEDERAL REGISTER, a [list of categories](#) of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the FEDERAL REGISTER. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.
- (b) An IRB may use the expedited review procedure to review either or both of the following:
 - (1) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,
 - (2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in [§46.108\(b\)](#).

- (c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.
- (d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

§46.111 Criteria for IRB approval of research.

- (a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:
 - (1) 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.
 - (2) 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 should consider 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 should 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 risks that fall within the purview of its responsibility.
 - (3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be 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.
 - (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by [§46.116](#).
 - (5) Informed consent will be appropriately documented, in accordance with, and to the extent required by [§46.117](#).
 - (6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
 - (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- (b) 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.

§46.112 Review by institution.

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§46.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the

IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head. (Approved by the Office of Management and Budget under control number 0990-0260.)

§46.114 Cooperative research.

Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

§46.115 IRB records.

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

- (1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
- (2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
- (3) Records of continuing review activities.
- (4) Copies of all correspondence between the IRB and the investigators.
- (5) A list of IRB members in the same detail as described in [§46.103\(b\)\(3\)](#).
- (6) Written procedures for the IRB in the same detail as described in [§46.103\(b\)\(4\)](#) and [§46.103\(b\)\(5\)](#).
- (7) Statements of significant new findings provided to subjects, as required by [§46.116\(b\)\(5\)](#).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner. (Approved by the Office of Management and Budget under control number 0990-0260.)

§46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

- (a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:
- (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
 - (2) A description of any reasonably foreseeable risks or discomforts to the subject;
 - (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
 - (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
 - (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
 - (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
 - (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
 - (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- (b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:
- (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
 - (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
 - (3) Any additional costs to the subject that may result from participation in the research;
 - (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
 - (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
 - (6) The approximate number of subjects involved in the study.
- (c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth 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:
 - (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; and

- (2) The research could not practicably be carried out without the waiver or alteration.
- (d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:
- (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.
- (e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.
- (f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law. (Approved by the Office of Management and Budget under control number 0990-0260.)

§46.117 Documentation of informed consent.

- (a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.
- (b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:
 - (1) A written consent document that embodies the elements of informed consent required by [§46.116](#). This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or
 - (2) A short form written consent document stating that the elements of informed consent required by [§46.116](#) have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.
- (c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
 - (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

- (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. (Approved by the Office of Management and Budget under control number 0990-0260.)

§46.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under [§46.101 \(b\) or \(i\)](#), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

§46.119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.

§46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

- (a) The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.
- (b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§46.121 [Reserved]

§46.122 Use of Federal funds.

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§46.123 Early termination of research support: Evaluation of applications and proposals.

- (a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.
- (b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a

termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

§46.124 Conditions.

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

Subpart B Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research. Source: 66 FR 56778, Nov. 13, 2001, unless otherwise noted.

§46.201 To what do these regulations apply?

- (a) Except as provided in paragraph (b) of this section, this subpart applies to all research involving pregnant women, human fetuses, neonates of uncertain viability, or nonviable neonates conducted or supported by the Department of Health and Human Services (DHHS). This includes all research conducted in DHHS facilities by any person and all research conducted in any facility by DHHS employees.
- (b) The exemptions at [§46.101\(b\)\(1\) through \(6\)](#) are applicable to this subpart.
- (c) The provisions of [§46.101\(c\) through \(i\)](#) are applicable to this subpart. Reference to State or local laws in this subpart and in [§46.101\(f\)](#) is intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.
- (d) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§46.202 Definitions.

The definitions in [§46.102](#) shall be applicable to this subpart as well. In addition, as used in this subpart:

- (a) Dead fetus means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.
- (b) Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means.
- (c) Fetus means the product of conception from implantation until delivery.
- (d) Neonate means a newborn.
- (e) Nonviable neonate means a neonate after delivery that, although living, is not viable.
- (f) Pregnancy encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.
- (g) Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

- (h) Viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the FEDERAL REGISTER guidelines to assist in determining whether a neonate is viable for purposes of this subpart. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of subparts A and D of this part.

§46.203 Duties of IRBs in connection with research involving pregnant women, fetuses, and neonates.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart and the other subparts of this part.

§46.204 Research involving pregnant women or fetuses.

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

- (a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
- (b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
- (c) Any risk is the least possible for achieving the objectives of the research;
- (d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part;
- (e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
- (f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
- (g) For children as defined in [§46.402\(a\)](#) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;
- (h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
- (i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
- (j) Individuals engaged in the research will have no part in determining the viability of a neonate.

§46.205 Research involving neonates.

- (a) Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

- (1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
 - (2) Each individual providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
 - (3) Individuals engaged in the research will have no part in determining the viability of a neonate.
 - (4) The requirements of paragraph (b) or (c) of this section have been met as applicable.
- (b) Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions have been met:
- (1) The IRB determines that:
 - (i) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or
 - (ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and
 - (2) The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.
- (c) Nonviable neonates. After delivery nonviable neonate may not be involved in research covered by this subpart unless all of the following additional conditions are met:
- (1) Vital functions of the neonate will not be artificially maintained;
 - (2) The research will not terminate the heartbeat or respiration of the neonate;
 - (3) There will be no added risk to the neonate resulting from the research;
 - (4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
 - (5) The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part, except that the waiver and alteration provisions of [§46.116\(c\)](#) **and (d)** do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph (c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5).
- (d) Viable neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of this part.

§46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.

- (a) Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities.

- (b) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

§46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

The Secretary will conduct or fund research that the IRB does not believe meets the requirements of [§46.204](#) or [§46.205](#) only if:

- (a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and
- (b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the FEDERAL REGISTER, has determined either:
- (1) That the research in fact satisfies the conditions of [§46.204](#), as applicable; or
 - (2) The following:
 - (i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;
 - (ii) The research will be conducted in accord with sound ethical principles; and
 - (iii) Informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part.

Subpart C Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects. Source: 43 FR 53655, Nov. 16, 1978, unless otherwise noted.

§46.301 Applicability.

- (a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health and Human Services involving prisoners as subjects.
- (b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.
- (c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§46.302 Purpose.

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

§46.303 Definitions.

As used in this subpart:

- (a) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.
- (b) *DHHS* means the Department of Health and Human Services.
- (c) *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 which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.
- (d) *Minimal risk* is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

§46.304 Composition of Institutional Review Boards where prisoners are involved.

In addition to satisfying the requirements in [§46.107](#) of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

- (a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.
- (b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

[43 FR 53655, Nov. 16, 1978, as amended at 46 FR 8366, Jan. 26, 1981]

§46.305 Additional duties of the Institutional Review Boards where prisoners are involved.

- (a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:
 - (1) The research under review represents one of the categories of research permissible under [§46.306\(a\)\(2\)](#);
 - (2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
 - (3) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
 - (4) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

- (5) The information is presented in language which is understandable to the subject population;
- (6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
- (7) Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.

(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

§46.306 Permitted research involving prisoners.

(a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

(1) The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under [§46.305](#) of this subpart; and

(2) In the judgment of the Secretary the proposed research involves solely the following:

(i) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(ii) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(iii) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or

(iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of the intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

Subpart D Additional Protections for Children Involved as Subjects in Research.
Source: 48 FR 9818, March 8, 1983, unless otherwise noted.

§46.401 To what do these regulations apply?

- (a) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.
- (1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.
- (2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (i) of [§46.101](#) of subpart A, waive the applicability of some or all of the requirements of these regulations for research of this type.
- (b) Exemptions at [§46.101\(b\)\(1\)](#) and [§46.101\(b\)\(3\) through \(b\)\(6\)](#) are applicable to this subpart. The exemption at [§46.101\(b\)\(2\)](#) regarding educational tests is also applicable to this subpart. However, the exemption at [§46.101\(b\)\(2\)](#) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.
- (c) The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of [§46.101](#) of [subpart A](#) are applicable to this subpart.

[48 FR 9818, Mar.8, 1983; 56 FR 28032, June 18, 1991; 56 FR 29757, June 28, 1991.]

§46.402 Definitions.

The definitions in [§46.102](#) of subpart A shall be applicable to this subpart as well. In addition, as used in this subpart:

- (a) *Children* are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.
- (b) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
- (c) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.
- (d) *Parent* means a child's biological or adoptive parent.
- (e) *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

§46.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

§46.404 Research not involving greater than minimal risk.

HHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in [§46.408](#).

§46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

- (a) The risk is justified by the anticipated benefit to the subjects;
- (b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
- (c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in [§46.408](#).

§46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

- (a) The risk represents a minor increase over minimal risk;
- (b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
- (c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
- (d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in [§46.408](#).

§46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

HHS will conduct or fund research that the IRB does not believe meets the requirements of [§46.404](#), [§46.405](#), or [§46.406](#) only if:

- (a) the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
- (b) the Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:
 - (1) that the research in fact satisfies the conditions of [§46.404](#), [§46.405](#), or [§46.406](#), as applicable, or

(2) the following:

- (i) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
- (ii) the research will be conducted in accordance with sound ethical principles;
- (iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in [§46.408](#).

§46.408 Requirements for permission by parents or guardians and for assent by children.

- (a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with [§46.116](#) of [Subpart A](#).
- (b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by [§46.116](#) of [Subpart A](#), that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under [§46.404](#) or [§46.405](#). Where research is covered by [§46.406](#) and [§46.407](#) and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
- (c) In addition to the provisions for waiver contained in [§46.116](#) of [subpart A](#), if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.
- (d) Permission by parents or guardians shall be documented in accordance with and to the extent required by [§46.117](#) of [subpart A](#).
- (e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

§46.409 Wards.

- (a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under [§46.406](#) or [§46.407](#) only if such research is:
- (1) Related to their status as wards; or
 - (2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.
- (b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

APPENDIX C

The Belmont Report
Office of the Secretary
Ethical Principles and Guidelines for the Protection of Human Subjects of Research
The National Commission for the Protection of Human Subjects
of Biomedical and Behavioral Research
April 18, 1979

AGENCY: Department of Health, Education, and Welfare.

ACTION: Notice of Report for Public Comment.

SUMMARY: On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, thereby creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. In carrying out the above, the Commission was directed to consider: (i) the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine, (ii) the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects, (iii) appropriate guidelines for the selection of human subjects for participation in such research and (iv) the nature and definition of informed consent in various research settings.

The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations. It is the outgrowth of an intensive four-day period of discussions that were held in February 1976 at the Smithsonian Institution's Belmont Conference Center supplemented by the monthly deliberations of the Commission that were held over a period of nearly four years. It is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects. By publishing the Report in the Federal Register, and providing reprints upon request, the Secretary intends that it may be made readily available to scientists, members of Institutional Review Boards, and federal employees. The two-volume Appendix, containing the lengthy reports of experts and specialists who assisted the Commission in fulfilling this part of its charge, is available as DHEW Publication No. (OS) 78-0013 and No. (OS) 78-0014, for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

Unlike most other reports of the Commission, the Belmont Report does not make specific recommendations for administrative action by the Secretary of Health, Education, and Welfare. Rather, the Commission recommended that the Belmont Report be adopted in its entirety, as a statement of the Department's policy. The Department requests public comment on this recommendation.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

Members of the Commission

Kenneth John Ryan, M.D., Chairman, Chief of Staff, Boston Hospital for Women.
Joseph V. Brady, Ph.D., Professor of Behavioral Biology, Johns Hopkins University.
Robert E. Cooke, M.D., President, Medical College of Pennsylvania.
Dorothy I. Height, President, National Council of Negro Women, Inc.
Albert R. Jonsen, Ph.D., Associate Professor of Bioethics, University of California at San Francisco.
Patricia King, J.D., Associate Professor of Law, Georgetown University Law Center.
Karen Lebacqz, Ph.D., Associate Professor of Christian Ethics, Pacific School of Religion.
*** David W. Louisell, J.D., Professor of Law, University of California at Berkeley.
Donald W. Seldin, M.D., Professor and Chairman, Department of Internal Medicine, University of Texas at Dallas.
*** Eliot Stellar, Ph.D., Provost of the University and Professor of Physiological Psychology, University of Pennsylvania.
*** Robert H. Turtle, LL.B., Attorney, VomBaur, Coburn, Simmons & Turtle, Washington, D.C.
*** Deceased.

Ethical Principles and Guidelines for Research Involving Human Subjects

Scientific research has produced substantial social benefits. It has also posed some troubling ethical questions. Public attention was drawn to these questions by reported abuses of human subjects in biomedical experiments, especially during the Second World War. During the Nuremberg War Crime Trials, the Nuremberg code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners. This code became the prototype of many later codes⁽¹⁾ intended to assure that research involving human subjects would be carried out in an ethical manner.

The codes consist of rules, some general, others specific, that guide the investigators or the reviewers of research in their work. Such rules often are inadequate to cover complex situations; at times they come into conflict, and they are frequently difficult to interpret or apply. Broader ethical principles will provide a basis on which specific rules may be formulated, criticized and interpreted.

Three principles, or general prescriptive judgments, that are relevant to research involving human subjects are identified in this statement. Other principles may also be relevant. These three are comprehensive, however, and are stated at a level of generalization that should assist scientists, subjects, reviewers and interested citizens to understand the ethical issues inherent in research involving human subjects. These principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.

This statement consists of a distinction between research and practice, a discussion of the three basic ethical principles, and remarks about the application of these principles.

Part A: Boundaries Between Practice and Research

A. Boundaries Between Practice and Research

It is important to distinguish between biomedical and behavioral research, on the one hand, and the practice of accepted therapy on the other, in order to know what activities ought to undergo review for the protection of human subjects of research. The distinction between research and practice is blurred partly because both often occur together (as in research designed to evaluate a therapy) and partly because notable departures from standard practice are often called "experimental" when the terms "experimental" and "research" are not carefully defined.

For the most part, the term "practice" refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals.⁽²⁾ By contrast, the term "research" designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is "experimental," in the sense of new, untested or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation be incorporated into a formal research project.⁽³⁾

Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects.

Part B: Basic Ethical Principles

B. Basic Ethical Principles

The expression "basic ethical principles" refers to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions. Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of respect of persons, beneficence and justice.

1. Respect for Persons. Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.

However, not every human being is capable of self-determination. The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

Some persons are in need of extensive protection, even to the point of excluding them from activities which may harm them; other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequence. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations.

In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however, application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to "volunteer" or to "protect" them presents a dilemma. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.

2. Beneficence. Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.

The Hippocratic maxim "do no harm" has long been a fundamental principle of medical ethics. Claude Bernard extended it to the realm of research, saying that one should not injure one person regardless of the benefits that might come to others. However, even avoiding harm requires learning what is harmful; and, in the process of obtaining this information, persons may be exposed to risk of harm. Further, the Hippocratic Oath requires physicians to benefit their patients "according to their best judgment." Learning what will in fact benefit may require exposing persons to risk. The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks.

The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.

The principle of beneficence often occupies a well-defined justifying role in many areas of research involving human subjects. An example is found in research involving children. Effective ways of treating childhood diseases and fostering healthy development are benefits that serve to justify research involving children - even when individual research subjects are not direct beneficiaries. Research also makes it possible to avoid the harm that may result from the application of previously accepted routine practices that on closer investigation turn out to be dangerous. But the role of the principle of beneficence is not always so unambiguous. A difficult ethical problem remains, for example, about research that presents more than minimal risk without immediate prospect of direct benefit to the children involved. Some have argued that such research is inadmissible, while others have pointed out that this limit would rule out much research promising great benefit to children in the future. Here again, as with all hard cases, the different claims covered by the principle of beneficence may come into conflict and force difficult choices.

3. Justice. Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are (1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, and (5) to each person according to merit.

Questions of justice have long been associated with social practices such as punishment, taxation and political representation. Until recently these questions have not generally been associated with scientific research. However, they are foreshadowed even in the earliest reflections on the ethics of research involving human subjects. For example, during the 19th and early 20th centuries the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. Subsequently, the exploitation of unwilling prisoners as research subjects in Nazi concentration camps was condemned as a particularly flagrant injustice. In this country, in the 1940's, the Tuskegee syphilis study used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population. These subjects were deprived of demonstrably effective treatment in order not to interrupt the project, long after such treatment became generally available.

Against this historical background, it can be seen how conceptions of justice are relevant to research involving human subjects. For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

Part C: Applications

C. Applications

Applications of the general principles to the conduct of research leads to consideration of the following requirements: informed consent, risk/benefit assessment, and the selection of subjects of research.

1. Informed Consent. Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.

While the importance of informed consent is unquestioned, controversy prevails over the nature and possibility of an informed consent. Nonetheless, there is widespread agreement that the consent process can be analyzed as containing three elements: information, comprehension and voluntariness.

Information. Most codes of research establish specific items for disclosure intended to assure that subjects are given sufficient information. These items generally include: the research procedure, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a

statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. Additional items have been proposed, including how subjects are selected, the person responsible for the research, etc.

However, a simple listing of items does not answer the question of what the standard should be for judging how much and what sort of information should be provided. One standard frequently invoked in medical practice, namely the information commonly provided by practitioners in the field or in the locale, is inadequate since research takes place precisely when a common understanding does not exist. Another standard, currently popular in malpractice law, requires the practitioner to reveal the information that reasonable persons would wish to know in order to make a decision regarding their care. This, too, seems insufficient since the research subject, being in essence a volunteer, may wish to know considerably more about risks gratuitously undertaken than do patients who deliver themselves into the hand of a clinician for needed care. It may be that a standard of "the reasonable volunteer" should be proposed: the extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the subjects should understand clearly the range of risk and the voluntary nature of participation.

A special problem of consent arises where informing subjects of some pertinent aspect of the research is likely to impair the validity of the research. In many cases, it is sufficient to indicate to subjects that they are being invited to participate in research of which some features will not be revealed until the research is concluded. In all cases of research involving incomplete disclosure, such research is justified only if it is clear that (1) incomplete disclosure is truly necessary to accomplish the goals of the research, (2) there are no undisclosed risks to subjects that are more than minimal, and (3) there is an adequate plan for debriefing subjects, when appropriate, and for dissemination of research results to them. Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research. Care should be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.

Comprehension. The manner and context in which information is conveyed is as important as the information itself. For example, presenting information in a disorganized and rapid fashion, allowing too little time for consideration or curtailing opportunities for questioning, all may adversely affect a subject's ability to make an informed choice.

Because the subject's ability to understand is a function of intelligence, rationality, maturity and language, it is necessary to adapt the presentation of the information to the subject's capacities. Investigators are responsible for ascertaining that the subject has comprehended the information. While there is always an obligation to ascertain that the information about risk to subjects is complete and adequately comprehended, when the risks are more serious, that obligation increases. On occasion, it may be suitable to give some oral or written tests of comprehension.

Special provision may need to be made when comprehension is severely limited - for example, by conditions of immaturity or mental disability. Each class of subjects that one might consider as incompetent (e.g., infants and young children, mentally disabled patients, the terminally ill and the comatose) should be considered on its own terms. Even for these persons, however, respect requires giving them the opportunity to choose to the extent they are able, whether or not to participate in research. The objections of these subjects to involvement should be honored, unless the research entails providing them a therapy unavailable elsewhere. Respect for persons also requires seeking the permission of other parties in order to protect the subjects from harm. Such persons are thus respected both by acknowledging their own wishes and by the use of third parties to protect them from harm.

The third parties chosen should be those who are most likely to understand the incompetent subject's situation and to act in that person's best interest. The person authorized to act on behalf of the subject should be given an opportunity to observe the research as it proceeds in order to be able to withdraw the subject from the research, if such action appears in the subject's best interest.

Voluntariness. An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.

Unjustifiable pressures usually occur when persons in positions of authority or commanding influence - especially where possible sanctions are involved - urge a course of action for a subject. A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins. But undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be entitled.

2. Assessment of Risks and Benefits. The assessment of risks and benefits requires a careful array of relevant data, including, in some cases, alternative ways of obtaining the benefits sought in the research. Thus, the assessment presents both an opportunity and a responsibility to gather systematic and comprehensive information about proposed research. For the investigator, it is a means to examine whether the proposed research is properly designed. For a review committee, it is a method for determining whether the risks that will be presented to subjects are justified. For prospective subjects, the assessment will assist the determination whether or not to participate.

The Nature and Scope of Risks and Benefits. The requirement that research be justified on the basis of a favorable risk/benefit assessment bears a close relation to the principle of beneficence, just as the moral requirement that informed consent be obtained is derived primarily from the principle of respect for persons. The term "risk" refers to a possibility that harm may occur. However, when expressions such as "small risk" or "high risk" are used, they usually refer (often ambiguously) both to the chance (probability) of experiencing a harm and the severity (magnitude) of the envisioned harm.

The term "benefit" is used in the research context to refer to something of positive value related to health or welfare. Unlike, "risk," "benefit" is not a term that expresses probabilities. Risk is properly contrasted to probability of benefits, and benefits are properly contrasted with harms rather than risks of harm. Accordingly, so-called risk/benefit assessments are concerned with the probabilities and magnitudes of possible harm and anticipated benefits. Many kinds of possible harms and benefits need to be taken into account. There are, for example, risks of psychological harm, physical harm, legal harm, social harm and economic harm and the corresponding benefits. While the most likely types of harms to research subjects are those of psychological or physical pain or injury, other possible kinds should not be overlooked.

Risks and benefits of research may affect the individual subjects, the families of the individual subjects, and society at large (or special groups of subjects in society). Previous codes and federal regulations have required that risks to subjects be outweighed by the sum of both the anticipated benefit to the subject, if any, and the anticipated benefit to society in the form of knowledge to be gained from the research. In balancing these different elements, the risks and benefits affecting the immediate research subject will normally carry special weight. On the other hand, interests other than those of the subject may on some occasions be sufficient by themselves to justify the risks involved in the research, so long as the subjects' rights have been protected. Beneficence thus requires that we protect against risk of harm to subjects and also that we be concerned about the loss of the substantial benefits that might be gained from research.

The Systematic Assessment of Risks and Benefits. It is commonly said that benefits and risks must be "balanced" and shown to be "in a favorable ratio." The metaphorical character of these terms draws attention to the difficulty of making precise judgments. Only on rare occasions will quantitative techniques be available for the scrutiny of research protocols. However, the idea of systematic, nonarbitrary analysis of risks and benefits should be emulated insofar as possible. This ideal requires those making decisions about the justifiability of research to be thorough in the accumulation and assessment of information about all aspects of the research, and to consider alternatives systematically. This procedure renders the assessment of research more rigorous and precise, while

making communication between review board members and investigators less subject to misinterpretation, misinformation and conflicting judgments. Thus, there should first be a determination of the validity of the presuppositions of the research; then the nature, probability and magnitude of risk should be distinguished with as much clarity as possible. The method of ascertaining risks should be explicit, especially where there is no alternative to the use of such vague categories as small or slight risk. It should also be determined whether an investigator's estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies.

Finally, assessment of the justifiability of research should reflect at least the following considerations: (i) Brutal or inhumane treatment of human subjects is never morally justified. (ii) Risks should be reduced to those necessary to achieve the research objective. It should be determined whether it is in fact necessary to use human subjects at all. Risk can perhaps never be entirely eliminated, but it can often be reduced by careful attention to alternative procedures. (iii) When research involves significant risk of serious impairment, review committees should be extraordinarily insistent on the justification of the risk (looking usually to the likelihood of benefit to the subject - or, in some rare cases, to the manifest voluntariness of the participation). (iv) When vulnerable populations are involved in research, the appropriateness of involving them should itself be demonstrated. A number of variables go into such judgments, including the nature and degree of risk, the condition of the particular population involved, and the nature and level of the anticipated benefits. (v) Relevant risks and benefits must be thoroughly arrayed in documents and procedures used in the informed consent process.

3. Selection of Subjects. Just as the principle of respect for persons finds expression in the requirements for consent, and the principle of beneficence in risk/benefit assessment, the principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects.

Justice is relevant to the selection of subjects of research at two levels: the social and the individual. Individual justice in the selection of subjects would require that researchers exhibit fairness: thus, they should not offer potentially beneficial research only to some patients who are in their favor or select only "undesirable" persons for risky research. Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons. Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects (e.g., adults before children) and that some classes of potential subjects (e.g., the institutionalized mentally infirm or prisoners) may be involved as research subjects, if at all, only on certain conditions.

Injustice may appear in the selection of subjects, even if individual subjects are selected fairly by investigators and treated fairly in the course of research. Thus injustice arises from social, racial, sexual and cultural biases institutionalized in society. Thus, even if individual researchers are treating their research subjects fairly, and even if IRBs are taking care to assure that subjects are selected fairly within a particular institution, unjust social patterns may nevertheless appear in the overall distribution of the burdens and benefits of research. Although individual institutions or investigators may not be able to resolve a problem that is pervasive in their social setting, they can consider distributive justice in selecting research subjects.

Some populations, especially institutionalized ones, are already burdened in many ways by their infirmities and environments. When research is proposed that involves risks and does not include a therapeutic component, other less burdened classes of persons should be called upon first to accept these risks of research, except where the research is directly related to the specific conditions of the class involved. Also, even though public funds for research may often flow in the same directions as public funds for health care, it seems unfair that populations dependent on public health care constitute a pool of preferred research subjects if more advantaged populations are likely to be the recipients of the benefits.

One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may

continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition.

- (1) Since 1945, various codes for the proper and responsible conduct of human experimentation in medical research have been adopted by different organizations. The best known of these codes are the Nuremberg Code of 1947, the Helsinki Declaration of 1964 (revised in 1975), and the 1971 Guidelines (codified into Federal Regulations in 1974) issued by the U.S. Department of Health, Education, and Welfare. Codes for the conduct of social and behavioral research have also been adopted, the best known being that of the American Psychological Association, published in 1973.
- (2) Although practice usually involves interventions designed solely to enhance the well-being of a particular individual, interventions are sometimes applied to one individual for the enhancement of the well-being of another (e.g., blood donation, skin grafts, organ transplants) or an intervention may have the dual purpose of enhancing the well-being of a particular individual, and, at the same time, providing some benefit to others (e.g., vaccination, which protects both the person who is vaccinated and society generally). The fact that some forms of practice have elements other than immediate benefit to the individual receiving an intervention, however, should not confuse the general distinction between research and practice. Even when a procedure applied in practice may benefit some other person, it remains an intervention designed to enhance the well-being of a particular individual or groups of individuals; thus, it is practice and need not be reviewed as research.
- (3) Because the problems related to social experimentation may differ substantially from those of biomedical and behavioral research, the Commission specifically declines to make any policy determination regarding such research at this time. Rather, the Commission believes that the problem ought to be addressed by one of its successor bodies.

THE NUREMBERG CODE

1. The voluntary consent of the human subject is absolutely essential.
 - o 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. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.
 - o The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seemed to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probably [sic] cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI

*Adopted by the 18th World Medical Assembly
Helsinki, Finland, June 1964
and amended by the
29th World Medical Assembly
Tokyo, Japan, October 1975
35th World Medical Assembly
Venice, Italy, October 1983
and the
41st World Medical Assembly
Hong Kong, September 1989*

Introduction

It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfillment of this mission.

The Declaration of Geneva of the World Medical Assembly binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

In the field of biomedical research a fundamental distinction must be recognized between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

I. Basic Principles

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.
2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and

the sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.

3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.
4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.
5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.
6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.
7. Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits.
8. In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.
9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely-given informed consent, preferably in writing.
10. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.
11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.

Whenever the minor child is in fact able to give a consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian.

12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II. Medical research combined with clinical care (*Clinical research*)

1. In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgment it offers hope of saving life, reestablishing health or alleviating suffering.
2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.
3. In any medical study, every patient – including those of a control group, if any – should be assured of the best proven diagnostic and therapeutic method.
4. The refusal of the patient to participate in a study must never interfere with the physician-patient relationship.
5. If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (1, 2).
6. The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III. Non-therapeutic biomedical research involving human subjects (*Non-clinical biomedical research*)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.
2. The subjects should be volunteers – either healthy persons or patients for whom the experimental design is not related to the patient's illness.
3. The investigator or the investigating team should discontinue the research if in his/her or their judgment it may, if continued, be harmful to the individual.
4. In research on man, the interest of science and society should never take precedence over considerations related to the well being of the subject.

APPENDIX D

Morehead State University
 Institutional Review Board (IRB) for the Protection of Human Subjects in Research
 PROTOCOL APPLICATION FOR THE USE OF HUMAN SUBJECTS IN RESEARCH

REQUEST FOR EXEMPTION FROM FEDERAL REGULATIONS

In accordance with federal regulations, the IRB determines whether research protocols involving human subjects may be exempted. Even though the research may qualify as exempt from federal regulations, the committee still has a responsibility to decide whether the protocol represents ethical research.

Principal Investigator(s)/Principal Researcher(s) Information: The Principal Investigator(s) (PI) conducts and directs the study. He/she acts as the main contact person for the IRB, and carries full responsibility for the study. **Principal Investigator(s)/Principal Researcher(s) must complete CITI training.**

Name:		Title:	
Department:		E-Mail:	
Campus Address:		Phone:	

Title of Research Project: (If internal or external funding will be requested, the title of the research project must be the same as the proposal title.)

Title:	
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Funding Source/Agency: (Provide name of funding source/agency and indicate if funds are internal or external. If funding will not be requested, mark N/A.)

Name:			
Internal:	<input type="checkbox"/>	External:	<input type="checkbox"/>
		N/A:	<input type="checkbox"/>

Period of Project:	From:	To:
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Co-Investigators: Co-investigators are those other than the Principal Investigator(s) who conduct, direct, and are responsible for the study. Please list the name, degree, department, telephone number, and e-mail address of each co-investigator. **Co-Investigators listed here must complete CITI training.**

Other Personnel: Other Personnel includes all team members other than the Principal Investigator(s) or Co-Investigator(s) who assist in the execution of the study, especially those who have subject contact. This may include students or graduate assistants. Please provide the names of any person who will have contact with subjects in connection with this study. **Other Personnel listed here must complete CITI training.**

For the categories of research listed below, researchers may request that the IRB exempt their protocols from federal regulations. If you believe your research protocol may be eligible for consideration as exempt from the federal regulations, consider which of the categories from the list below applies and check all that apply.

EXEMPT CATEGORIES – 46.101(b)	
<input type="checkbox"/>	1. Research 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.
<input type="checkbox"/>	2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
<input type="checkbox"/>	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 (b)(2) of this section, 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.
<input type="checkbox"/>	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.
<input type="checkbox"/>	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, 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.
<input type="checkbox"/>	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.

The exemptions at 45 CFR 46.101 (b) do not apply to research involving prisoners, Subpart C. The exemption at 45 CFR 46.101 (b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, Subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Justification: Please provide a justification for why this research meets the exempt category (i.e., explain how the research you are proposing belongs to the selected categories above): (Boxes will expand, or if necessary, attach additional pages.)

PROJECT DESCRIPTION

Abstract: Provide an abstract of the proposed research *in language that can be understood by a non-scientist*. The abstract should summarize the objectives of this project and the procedures to be used, with an emphasis on what will happen to the subjects. Feel free to use as much space as needed to provide a thorough abstract. (Boxes will expand, or if necessary, attach additional pages.)

Subjects: Describe and quantify the subject population for this study, including the number of subjects expected to be enrolled, and describe how the subjects will be recruited for participation. (Boxes will expand, or if necessary, attach additional pages.)

Consent: Describe the process by which consent will be obtained and documented from subjects. If consent or documentation of consent is not being obtained, you must formally request a waiver from the IRB and fully justify why the informed consent and/or signed informed consent requirement(s) should be waived. (Boxes will expand, or if necessary, attach additional pages.)

Are MSU student subjects being recruited through courses? YES NO

If you answered yes, clearly address all items in the "MSU STUDENTS AS SUBJECTS" Form before submitting your protocol application. If you answered no, simply indicate that the items are not applicable to your research.

MSU STUDENTS AS SUBJECTS

The following sections must be completed if applicable to your research. (Note: The information also must be included in the informed consent documents as required by federal and IRB regulations.)

Clearly address all items below before proceeding to the next question or if you answered no, simply indicate that the items are not applicable to your research.

Instructor (not subject) Safeguards:

Describe how permission to use subjects in a colleague's class will be obtained. (Boxes will expand or, if necessary, attach additional pages.)

Explain how you will inform instructors that they can refuse to allow the research to be conducted in their class. (Boxes will expand or, if necessary, attach additional pages.)

Describe safeguards to protect the rights of the instructor in the event of refusal to allow use of subjects in a class. (Boxes will expand or, if necessary, attach additional pages.)

Additional Information:

Clearly indicate whether participation as a research subject in this study fulfills a course requirement (i.e., all students are expected to participate in exchange for course credit) or will be conducted without fulfilling a course requirement (i.e., students may choose whether or not to participate without considering course requirements). If participation will fulfill a course requirement, clearly indicate that the instructors for the courses involved will establish appropriate alternative assignments that students may complete if they choose not to be a subject in this research. (Boxes will expand or, if necessary, attach additional pages.)

Clearly indicate how the students will be informed that no penalty will be incurred for non-participation in the research. (Boxes will expand or, if necessary, attach additional pages.)

Are any of the MSU student subjects in the researcher's class or under his/her direct supervision?

YES NO

NOTE: Researcher must use a third party to solicit participation, administer the study, and collect data from subjects when they are students in the researcher's class or when they are employees or supervisees of the researcher.

If you answered yes, clearly address all items in the subject safeguards section below before proceeding. If you answered no, simply indicate that the items are not applicable to your research.

Subject Safeguards:

Identify third party who will solicit subjects, administer and collect informed consent and all instruments, and retain documents until final grades are submitted. (Boxes will expand or, if necessary, attach additional pages.)

Identify third party as a contact for subjects to notify if they wish to withdraw from the research project. (Boxes will expand or, if necessary, attach additional pages.)

Online training in the protection of human subjects in research is required for all researchers using human subjects in research. To complete this training, known as CITI training, go to <http://www.moreheadstate.edu/rgc/secure/index.aspx?id=6943> and click the appropriate link. Once you have completed your online training, please attach a copy of your Course Completion Record to your completed protocol application. If your research involves prisoners, children, elementary and secondary schools, international or internet research, you must complete special CITI online training and provide your Course Completion Record on the relevant topic(s).

After you have completed all other parts of your protocol application, read the information below and sign if you agree with the researcher assurances and responsibilities.

Researcher Assurances and Responsibilities:

As principal investigator(s)/researcher(s), I hereby assure that I will follow procedures to safeguard and protect the rights and welfare of the subjects of my research. I will not begin data collection until I receive a written approval from the IRB.

If data are to be collected from college students and/or other MSU employees, I will use a third party to solicit participation, administer the study, or collect data when subjects are either students in a course for which I am the instructor or under my direct supervision.

As principal investigator(s)/researcher(s), I acknowledge responsibility for protecting the rights and welfare of human subjects; complying with all applicable federal and IRB regulations; conducting the research according to the IRB *exempt* protocol; reporting any changes in previously approved protocols to the IRB prior to implementation; reporting unanticipated injuries or problems involving risks to human subjects to the IRB; maintaining all approved protocol documents and notifications for three years after completion of the protocol; supervising research conducted by students; and obtaining approval for continuation protocols.

If your study is determined to be exempt by the IRB committee, you are not required to complete continuation or final review reports. However, if any revisions are made to a project or if any unexpected risks arise during an investigation, it is your responsibility to notify the IRB by submitting a Part H (Change of Status) fully explaining all changes or unexpected risks, prior to making any changes to the study. Please note that changes made to an exempt protocol may disqualify it from exempt status and may require an expedited or full-board review.

After your application is approved, The Office of Research and Sponsored Programs will hold your exemption application for six years. Before the end of the sixth year, you will be notified that your protocol will be closed. If your project is still ongoing, you will need to contact the Office of Research and Sponsored Programs upon receipt of that letter and follow the instructions for completing a new exemption application. *It is important that you keep your address current with the Office of Research and Sponsored Programs.*

_____	_____
Signature of Principal Investigator(s)/Researcher(s)	Date

As faculty advisor, I hereby accept responsibility for the conduct of this project.

_____	_____
Signature of Faculty Advisor	Date

Do not write below this line

Date Received:	Protocol Review Number:
Review Completed:	Notification Sent:

It should be noted that research involving children may not qualify for exemption.

Please submit two (2) copies of the completed protocol application and CITI Training documentation in paper form to the IRB Administrative Assistant in the Office of Research and Sponsored Programs (901 Ginger Hall).

**Morehead State University
Institutional Review Board (IRB) for the Protection of Human Subjects in Research
PROTOCOL APPLICATION FOR THE USE OF HUMAN SUBJECTS IN RESEARCH**

APPLICATION FOR EXPEDITED OR FULL BOARD REVIEW

(Note: The IRB will make a final determination as to whether the research is eligible for Expedited Review. Research which is not eligible will be submitted to the Full Board for review.)

Principal Investigator(s)/Researcher(s) Information: The Principal Investigator(s) (PI) conducts and directs the study. He/she acts as the main contact person for the IRB, and carries full responsibility for the study. **Principal Investigator(s)/Researcher(s) must complete CITI training.**

Name:		Title:	
Department:		E-Mail:	
Campus Address:		Phone:	

Title of Research Project: (If internal or external funding will be requested, the title of the research project must be the same as the proposal title.)

Title:	
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Funding Source/Agency: (Provide name of funding source/agency and indicate if funds are internal or external. If funding will not be requested, mark N/A.)

Name:	
Internal: <input type="checkbox"/>	External: <input type="checkbox"/> N/A: <input type="checkbox"/>

Period of Project:	From:	To:
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Co-Investigators: Co-investigators are those other than the Principal Investigator(s) who conduct, direct, and are responsible for the study. Please list the name, degree, department, telephone number, and e-mail address of each co-investigator. **Co-Investigators listed here must complete CITI training.**

Other Personnel: Other Personnel includes all team members other than the Principal Investigator(s) or Co-Investigator(s) who assist in the execution of the study, especially those who have subject contact. This may include students or graduate assistants. Please provide the names of any person who will have contact with subjects in connection with this study. **Other Personnel listed here must complete CITI training.**

Online training in the protection of human subjects in research is required for all researchers using human subjects in research. To complete this training, known as CITI training, go to <http://www.moreheadstate.edu/rgc/secure/index.aspx?id=6943> and click the appropriate link. Once you have completed your online training, please attach a copy of your Course Completion Record to your completed protocol application. If your research involves data collection from special populations (including minors, prisoners, elementary and/or secondary schools), or international or internet research, you must complete special CITI online training and attach your Course Completion Record on the relevant topic(s) to your completed application.

Morehead State University
Institutional Review Board (IRB) for the Protection of Human Subjects in Research
PROTOCOL APPLICATION FOR THE USE OF HUMAN SUBJECTS IN RESEARCH

For Expedited Review Only:

Federal regulations allow expedited review for research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the published categories below.

“Minimal risk” is defined as a risk where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than that ordinarily experienced in daily life or during the performance of routine physical or psychological examinations or tests.

NOTE: The activities included in the list should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

Research Categories: (Check all that apply)

<input type="checkbox"/>	(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.
<input type="checkbox"/>	(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 ¹ 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.
<input type="checkbox"/>	(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.
<input type="checkbox"/>	(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 are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) 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.
<input type="checkbox"/>	(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.)
<input type="checkbox"/>	(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

<input type="checkbox"/>	(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.)
<input type="checkbox"/>	(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.
<input type="checkbox"/>	(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.
	¹ Children are defined in the HHS regulations as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.” 45 CFR 46.402(a) .

In your opinion, does your research protocol qualify for expedited review? Yes No
If you answered yes, provide justification for expedited review below. If you answered no, proceed to Part A “Detailed Research Description.”

Justification for Expedited Review: Please provide a justification for why this research involves no more than minimal risk and qualifies in the expedited category indicated: (Boxes will expand or, if necessary, attach additional pages.)

Proceed to the next section.

REQUIREMENTS FOR EXPEDITED AND FULL BOARD REVIEW

For all non-exempt protocols, Parts A and B must be completed. For research involving MSU students, minors, prisoners, or cognitively impaired persons, or if the protocol involves international or internet research or data collection in elementary or secondary schools, additional information must be provided as follows:

- If your research protocol involves data collection with *college students at Morehead State University*, complete the “MSU Students as Subjects” section of this application (Part C).
- If your research protocol involves data collection with *minors*, you must do the following:
 1. Complete the “Research Involving Minors” section of this application and the section entitled “Parental Permission and Assent” (Part D)
 2. Provide the committee with a 1-2 page description of your qualifications or special expertise for conducting research with minors
 3. Complete the special CITI training module entitled “Research with Children” and provide documentation of your special Course Completion Record in this area to the committee with your application
- If your research protocol involves data collection with *prisoners*, you must do the following:
 1. Complete the “Prisoners As Subjects” section of this application (Part E)
 2. Provide the committee with a 1-2 page description of your qualifications or special expertise for conducting research with prisoners
 3. Complete the special CITI training module entitled “Research with Prisoners” and provide documentation of your special Course Completion Record in this area to the committee with your application
- If your research protocol involves data collection with *cognitively impaired persons*, you must do the following:
 1. Complete the “Cognitively Impaired Persons” section of this application (Part F). If the impaired persons also are minors you also must complete the “Research Involving Minors” and the “Parental Permission and Assent” sections of this application (Part D)
 2. Provide the committee with a 1-2 page description of your qualifications or special expertise for conducting research with cognitively impaired persons (and minors if applicable)
- If your research protocol involves *international research, internet research, or data collection from elementary and/or secondary schools*, provide documentation of your special CITI online Course Completion Record in this area to the committee with your application.

PART A

DETAILED RESEARCH DESCRIPTION

1. **Abstract.** Provide an abstract of the proposed research *in language that can be understood by a non-scientist*. The abstract should summarize the objectives of this project and the procedures to be used, with an emphasis on what will happen to the subjects. Feel free to use as much space as needed to provide a thorough abstract. (Boxes will expand or, if necessary, attach additional pages.)

2. Objectives: List your research objectives. (Boxes will expand or, if necessary, attach additional pages.)

3. Research Procedures: Provide a detailed description of the research design and a step-by-step description of the methodological procedure and its relationship to the objectives. In addition, researcher must include a time line of the project, description of the materials used and the disposition of the data at the conclusion of the study (i.e. archived, destroyed, etc.). (Boxes will expand or, if necessary, attach additional pages.)

4. Subjects:

Subject Population:

Number of subjects to be enrolled in the study: Total: Males: Females:

Check all that apply:

Adults, non-students

Prisoners (Complete Part E)

MSU students (Complete Part C)

Cognitively Impaired (Complete Part F)

Students 18 and older

Minor Student

Minors non-MSU students (Under 18)

Other (explain)

Age Range of Minors:
(Complete Part D)

Subject's Role:

Describe the subject's role in the research project. (Boxes will expand or, if necessary, attach additional pages.)

Identify the data collection procedures. (Boxes will expand or, if necessary, attach additional pages.)

Provide the expected duration of the subject's participation. (Boxes will expand or, if necessary, attach additional pages.)

Subject Recruitment:

Identify all sources of potential subjects. (Boxes will expand or, if necessary, attach additional pages.)

Explain all the ways subjects will be selected. (Boxes will expand or, if necessary, attach additional pages.)

Describe all the ways subjects will be recruited and contacted (provide copies of all recruitment documents as Appendices). (Boxes will expand or, if necessary, attach additional pages.)

5. Risks:

Provide a description of the risks whether minimal or greater than minimal. (Boxes will expand or, if necessary, attach additional pages.)

Describe procedures that will be followed to minimize the risks. (Boxes will expand or, if necessary, attach additional pages.)

Describe additional safeguards that are provided if medical research procedures are involved. (Boxes will expand or, if necessary, attach additional pages.)

6. Benefits:

Identify the anticipated benefits to the subjects and the knowledge the researchers are expected to gain. (Payments or another form of compensation offered to subjects as an incentive for participation ARE NOT considered a benefit to be gained from the research project.) (Boxes will expand or, if necessary, attach additional pages.)

7. Confidentiality:

Describe how the confidentiality of the information will be safeguarded, how and where data will be secured, e.g., locked filing cabinet or locked desk. (Boxes will expand or, if necessary, attach additional pages.)

Describe how the anonymity of the subjects will be protected. *Please note: demographics may compromise the anonymity of the subjects; therefore, a larger subject pool may be necessary to protect anonymity.* (Boxes will expand or, if necessary, attach additional pages.)

State who will have access to the data, (e.g., PI, Co-PI, undergraduate assistants, graduate assistants). (Boxes will expand or, if necessary, attach additional pages.)

State when and how the data will be destroyed or archived. (Boxes will expand or, if necessary, attach additional pages.)

PART B

INFORMED CONSENT

Unless waived by the IRB, informed consent is necessary for all research involving human subjects and must be documented in some manner. The investigator may determine which method would best serve the interest of the subject population, but the IRB reserves the right to require alternative or more stringent means of securing consent. Use of subjects unable to give personal consent for reasons of age, mental state, legal or other such status, requires that consent be secured from parents or a legal guardian.

Waiver of Informed Consent Requested

To request a waiver of informed consent, the researcher(s) must provide a written justification, explicitly addressing **ALL** of the four (4) points below: (Boxes will expand or, if necessary, attach additional pages.)

- (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 subject
- (3) the research could not practicably be carried out without the waiver or alteration
- (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation

Informed Consent Process

1. Describe procedures used to obtain informed consent including how and where informed consent will be obtained and who will obtain the consent. (Boxes will expand or, if necessary, attach additional pages.)
2. How will it be determined that the subjects or the subjects' authorized representatives understand the information presented? If English is not the subjects' native language, how will translation be provided? (Boxes will expand or, if necessary, attach additional pages.)
3. Will all adult subjects be competent to give informed consent? If not, how will competency be assessed and how will proxy consent be obtained? (Boxes will expand or, if necessary, attach additional pages.)

Note: For research involving minors, describe how parental permission and assent of the minors will be obtained in Part D "Research Involving Minors."

DOCUMENTATION OF CONSENT

Note: Signed, written consent forms are required unless waived by the IRB, but are not the only, or most effective forms of documentation. You must provide copies of all written consent forms. Please see the IRB Handbook <http://www.moreheadstate.edu/files/units/rgc/secure/irb-handbook.pdf> for the basic required elements of informed consent that should be included in adult consent forms.

Waiver of Signed Consent Form Requested

To request a waiver of a SIGNED CONSENT FORM, the research must meet one of the following criteria and researcher(s) must provide a written justification: (Boxes will expand or, if necessary, attach additional pages.)

- The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. [In this case, each subject will be asked whether he or she wants documentation linking the subject with the research, and the subject's wishes will govern.]

Justification:

- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Justification:

Documentation of Consent

How will the subjects' informed consent be documented? Please indicate all the ways in which consent is documented: (Boxes will expand or, if necessary, attach additional pages.)

A copy of the consent form must be attached to this application.

Note: For research involving minors, describe how parental permission and assent of the minors will be obtained in Part D "Research Involving Minors."

PART C

MSU STUDENTS AS SUBJECTS

The following sections must be completed if applicable to your research. (Note: The information also must be included in the informed consent documents as required by federal and IRB regulations.)

Are MSU student subjects being recruited through courses? YES NO

If you answered yes, clearly address all items in the instructor safeguards section below before proceeding to the next questions. If you answered no, simply indicate that the items are not applicable to your research.

Instructor (not subject) Safeguards:

Describe how permission to use subjects in a colleague's class will be obtained. (Boxes will expand or, if necessary, attach additional pages.)

Explain how you will inform instructors that they can refuse to allow the research to be conducted in their class. (Boxes will expand or, if necessary, attach additional pages.)

Describe safeguards to protect the rights of the instructor in the event of refusal to allow use of subjects in a class. (Boxes will expand or, if necessary, attach additional pages.)

Additional Information:

Clearly indicate whether participation as a research subject in this study fulfills a course requirement (i.e., all students are expected to participate in exchange for course credit) or will be conducted without fulfilling a course requirement (i.e., students may choose whether or not to participate without considering course requirements). If participation will fulfill a course requirement, clearly indicate that the instructors for the courses involved will establish appropriate alternative assignments that students may complete if they choose not to be a subject in this research. (Boxes will expand or, if necessary, attach additional pages.)

Clearly indicate how the students will be informed that no penalty will be incurred for non-participation in the research. (Boxes will expand or, if necessary, attach additional pages.)

Are any of the MSU student subjects in the researcher's class or under his/her direct supervision?

YES NO

NOTE: Researcher must use a third party to solicit participation, administer the study, and collect data from subjects when they are students in the researcher's class or when they are employees or supervisees of the researcher.

If you answered yes, clearly address all items in the subject safeguards section below before proceeding to the next questions. If you answered no, simply indicate that the items are not applicable to your research.

Subject Safeguards:

Identify third party who will solicit subjects, administer and collect informed consent and all instruments, and retain documents until final grades are submitted. (Boxes will expand or, if necessary, attach additional pages.)

Identify third party as a contact for subjects to notify if they wish to withdraw from the research project. (Boxes will expand or, if necessary, attach additional pages.)

SPECIAL POPULATIONS

PART D

RESEARCH INVOLVING MINORS

The IRB is required to consider the benefits, risks and discomforts of the research and assess the justification for children's participation in light of the benefits to the child-subject or to society as a whole. In calculating the risks and benefits, the IRB must consider the circumstances of the children under study, the magnitude of risks or discomforts that may result from participating in the research, and the potential benefits the research may provide to the child or to other children with the same disease or condition.

“Minimal risk” is defined as a risk where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than that ordinarily experienced in daily life or during the performance of routine physical or psychological examinations or tests.

Check the category below that best represents the degree of risk and benefit to which the children in this research will be exposed and justify including this research in that category.

The proposed research poses no more than minimal risk as defined above. (Boxes will expand or, if necessary, attach additional pages.)

Justification:

The proposed research poses a greater than minimal risk with the potential for direct benefit to subjects. (Boxes will expand or, if necessary, attach additional pages.)

Justification:

Please note: If your research falls in this category you must answer the following questions and include this information within the Risks section of the protocol application.

How is the risk justified by the benefit? (Boxes will expand or, if necessary, attach additional pages.)

How is the benefit to risk assessment at least as favorable as that presented by alternative approaches? (Boxes will expand or, if necessary, attach additional pages.)

- The proposed research poses a greater than minimal risk with no potential for direct benefit to individuals, but likely to yield generalizable knowledge about the subjects' conditions. (Boxes will expand or, if necessary, attach additional pages.)

Justification:

Please note: If your research falls in this category you must answer the following questions and include this information within the Risks section of the protocol application. Also, research in this category requires permission from BOTH parents (unavailability, incompetence, or temporary incapacity not withstanding) so be sure to address this in the parental permission.

How is the risk of the protocol an increase over minimal risk? (Boxes will expand or, if necessary, attach additional pages.)

How does the procedure present experiences to subjects that are reasonably commensurate with those inherent in their actual or expected situations? (Boxes will expand or, if necessary, attach additional pages.)

How is the knowledge to be gained of vital importance for the understanding or amelioration of the condition? (Boxes will expand or, if necessary, attach additional pages.)

PARENTAL PERMISSION AND ASSENT OF MINORS

Parental Permission

1. Describe procedures used to obtain permission from parents including how and where permission will be obtained and who will obtain the permission. (Boxes will expand or, if necessary, attach additional pages.)

2. How will the subjects' informed consent be documented? (Boxes will expand or, if necessary, attach additional pages.)

Note: If the proposed research poses a greater than minimal risk with no potential for direct benefit to the children, then permission from BOTH parents is required.

Assent of Minor

Assent: Adequate provisions must be made for soliciting the assent of children when in the judgment of the IRB the children are capable of providing assent and for soliciting the permission of their parents or guardians.

1. Please indicate whether the children you will study are generally capable of providing assent; evaluate age, maturity and psychological state of the children involved. Please be specific: (Boxes will expand or, if necessary, attach additional pages.)

 None are capable:

 All are capable:

 Some are capable:

2. Describe procedures used to obtain assent from the subjects including how and where assent will be obtained and who will obtain the assent. (Boxes will expand or, if necessary, attach additional pages.)

3. How will the subjects' assent be documented? (Boxes will expand or, if necessary, attach additional pages.)

Waiver of Parental Permission/Assent Requested

To request a waiver of parental permission or assent, the researcher(s) must provide a written justification, explicitly addressing the four (4) points below, and describe an appropriate mechanism for protecting the children. [See 45 CFR 46.408(c)] (Boxes will expand or, if necessary, attach additional pages.)

(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 subject

(3) the research could not practicably be carried out without the waiver or alteration

(4) whenever appropriate, the subjects will be provided with additional pertinent information after participation

Waiver of Signed Permission Form Requested

To request a waiver of a SIGNED PERMISSION FORM, the research must meet one of the following criteria and researcher(s) must provide a written justification: (Boxes will expand or, if necessary, attach additional pages.)

The only record linking the subject and the research would be the permission document and the principal risk would be potential harm resulting from a breach of confidentiality. [In this case, each subject will be asked whether he or she wants documentation linking the subject with the research, and the subject's wishes will govern.]

Justification:

The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Justification:

SPECIAL POPULATIONS
PART E
PRISONERS AS SUBJECTS

Special considerations must be given to research involving prisoners because they may be under constraints due to their incarceration. Such constraints could affect their ability to make truly voluntary and un-coerced decisions whether or not to participate as subjects in research.

Minimal Risk: The federal regulations divide research into different risk categories: research that is minimal or not greater than minimal risk to the participant and research that is greater than minimal risk. The definition of minimal risk for research involving prisoners is as follows:

Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

1. Permissible Categories of Research

Please check only one box and offer a complete explanation of the study's rationale. The IRB can only approve research that falls into one of the following categories: (Boxes will expand or, if necessary, attach additional pages.)

Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects. (Boxes will expand or, if necessary, attach additional pages.)

Explanation:

Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects. (Boxes will expand or, if necessary, attach additional pages.)

Explanation:

Research on conditions particularly affecting prisoners as a class (for example, research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults). (Boxes will expand or, if necessary, attach additional pages.)

Explanation:

Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. (Boxes will expand or, if necessary, attach additional pages.)

Explanation:

Epidemiological Research - defined as 'public health research that focuses on a particular condition or disease in order to (i) describe its prevalence or incidence by identifying all cases, including prisoner cases, or (ii) study potential risk factor associations, where the human subjects may include prisoners in the study population but not exclusively as a target group, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.' (Boxes will expand or, if necessary, attach additional pages.)

Explanation:

2. Are there any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired? (Boxes will expand or, if necessary, attach additional pages.)

3. Are the risks involved in the research commensurate with risks that would be accepted by nonprisoner volunteers? (Boxes will expand or, if necessary, attach additional pages.)

4. Are the procedures for the selection of subjects within the prison fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners? *Note: Unless the PI provides a justification to the contrary, control subjects must be randomly selected from the group of available prisoners meeting the needed study characteristics.* (Boxes will expand or, if necessary, attach additional pages.)

5. Is the information (i.e., within consent documents) presented in a language that is understandable to the subject population? (Boxes will expand or, if necessary, attach additional pages.)

6. Do adequate assurances exist that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole? (Boxes will expand or, if necessary, attach additional pages.)

7. As there may be a need for follow-up examination or care after the end of the study, are adequate provisions made for such care, taking into account the varying lengths of individual prisoner's sentences and for informing participants of this fact? (Boxes will expand or, if necessary, attach additional pages.)

SPECIAL POPULATIONS

PART F

COGNITIVELY IMPAIRED SUBJECTS

Please answer the following questions:

1. Is the use of this population justified? Could the unimpaired population be substituted? (Boxes will expand or, if necessary, attach additional pages.)
2. Are there institutionalized participants involved? Can the non-institutionalized be substituted? (Boxes will expand or, if necessary, attach additional pages.)
3. Are current medication/therapies going to be changed during the course of the study? Are these risks explained to the participant or their representative? (Boxes will expand or, if necessary, attach additional pages.)
4. Will any part of the study cause distress, stress or anxiety to the participant? Does the consent form appropriately explain this? (Boxes will expand or, if necessary, attach additional pages.)
5. What added protections are incorporated into the study (i.e., increased monitoring, low threshold for study withdrawal, palliative therapy, inpatient care)? (Boxes will expand or, if necessary, attach additional pages.)
6. Will there be a need for a legally authorized representative? How will the participant's capacity to consent be evaluated (i.e., mental status exam, clinical judgment)? (Boxes will expand or, if necessary, attach additional pages.)
7. Is the participant's right to refuse treatment explicit? What are the methods of evaluating dissent? (Boxes will expand or, if necessary, attach additional pages.)
8. Will an independent examiner or ombudsman be used? Should one be assigned? (Boxes will expand or, if necessary, attach additional pages.)

PART G

ASSURANCES AND RESPONSIBILITIES

After you have completed all other parts of your protocol application, read the information below and sign if you agree with the researcher assurances and responsibilities.

Researcher Assurances and Responsibilities:	
As principal investigator(s)/researcher(s), I hereby assure that I will follow procedures to safeguard and protect the rights and welfare of the subjects of my research. I will not begin data collection until I receive a written approval from the IRB.	
If data are to be collected from college students or other MSU employees, I will use a third party to solicit participation, administer the study, or collect data when subjects are either students in a course for which I am the instructor or under my direct supervision.	
As principal investigator(s)/researcher(s), I acknowledge responsibility for protecting the rights and welfare of human subjects; complying with all applicable federal and IRB regulations; conducting the research according to the IRB <i>expedited or full board</i> protocol; reporting any changes in previously approved protocols to the IRB prior to implementation; reporting unanticipated injuries or problems involving risks to human subjects to the IRB; maintaining all approved protocol documents and notifications for three years after completion of the protocol; supervising research conducted by students; and obtaining approval for continuation protocols.	
<i>(Committee approval is granted for a fixed period of time based on risk to subjects. Projects that are intended to continue for longer than the approval period must be resubmitted for review prior to the approval expiration date.)</i>	
_____	_____
Signature of Principal Investigator(s)/Researcher(s)	Date
As faculty advisor, I hereby accept responsibility for the conduct of this project.	
_____	_____
Signature of Faculty Advisor	Date
Do not write below this line	
Date Received:	Protocol Review Number:
Review Completed:	Notification Sent:

For Expedited Protocol Applications, please submit two (2) copies of the completed protocol application in paper form to the IRB Administrative Assistant in the Office of Research and Sponsored Programs (901 Ginger Hall).

For Full Board Protocol applications, please submit ten (10) copies of the completed protocol application in paper form to the IRB Administrative Assistant in the Office of Research and Sponsored Programs (901 Ginger Hall).

Morehead State University
Institutional Review Board (IRB) for the Protection of Human Subjects in Research
PROTOCOL APPLICATION FOR THE USE OF HUMAN SUBJECTS IN RESEARCH

PART H
CHANGE OF STATUS / ANNUAL CONTINUING REVIEW / FINAL REPORT

ONLY COMPLETE FORM AFTER PROTOCOL HAS BEEN APPROVED AND WHEN NECESSARY TO OBTAIN IRB APPROVAL FOR CHANGE OF STATUS OR ANNUAL CONTINUING REVIEW OR TO PROVIDE THE FINAL REPORT:

(Please Mark Choice[s]) Change of Status Annual Continuing Review Final Report

Principal Investigator(s)/ Researcher(s):		Title:	
Department:		E-Mail:	
Campus Address:		Phone:	
Title of Research Project:			
Original Period of Research Project:		From:	To:
Protocol Number:		IRB Initial Review Date:	
Yes	No	Request to Change Identity/Identities of Principal Investigator(s)/Researcher(s)	
<input type="checkbox"/>	<input type="checkbox"/>	New Principal Investigator(s)/Researcher(s):	
IMPORTANT: If you are requesting that the Principal Investigator(s)/Researcher(s) for the approved protocol be changed, you must attach a memorandum from the original Principal Investigator(s)/ Researcher(s) giving permission for the change.			
Yes	No	Request to Extend Ending Date of Project	
<input type="checkbox"/>	<input type="checkbox"/>	From:	To:
Yes	No	Section I – Change of Status	
<input type="checkbox"/>	<input type="checkbox"/>	Are there any proposed changes in the research procedures not included at the time of initial IRB review? If yes, provide committee with detailed explanation of changes (attach explanation).	
<input type="checkbox"/>	<input type="checkbox"/>	Has there been any major change in the research project since its most recent review? If yes, describe changes in procedures/risks used with human subjects (attach description of changes).	
<input type="checkbox"/>	<input type="checkbox"/>	Has there been any adverse reaction or other indication of risks to subjects since last review? If yes, describe the adverse reaction or other indication of risks to subjects (attach description).	
<input type="checkbox"/>	<input type="checkbox"/>	Have increased risks occurred in above mentioned research project? If yes, explain and provide appropriate remedies (attach explanation and recommendations).	
Yes	No	Section II – Annual Continuing Review (i.e., due annually for multi-year projects – approval is only for one year or less based on level of risk)	
<input type="checkbox"/>	<input type="checkbox"/>	Has there been any major change in the research project since its most recent review? If yes, describe changes in procedures/risks used with human subjects (attach description of changes).	
<input type="checkbox"/>	<input type="checkbox"/>	Has there been any adverse reaction or other indication of risks to subjects since last review? If yes, describe the adverse reaction or other indication of risks to subjects (attach description).	
<input type="checkbox"/>	<input type="checkbox"/>	Have increased risks occurred in above mentioned research project? If yes, explain and provide appropriate remedies (attach explanation and recommendations).	
Yes	No	Section III – Final Report	
<input type="checkbox"/>	<input type="checkbox"/>	Project completed?	
<input type="checkbox"/>	<input type="checkbox"/>	Has there been any major change in the research project since its most recent review? If yes, describe changes in procedures/risks used with human subjects (attach description of changes).	
<input type="checkbox"/>	<input type="checkbox"/>	Has there been any adverse reaction or other indication of risks to subjects since last review? If yes, describe the adverse reaction or other indication of risks to subjects (attach description).	
<input type="checkbox"/>	<input type="checkbox"/>	Have increased risks occurred in above mentioned research project? If yes, explain and provide appropriate remedies (attach explanation and recommendations).	

Please submit 2 copies to the IRB committee at 901 Ginger Hall.

Signature of Researcher _____ Date _____

APPENDIX E

Policy: PAc-32

Subject

Misconduct in Research

Approval Date: 10/04/91

Revision Date:

PURPOSE: To establish and maintain institutional compliance with applicable Federal, State and local regulations regarding misconduct in research.

APPLICABILITY: This policy applies to research, research-training, or research-related activities conducted at Morehead State University or sponsored by the institution.

This policy does not supersede and is not intended to set an alternative to established University and/or Federal procedures for resolving fiscal improprieties, issues concerning the ethical treatment of human or animal subjects, or criminal matters.

INSTITUTIONAL PRINCIPLES: In accordance with the fundamental ideals of integrity and credibility which are inherent in the conduct of research, this institution holds in high esteem the proper conduct of all research. Any compromise by faculty, staff, or students of the ethical standards required for conducting research must be reported and promptly addressed in order that these ideals be maintained.

Due to the serious effects that allegations of research misconduct may have upon the reputations and careers of those accused, this institution shall hold any proceedings which follow in the strictest confidence allowable by law. Breaches of confidentiality by those appointed to conduct the proceedings shall be treated as serious offenses. Furthermore, allegations are expected to be made in good faith and not for harassment.

In the event that allegations of research misconduct are subsequently found to be groundless, this institution shall undertake diligent efforts, as appropriate, to restore the reputations of those alleged to have engaged in misconduct.

In the event that allegations of research misconduct are substantiated by a preponderance of the evidence, this institution shall pursue the imposition of appropriate sanctions as authorized by statute or University personnel regulations upon those persons found to be responsible for the misconduct.

Additionally, this institution shall undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

INSTITUTIONAL ASSURANCES: Morehead State University hereby gives assurance that it shall:

1. Establish, keep current, and upon request provide this policy and any regulations designed to implement this policy to the appropriate agencies authorized by the regulations.
2. Inform its research and administrative staff of this policy, any regulations designed to implement this policy and the importance of compliance with them.
3. Take appropriate action as soon as research misconduct on the part of employees or persons within the organizations' control is suspected or alleged.
4. Inform, in accordance with any regulations, and cooperate with the authorized agencies regarding each investigation of alleged misconduct.
5. Foster a research environment that discourages misconduct in all research and that deals forthrightly with possible misconduct.

DEFINITIONS:

"University" or "institution" means Morehead State University.

"President" means the President of Morehead State University.

"Vice President" means the Vice President for Academic Affairs of Morehead State University.

"Allegation" means charges of fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the research community for proposing, conducting, or reporting research.

"Misconduct," "misconduct in research," or "research misconduct" means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the research community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

"Complainant(s)" means those person(s) who make formal allegations of misconduct in research.

"Respondent(s)" means those person(s) who are alleged to have engaged in research misconduct.

"Inquiry" means information gathering and initial fact finding to determine whether an allegation or apparent instance of misconduct warrant an investigation.

"Investigation" means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred.

"Research Review Committee" is the committee appointed by the Vice President to conduct an inquiry and, if warranted, an investigation into allegations of misconduct. The Research Review Committee shall consist of three (3) tenured faculty members chosen with due consideration of the need for appropriate expertise and avoiding conflicts of interest on the part of the committee members. The Research Review Committee shall elect a chair from the membership.

"Inquiry report" means the report submitted to the Vice President by the Research Review Committee following completion of an inquiry.

"Investigation report" means the report submitted to the Vice President by the Research Review Committee following completion of an investigation.

"Appeal" means the official re-examination of the findings of an investigation at the request of the respondent(s).

"Research Appeal Committee" is the committee appointed by the Vice President at the request of the respondent(s) to re-examine the findings of an investigation. The Research Appeal Committee shall consist of three (3) tenured faculty members chosen with due consideration of the need for appropriate expertise and avoiding conflicts of interest on the part of the committee members. No member of the Research Review Committee for a given case may serve on the Research Appeal Committee for that same case. The Research Appeal Committee shall elect a chair from the membership.

"Appeal report" means the report submitted by the Research Appeal Committee to the Vice President following an appellate review of an investigation.

"Final Report" means the report submitted to the OSI after the completion of a formal investigation. It must describe the policies and procedures under which the investigation was conducted, how and from whom information was obtained relevant to the investigation, the findings, and the basis for the findings, and include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct, as well as a description of any sanctions taken by the institution.

"OSI" means the Office of Scientific Integrity, a component of the Office of the Director of National Institutes for Health (NIH), which oversees the implementation of all PHS policies and procedures related to research misconduct; monitors the individual investigations into alleged or suspected research misconduct conducted by institutions that receive PHS funds for biomedical or behavioral research projects or programs; and conducts investigations as necessary.

"OSIR" means the Office of Scientific Integrity Review, a component of the Office of the Assistant Secretary for Health, which is responsible for establishing overall PHS policies and procedures for dealing with misconduct in research, overseeing the activities of PHS research agencies to ensure that these policies and procedures are implemented, and reviewing all final reports of investigations to assure that any findings and recommendations are sufficiently documented. The OSIR also makes final recommendations to the Assistant Secretary for Health on whether any sanctions should be imposed and, if so, what they should be in any case where research misconduct has been established.

"PHS" means the Public Health Service, an operating division of the Department of Health and Human Services (HHS). References to PHS include organizational units within the PHS that have delegated authority to award financial assistance to support research activities, e.g., Bureaus, Institutes, Divisions, Centers or Offices.

"Secretary" means the Secretary of HHS and any other officer or employee of the DHHS to whom the authority involved may be delegated.

"Department" or "Departmental" means the U.S. Department of Health and Human Services (HHS).

PROCEDURAL
SUMMARY:

The following summary is intended to provide an overview of the procedures to be followed under this policy. Detailed information regarding these procedures is found in subsequent sections.

- A. Allegations of research misconduct shall be directed to the Vice President in writing.
- B. If the alleged incident falls under the definition of research misconduct in this policy, the Vice President shall immediately (within one week) appoint and convene a Research Review Committee and notify the respondent(s) in writing of the allegations and the initiation of an inquiry.
- C. The Research Review Committee conducts an inquiry which must be completed within 60 days of its initiation.
- D. At the completion of the inquiry, the Research Review Committee files a written inquiry report with the Vice President including notification of whether a formal investigation is warranted. This report shall not identify the complainant(s).
- E. If the Research Review Committee does not find grounds for an investigation, the Vice President notifies the respondent(s) and the complainant(s) and the case is closed.
- F. If the Research Review Committee determines that an investigation is warranted, the Vice President notifies the respondent(s) and complainant(s) that an investigation is being initiated. The Vice President shall also inform the President of the need to notify the OSI of the impending investigation.
- G. The Research Review Committee shall begin the investigation within 30 days of completing the inquiry. The entire investigatory process (including the investigation, appeal, administrative actions and reporting to the OSI) must be completed within 120 days of initiating an investigation.
- H. Upon completion of the investigation, the Research Review Committee shall submit to the Vice President an investigation report with its determination regarding the allegations. This report shall not identify the complainant(s).
- I. The Vice President shall notify the respondent(s) in writing of the Research Review Committees' decision and provide them with a copy of the investigation report.
- J. The respondent(s) may respond to the investigation report and/or appeal the decision within two weeks of receiving this notification by writing to the Vice President.
- K. Should the respondent(s) request an appeal, the Vice President shall appoint a Research Appeal Committee to re-examine the allegations, and the information contained in the inquiry and investigation reports. An appeal report of the findings is submitted to the Vice President.
- L. Upon completion of the investigation and appeal process the Vice President reports the outcome to the President.

- M. The President may take whatever action is deemed appropriate to the situation within the bounds of Federal, State, and University personnel regulations.
- N. The President submits the Final Report to the OSI within the 120 day investigative time limit or as negotiated with the OSI.
- O. The OSI may respond, reinvestigate, or impose sanctions of its own.

INQUIRIES:

An inquiry consists of information gathering and initial fact finding to determine whether an allegation or apparent instance of misconduct warrant an investigation.

- A. The University shall inquire immediately (within one week) into any allegation or other evidence of possible research misconduct which falls under the definition of misconduct in this policy. An inquiry must be completed within 60 calendar days of its initiation unless circumstances clearly warrant a longer period.
- B. A written inquiry report shall be prepared that states what evidence was reviewed, summarizes relevant interviews, and includes the conclusions of the inquiry. If the inquiry takes longer than 60 days to complete, the inquiry report shall include documentation of the reasons for exceeding the 60-day period.
- C. The inquiry shall be conducted by a Research Review Committee appointed by the Vice President. The Research Review Committee shall consist of three (3) tenured faculty members chosen with due consideration of the need for appropriate expertise and avoiding conflicts of interest on the part of the committee members. The Research Review Committee shall elect a chair from the membership.
- D. The Research Review Committee may consult with the University Attorney and/or research experts within or outside the University in the course of the inquiry.
- E. The Research Review Committee shall take diligent efforts to maintain confidentiality and to protect the privacy of the complainant(s) and the respondent(s).
- F. If at any time during the inquiry the Research Review Committee becomes aware of any conditions denoted in the "Notification Requirements" section, the Vice President must be notified immediately. The Vice President shall notify the President of any need to make official notification to the OSI.
- G. The Research Review Committee shall maintain sufficiently detailed documentation of the inquiry to permit a later assessment, if necessary, of the reasons for determining that an investigation was not warranted. Such records shall be maintained in a secure manner by the Vice President for a period of at least three years after completion of the inquiry, and shall, upon request, be provided to authorized HHS personnel, or the appropriate Federal granting agency.
- H. Complete summaries of any interviews shall be prepared, provided to the interviewed party for comment or revision, and included as part of the inquiry report by the Research Review Committee.
- I. The Vice President shall give a copy of the inquiry report to the respondent(s) for response. If a written response is returned, it shall become part of the inquiry report.

INVESTIGATIONS:

An investigation consists of the formal examination and evaluation of all relevant facts to determine if misconduct has occurred.

- A. An investigation shall be initiated within thirty (30) days of the completion of an inquiry if the Research Review Committee determines that a full investigation is warranted.
- B. The Vice President shall notify the President that an investigation is being initiated and of the need to notify the OSI prior to the date the investigation will begin.
- C. The Vice President shall notify the complainant(s), and the respondent(s) in writing that an investigation is being initiated.
- D. The investigation shall be conducted by the Research Review Committee previously appointed by the Vice President for conducting the inquiry.

- E. The investigation shall include examination of all documentation, including but not necessarily limited to relevant research data and proposals, publications, correspondence, and memoranda of telephone calls. Whenever possible, interviews shall be conducted of all individuals involved either in making the allegation or against whom the allegations are made, as well as other individuals who might have information regarding key aspects of the allegations. Complete summaries of the interviews shall be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file by the Research Review Committee.
- F. The Research Review Committee may consult with the University Attorney and/or research experts within or outside the University in the course of the investigation.
- G. If at any time during the investigation the Research Review Committee becomes aware of any conditions denoted in the "Notification Requirements" section, the Vice President must be notified immediately. The Vice President shall notify the President of any need to make official notification to the OSI.
- H. The Research Review Committee shall prepare documentation to substantiate its findings. This documentation becomes part of the investigation report which shall be submitted to the Vice President upon completion of the investigation.
- I. It is expected that the entire investigative process shall be completed within 120 days of its initiation. This includes the investigation, preparing the investigation report, making the report available for comment by the respondent(s), completion of the appeal process (if requested), taking administrative actions, and submitting the Final Report to the OSI.
- J. If the University cannot complete the entire investigative process (including appeal, sanctions, and reporting) within 120 days of its initiation, the President shall submit to the OSI a written request with an explanation for the delay that includes an interim report on the progress to date and an estimate for the date of completion of the Final Report and other necessary steps. Any consideration for an extension must balance the need for a thorough and rigorous examination of the facts versus the interests of the subject(s) of the investigation and the PHS in a timely resolution of the matter. If the extension is granted, the President shall file periodic progress reports as requested by the OSI. If satisfactory progress is not made by the University, the OSI may undertake its own investigation.
- K. At the conclusion of the investigation, the Research Review Committee shall submit its investigation report to the Vice President with the determination of whether the allegations have or have not been substantiated by a preponderance of the evidence.
- L. The Vice President shall give a copy of the investigation report to the respondent(s) for response. If a written response is returned, it shall be made part of the investigation report.
- M. The respondent(s) may request an appeal of the Research Review Committees' decision by making a written request to the Vice President within two weeks of receiving notification of the investigations' outcome.
- N. Should an appeal be requested, the Vice President shall appoint a Research Appeal Committee composed of three (3) tenured faculty members chosen with due consideration of the need for appropriate expertise and avoiding conflicts of interest on the part of the committee members. No member of the Research Review Committee for a given case may serve on the Research Appeal Committee for that same case. The Research Appeal Committee shall elect a chair from the membership.
- O. The Research Appeal Committee shall examine the allegations, evidence, and testimony which is contained within the inquiry and investigation reports to determine whether the conclusions drawn by the Research Review Committee are substantiated therein. Additional interviews may be conducted as needed.
- P. The Research Appeal Committee is expected to complete its deliberations within the time remaining for the 120 day investigative process, or, failing this to notify the Vice President of the need to request an extension from the OSI.

- Q. The Research Appeal Committee shall prepare an appeal report and submit it to the Vice President. The appeal report shall indicate whether or not the Research Appeal Committee concurs with the previous findings and on what basis this decision was made.
- R. After completion of the investigation/appeal process the Vice President shall report to the President regarding the outcome of the investigation/appeal.
- S. The President may take whatever action is deemed appropriate to the situation within the bounds of Federal, State, and University Personnel regulations.
- T. Within 120 days of the initiation of the investigation, (or in accordance with any extension negotiated with the OSI), the President shall submit the Final Report to the Director of the OSI.

**NOTIFICATION
REQUIREMENTS:**

Notification to the OSI shall be made as follows with regard to research activities connected with PHS-sponsored biomedical and behavioral research conducted at or sponsored by this institution:

- A. The University, through the President, shall submit annually to the OSI, it's assurance that these policies and procedures are being followed and such aggregate information on allegations, inquiries, and investigations/appeals as the Secretary may prescribe.
- B. The decision to initiate an investigation shall be reported in writing to the OSI on or before the date the investigation begins. At a minimum, the notification by the President to the OSI shall include the following information:
 - (1) name of person(s) against whom the allegations have been made;
 - (2) general nature of the allegations; and the
 - (3) PHS applicant or grant number(s) involved.
- C. The President shall notify the OSI at any stage of an inquiry or investigation if any of the following conditions exist:
 - (1) immediate health hazard involved;
 - (2) immediate need to protect Federal funds or equipment;
 - (3) immediate need to protect the interest of the complainant(s) or respondent(s);
 - (4) probability that the alleged incident will be reported publicly;
 - (5) any reasonable indication of possible criminal violations associated with research activities for which federal funds have been provided or requested is obtained. In this instance notification must occur within 24 hours of obtaining the information.
 - (6) any developments which disclose facts that may affect current or potential HHS funding for the individual(s) under investigation or that the PHS needs to know to ensure appropriate use of federal funds and otherwise protect the public interest.
- D. After completion of the investigation/appeal process, the President shall send the Final Report to the Director, OSI, who will decide whether that Office will either proceed with its own investigation or will act on the institution's findings.
- E. If the Final Report cannot be completed within 120 days of initiating an investigation, the President shall request an extension from the OSI.
- F. If the University plans to terminate an inquiry or investigation for any reason without completing the requirements of the Final Rule, a report of such planned termination including a description of the reasons for such termination, shall be made to the OSI, which will decide whether further investigation should be taken.

ADMINISTRATIVE
ACTIONS:

The University may take administrative action as warranted during or following an inquiry or investigation.

- A. At any time during the course of an inquiry or investigation, the University, acting through the President may take interim administrative actions, as appropriate, to protect Federal funds and insure that the purposes of the Federal financial assistance are carried out. Notification to the OSI shall be made as appropriate under this policy.
- B. In the event an investigation/appeal process finds the allegations groundless, all Federal agencies or other entities initially informed of the investigation shall be notified of the exoneration by the President within one week of completing the Final Report. Additionally, efforts shall be made to restore the reputations of the respondent(s) as appropriate.
- C. When an investigation/appeal process finds support for allegations of misconduct, all Federal agencies or other entities initially informed of the investigation shall be notified of the finding of misconduct by the President within one week of completing the Final Report. Consideration shall be given to formal notifications of other involved parties such as, but not all inclusive:
 - (1) co-authors, co-investigators, and collaborators affiliated with the affected research;
 - (2) editors of journals in which the affected research was published or submitted for publication;
 - (3) sponsoring agencies and funding sources affiliated with the affected research.
- D. When allegations of misconduct are substantiated, the President may take whatever action is deemed appropriate to the situation within the bounds of Federal, State, and University Personnel regulations. The Final Report to the OSI must indicate what sanctions were imposed, and this report must be filed within 120 days of initiating the investigation unless an extension is granted by the OSI.