University of Northern Iowa

Policies & Procedures
for
Protections of Human Research Participants

2005

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BACKGROUND & PRINCIPLES

It is the policy of the University of Northern Iowa (UNI) to ensure that the rights and welfare of human research participants are adequately protected in all research activities conducted under its auspices.

In addition, federal and state laws and regulations require these protections. In order for the University to fulfill its responsibility and to comply with the law and regulations, all human participants research conducted under University auspices must receive appropriate review and approval. In its Federalwide Assurance, on file with the Office for Human Research Protections (OHRP), U.S. Department of Health and Human Services, the University assures compliance with all requirements of Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) for all federally-sponsored research, and all other human participants research, regardless of source of support.

Ethical Violations in Research with Human Participants

Examples of inhuman and unethical treatment of humans in the name of research have been documented throughout recent history. The Nuremberg trials documented the unethical behavior of Nazi physicians. American researchers from the Public Health Service studied 400 African American men with syphilis in the Tuskegee syphilis study between 1933 and 1972. These men were not asked for their informed consent or authorization to be in the study and they were, in fact, given misinformation about their treatment. After penicillin became available and was known to be effective in the treatment of syphilis, it was withheld from these subjects because the researchers were interested in the natural history of the disease. Researchers from Harvard and MIT formed a "science club" of 19 mentally impaired boys at the Fernald State School between 1946 and 1956. These boys were fed forms of radioactive iron or calcium, sometimes in their milk, to enable the researchers to study the body's ability to digest minerals. Doctors at the Jewish Chronic Disease Hospital conducted studies of human transplant rejection using cancer cells. The subjects were not asked for informed consent or authorization and provided no written consent or authorization to participate in the study. Between 1963 and 1966, children at the Willowbrook State School, a state school for "mentally defective" youths were purposely infected with the hepatitis virus in a study of that disease. During the course of this study the institution closed its doors to new clients, claiming overcrowding. However, the wing housing the hepatitis program was willing to admit new clients if their parents agreed to allow their children to participate in the ongoing studies. (These descriptions of unethical research conduct are based on the NIH tutorial for ethical training. That training module is at http://cme.nci.nih.gov/.)

Behavioral and social science researchers have exposed other humans to severe trauma and psychological stress in investigations of power. The participants in Milgram's "obedience" studies, conducted in the early 1960s, were told that they had to continue to participate in the study and shock another person at increasingly intense voltages. Studies supported by the Human Resources Research Office of the U.S. Army introduced severe stress to army recruits by threatening them with death from errant artillery rounds or by causing the recruits to think that they, by making a mistake in wiring an instrument, had caused the injury or death of others in their units. Despite potentially important knowledge gained from such studies, the risks to the participants were extreme.

Codes of Research Ethics

Codes of research ethics have been developed, in part to address the disregard for human safety and dignity that these research projects reflect. The Nuremberg Code of 1947 was the first international
code of research ethics. Its first principle is "The voluntary consent/authorization of the human subject is absolutely essential." The accompanying text made it clear that this voluntary consent/authorization should also be informed consent/authorization: "...the person involved ... 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 principle of "free and informed consent/authorization" remains the basic foundation of ethical research with human participants.

Another early code was the Helsinki Declaration, adopted by the World Medical Assembly at its meeting in Helsinki, Finland in 1964. Its second principle, "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..." established the concept of ethical review.

The first ethical code covering social and behavioral research was a set of 10 ethical principles adopted by the American Psychological Association in 1972. The bases for these principles were critical incidents. Psychologists were asked to submit examples of research that they deemed unethical or of questionable ethicality. The committee charged with developing ethical standards for psychological research then developed principles that would guide the conduct of researchers when conducting research that could pose ethical problems. The American Psychological Association's principles were the first to recognize the principle of confidentiality. Principle 10 states: "Information obtained about the research participants during the course of an investigation is confidential. When the possibility exists that others may obtain access to such information, ethical research practice requires that this possibility, together with the plans for protecting confidentiality, be explained to the participants as a part of the procedure for obtaining informed consent/authorization." Most professional organizations have ethical codes, and most require authors of manuscripts submitted to the journals of these organizations to state that they have followed these ethical principles in their research.

The U. S. Department of Health, Education, and Welfare issued ethical guidelines in 1971 which were codified into Federal Regulations in 1974. However, the primary impetus for current government ethical regulation began with the establishment of a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research under the aegis of the Department of Health, Education, and Welfare in 1974. The Commission was charged with identifying the basic ethical principles that should underlie research with human subjects. The report of the Commission, called The Belmont Report because it was based on deliberations held at the Smithsonian Institution's Belmont Conference Center, was published in 1978. The Belmont Report identified three basic ethical principles. They are:

(1) **Respect for Persons (autonomy):** This principle acknowledges the dignity and freedom of every person. It requires obtaining informed consent/authorization from all potential research subjects (or their legally authorized representatives).

(2) **Beneficence:** This principle requires that researchers maximize benefits and minimize harms or risks associated with research. Research-related risks must be reasonable in light of expected benefits.

(3) **Justice:** This principle requires the equitable selection and recruitment and fair treatment of research subjects.
These three principles were the underpinnings of both an early (1980) version of a Common Federal Policy for the Protection of Human Research Subjects and the current version of that policy. The current version has been adopted by sixteen federal departments and agencies, including the Department of Health and Human Services, the National Science Foundation, the Department of Education, and the Central Intelligence Agency. The Food and Drug Administration (FDA) has concurred with the Federal Policy and has made changes in its IRB and informed consent/authorization regulations so that they correspond to the Federal Policy. This Federal Policy, sometimes called the Common Rule, is codified as the Common Federal Policy for the Protection of Human Subjects and was published in the Federal Register in 1991. It is referred to as 45 CFR 46 and its regulations underlie the decisions of IRB. The regulations further require that each institution at which federally funded research is conducted adhere to the principles of The Belmont Report and set forth in writing its ethical principles, policies, and procedures. This institution's agreement to abide by the Belmont Report and by 45 CFR 46 (called a Federal Wide Assurance or FWA) is approved by the federal agency that oversees ethical issues in human research. Because UNI has an FWA (FWA00002159), UNI can establish an IRB that can review all research projects involving human subjects.

**Administration of Research Ethics -- Federal**

The audits conducted by the federal department responsible for human subject protection, now known as the Office for Human Research Protections (OHRP), of the performance of IRBs and the conduct of research with human participants at several medical schools have resulted in temporary injunctions of research with humans at those schools. The death of a participant in a gene therapy research study suggested a lapse of oversight at the site of that study. News reports of clinical trials have suggested that doctors may receive financial benefits by enrolling their patients in such trials and that the patients may not benefit or may be at risk.

Since the conduct of research with human beings may raise fundamental ethical and civil rights questions, no distinctions in the monitoring of research are drawn between funded and non-funded research, or between research conducted by faculty, students, other University personnel, or affiliated researchers.

The policies in this document apply equally to all research involving human participants conducted under the auspices of the University of Northern Iowa. All faculty members, staff, students and affiliated researchers who conduct or anticipate conducting research projects (either on or off campus) involving human participants are responsible for familiarizing themselves and complying with these policies.

**DEFINITIONS**

The University of Northern Iowa has adopted the definitions included in the Federal regulations on the protections of human participants in research (45 CFR 46.102).

- **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.

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

**Human participant** means a living individual about whom an investigator (whether faculty 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 and manipulations of the participant or the participant’s environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and participant. Private information includes communication 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. Private information must be individually identifiable (i.e., the identity of the participant 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 participants.

**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 participant’s participation in the procedure(s) involved in the research.

**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.

**INSTITUTIONAL RESPONSIBILITIES**

**Scope of Responsibility**

- The University has an Institutional Review Board (IRB) to review and approve human participants research.
- The University of Northern Iowa acknowledges that it bears full responsibility for the performance of all research involving human participants conducted under its auspices, including compliance with Federal, state, or local laws as they relate to such research.
- The University of Northern Iowa and the individual members of its faculty, staff, and student body acknowledge and accept their responsibilities for protecting the rights and welfare of human participants in research. This policy applies to all research involving human participants, and all activities which even in part involve such research, regardless of sponsorship, if the research:

  - is sponsored by this institution, or
  - is conducted by or under the direction of University of Northern Iowa faculty, staff, or students in connection with the fulfillment of institutional responsibilities or academic requirements; or
  - is performed with or involves the use of University records, facilities or equipment belonging to the University.
The University encourages and promotes constructive communication among research investigators, the IRB, and human participants as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the participants. The University assumes responsibility for communicating and explaining these policies to faculty, students, and other personnel, and for providing procedural guidelines to facilitate their observance.

**Performance Sites**

The University is responsible for ensuring that no performance site cooperating in the conduct of Federally sponsored research to which the University/DHHS Federal Wide Assurance applies does so without Federal department or agency approval of an appropriate assurance and satisfaction of IRB certification requirements.

**Protections for Vulnerable Populations**

The University requires more stringent safeguards for certain research activities and for participants likely to be vulnerable to coercion or undue influence such as:

1. pregnant women
2. prisoners
3. children
4. physically or mentally impaired persons
5. economically or educationally disadvantaged persons
6. other potentially vulnerable groups, and
7. activities involving fetuses and human in vitro fertilization.

University students and employees are also vulnerable populations because a decision to participate in a research project may be perceived to be required to prevent discrimination either in determination of course grades, employee evaluations or in other activities of the academic department or unit. Special efforts must be made to avoid coercion. Specific guidance is provided in the Information for Investigators ([www.uni.edu/osp/research/investigatorinformation.htm](http://www.uni.edu/osp/research/investigatorinformation.htm)).

**Provision of Resources**

The University will provide the IRB with resources, meeting space, professional staff and support staff to carry out its responsibilities efficiently and effectively.

**Education and Training**

The University will ensure that the IRB Chairpersons, the IRB members, human participants investigators, and relevant administrative personnel complete appropriate initial and continuing education related to the protection of human participants before reviewing or conducting human participants research. (See Education and Training section under THE INSTITUTIONAL REVIEW BOARD (IRB) REVIEW PROCESS)

**Collaborating Institutions**
The University will ensure that all collaborating institutions (including subcontractors and subgrantees) engaged in human participants research have appropriate approved assurances on file with OHRP prior to the initiation of research. (See Cooperative Research.)

Administrative Oversight

As put forth in the Federal regulations, to assure independence and to avoid potential political influence, the IRB functions independently. However, the designated Institutional Official (IO) will exercise appropriate administrative overview to ensure that the procedures designed for the protection of the rights and welfare of human participants and records are in compliance with the requirements of 45 CFR 46.103 and this policy. A copy of this policy will be available at the Office of Sponsored Programs, on the Office of Sponsored Programs website, and will be sent to faculty, staff, or students requesting copies.

Responsibilities of the Human Protections Administrator

- The IO has assigned compliance with federal regulations and University policy regarding human participants research to the Human Protections Administrator.
- The Human Protections Administrator shall receive from investigators all research protocols that involve human participants, and keep investigators informed of review decisions.
- The Human Protections Administrator shall forward certification of IRB approval of proposed research to the appropriate Federal department or agency (when required) only after all IRB-required modifications have been incorporated to the satisfaction of the IRB.
- The Human Protections Administrator shall provide advice on the preparation of the Human Participants Application Review Form and other documents, and other advice that will facilitate the IRB review process.
- The Human Protections Administrator shall maintain and arrange access for inspection of IRB records, in accordance with 45 CFR 46, Section 115.
- The Human Protections Administrator is responsible for ensuring constructive communication among research administrators, department heads, research investigators, human participants, and institutional officials as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the participants.
- The Human Protections Administrator shall arrange for and document in his/her records that each individual who conducts or reviews human participants has ready access to this policy, copies of 45 CFR 46, regulations of other Federal departments or agencies as may apply, the Belmont Report, and all other pertinent Federal policies and guidelines related to the involvement of human participants in research.
- The Human Protections Administrator will ensure (a) solicitation (or confirmation where applicable assurances to comply already exist), receipt, and management of all assurances of compliance (whatever the appropriate format), and (b) certifications of IRB review (where appropriate) for all performance sites of this institution (including those listed on the Federal Wide Assurance), and subsequent submission of new documents to the proper Federal Department or Agency authorities as a condition for involvement of each site in human participants research activities sponsored by the Department of Health and Human Services or any other Federal department or agency.
THE INSTITUTIONAL REVIEW BOARD (IRB) REVIEW PROCESS

Membership of the IRB

This University has established its IRB in accordance with the compositional requirements of 45 CFR 46, Section 107. The committee must be sufficiently qualified through the maturity, experience, and expertise of their members and diversity of membership to insure respect for their advice and counsel specific to safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific activities, the committee must be able to ascertain the acceptability of proposals in terms of organizational commitments, regulations, applicable law, standards of professional conduct and practice, and community attitudes.

IRB membership requirements.

- Each IRB shall be comprised of at least 5 members from diverse backgrounds to promote complete and adequate review of research activities commonly conducted at the University.
- The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of its members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes and issues related to vulnerable populations, to promote respect for its advice and counsel safeguarding the rights and welfare of human participants.
- 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 and shall, therefore, include persons knowledgeable in these areas.
- The IRB shall include qualified persons of both sexes so long as no selection is made on the basis of gender.
- The IRB shall include at least one member whose primary concerns are in a non-scientific area and at least one member whose primary concerns are in a scientific area.
- The IRB shall include at least one member who is not otherwise affiliated with the University and who is not part of the immediate family of a person who is affiliated with the University.
- No IRB member may 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.
- The IRB may, at their discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB.

IRB appointment

- The Institutional Official, in consultation with the IRB Chair and Human Protections Administrator, shall make formal appointments of full-time UNI faculty to the IRB for terms not more than 3 years in length. Terms are renewable.
- The Institutional Official, with input from the Human Protections Administrator and IRB members, shall appoint the chair of the IRB for a 3-year renewable term.

IRB membership lists and qualifications
• The names, qualifications and affiliations of the members of the IRB shall be on file with the U.S. Office for Human Research Protections (OHRP), in accordance with the requirements of the University/PHS Federal Wide Assurance, and at the Office of Sponsored Programs in 213 East Bartlett Hall.
• All changes in IRB membership are reported to OHRP as appropriate.

In addition to faculty members representing different disciplines, the IRB currently has two community members; both are deemed to represent non-scientific areas; one is a prisoner representative. At times, the IRB may not have the necessary expertise to judge the scientific soundness of a research protocol and may be unable to make a fair and accurate determination of the risk-benefit ratio. For these protocols, the IRB may call upon ad hoc consultants for assistance in review for scientific merit.

Member files are kept in the Office of Sponsored Programs. They include: 1) a letter of appointment, 2) a current curriculum vitae, and 3) documentation of human protections education, which includes a) a statement that the member has read "Information for Investigators" and b) a certificate that shows the member has completed the NIH tutorial for IRB members.

In addition, educational materials are made available to members of the IRB and are generally distributed and discussed at each IRB meeting.

Meetings

The IRB shall hold one regularly scheduled meeting per month, at a time and place to be pre-determined and posted on the web site www.uni.edu/osp/research/investigatorinformation.htm. If no protocols are pending review by the full IRB, the Chair may elect to cancel a meeting.

Confidentiality of the Review Process

During the process of initial or continuing review of an activity, material provided to the Institutional Review Board shall be considered privileged information and the Board shall assure the confidentiality of the data contained therein. At meetings of the full IRB, in order to answer questions or provide clarification, investigators are invited but are not required to attend the portion of the meeting at which their protocol will be discussed. Investigators will be seated outside the conference room and will be called at the time their protocol is discussed. To maintain the confidentiality of research protocols and proprietary information that may be contained in them, visitors are not routinely invited to attend IRB meetings. Any requests to attend an IRB meeting must be approved by the chair and all visitors must sign a confidentiality agreement prior to their attendance.

General Principles of IRB Review

It is the policy of the University that its IRB review all research involving human participants. The IRB has the responsibility and authority to review, approve, disapprove, or require changes in and monitor research activities involving human participants. No individual involved in the conduct and/or supervision of a specific project shall participate in IRB review, except to provide information.

In accordance with the compositional requirements of 45 CFR 46, the University has established the IRB.
Federal guidelines grant the IRB autonomy in the interpretation of regulations. Thus, each IRB must apply its own discretion when deciding how a research proposal will be judged to meet the ethical criteria provided in the regulations. And, in the case of informed consent, 45 CFR 46 allows the IRB to waive this requirement under a variety of circumstances. This means that each IRB must independently determine the nature of research risks and research benefits, the extent to which risks to subjects are "reasonable" in relation to anticipated benefits, when research risks and benefits justify modification in the informed consent requirement, and what constitutes equitable participant selection.

No involvement of human participants in research, including recruitment, is permitted until the IRB has reviewed and approved the research protocol and informed consent has been obtained. It is the responsibility of the investigator to obtain approval from the IRB prior to the initiation of any research, including pilot or pre-test studies, involving the use of human participants.

- All activities involving humans as research participants must provide for the safety, health, and welfare of every individual. Rights, including the right to privacy, must not be infringed. No participant in a research activity shall be exposed to unreasonable risk to health or well-being.
- An individual does not abdicate any rights by consenting to be a research participant. A participant has the right to withdraw from a research project at any time or can refuse to participate without loss of benefits to which the subject would otherwise be entitled. Further, a participant has the right to receive appropriate professional care, to enjoy privacy and confidentiality in the use of personal information, and to be free from undue embarrassment, discomfort, anxiety, and harassment.
- The direct or potential benefits to the participant, or the importance of the knowledge to be gained, must not preclude consideration of the inherent risks to the individual.
- The confidentiality of information received from participants in experiments or respondents to questionnaires or surveys shall be fully protected, both during and after the conduct of a research activity, within the limits of the law.
- Participation in projects must be voluntary. Informed consent must be obtained from all participants and must be documented (unless the requirement for documentation of consent is specifically waived by the IRB). Methods in accordance with the requirements of 45 CFR 46.116 and 46.117, appropriate to the risks of the research, must be used to obtain the participants' informed consent.
- In research involving more than minimal risk or substantial stress or discomfort, such risk, stress, or discomfort shall be carefully explained to the participant before his or her participation and justified by the expected benefits of the research. The investigator shall be satisfied that the explanation has been understood by the participant; and the written consent of the participant (unless otherwise waived by the IRB), containing the substance of the explanation, shall be obtained and kept as a matter of record for 3 years.

**IRB Responsibilities**

- The IRB shall follow the written policies and procedures of the University of Northern Iowa for the protection of human participants in research. These policies and procedures are in compliance with Federal regulations and State law.
- Except when exemption or expedited review procedures are applicable, the IRB shall review proposed research at convened meetings at which a majority of the members are present, including at least one member whose primary concerns are in non-scientific areas. In order for
The research to be approved, it shall receive the approval of a majority of those members present at the meeting.

- The IRB shall review and have the authority to approve, require modifications in (to secure approval), or disapprove all research activities, including changes in previously approved human participants research.
- The IRB shall require that information given to participants as part of the informed consent process is in accordance with 45 CFR 46.116. The IRB may require that information, in addition to those required elements specified in 45 CFR 46.116(a), be given to participants when in the IRB’s judgment the information would meaningfully add to the protection of the rights and welfare of the participants.
- The IRB shall require documentation of informed consent or may waive documentation in accordance with 45 CFR 46.117.
- The IRB, through the Human Protections Administrator, shall notify investigators in writing (via email or letter) of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of research activity. If the IRB disapproves or requests modifications to the 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.
- Certification of IRB review and approval for all Federally-sponsored research involving human participants will be submitted to the Human Protections Administrator for forwarding to the appropriate Federal department or agency as required. Compliance will occur within the time and manner prescribed for forwarding certifications or IRB review to DHHS or other Federal department or agency.
- The Human Protections Administrator shall designate procedures for the retention of University IRB records and documents for at least three (3) years past completion of the research activity.

Review Procedures

To initiate an IRB review, 3 completed and signed copies of the current Human Research Participant Review Application (available at www.uni.edu/osp/research/IRBforms.htm) must be submitted to the Human Participants Review Committee (IRB) Office of Sponsored Programs, 213 East Bartlett Hall. After submission, each new protocol is given an IRB protocol number for tracking purposes.

The IRB has the authority to approve, require modifications to (to secure approval), or disapprove research. To ensure the ethical treatment of all research participants, no research is excluded from review. During the initial review process, the IRB Chairperson (or his/her designated reviewer) determines whether a particular study is classified as Exempt from Continuing Review, Expedited, or requires Full Board review. The IRB communicates its findings via email or official letter to the Investigator. A researcher may begin a study only after notification of approval from the IRB.

Shortly after review, a notice is sent to each investigator whose protocol was reviewed. This notice is always sent to the faculty member whose signature appears first on the protocol form. The notice will indicate what action was taken by the IRB (i.e., approved, approved pending minor modifications, or deferred for additional information), as well as the review interval (duration of the approval.) If the protocol is approved pending modifications or deferred for additional information, there will be an additional explanation about what information is needed in order to receive approval. In the case of an approval pending modifications, these are most commonly slight changes to the consent form or some
additional information the IRB requires in the protocol. Any protocol not receiving approval will be discussed with the investigator. The Chair may not disapprove a protocol and will offer to forward the application to the entire IRB for further review. All concerns of the IRB Chair will be described, in the notice of action communication.

If the protocol is deferred by the full IRB and additional information is requested from the investigator, it will be reviewed at the first regularly scheduled meeting of the IRB after receipt of the requested information.

Another notice will be sent to the investigator after that meeting to inform him/her of the disposition of the protocol.

If the protocol is approved pending modifications, the requested information should be returned to the IRB office or IRB chair, as requested. As soon as possible after the material is received, it will be reviewed to ensure that it responds to the concerns of the IRB. An acknowledgement of the receipt of the requested information will then be sent to the investigator. The modifications must be made and approved by the IRB before an investigator may begin to recruit participants for involvement in the research.

Additional detailed information about review procedures and consent requirements is provided in UNI Information for Investigators located at www.uni.edu/osp/research/investigatorinformation.htm.

Review Process - Minimal Risk Protocols

Protocols determined to be minimal risk, may be considered for Expedited review or Exempt review if they fall into the categories outlined in the Federal regulations (45 CFR 46.110 or 45 CFR 46.101). Protocols fulfilling all requirements for Exempt or Expedited Review are reviewed by the Human Protections Administrator for completeness who corresponds with the principal investigator by e-mail and/or phone until the packet is complete. Then the packet is reviewed by the IRB Chair.

The Chair reports all protocol numbers and PIs in the appropriate agenda and minutes to the IRB at the next meeting. Protocols that may be minimal risk but include vulnerable populations are referred for full board review.

Review Process - More Than Minimal Risk Protocols

Once the protocol has been determined to be more than minimal risk or includes vulnerable populations, by regulation, it must be reviewed and approved, at a convened meeting of the entire IRB. To facilitate thorough review of each protocol according to Federal regulations, the following process is followed:

A complete set of documents is sent to each IRB member who is asked to review the protocol and supporting documentation in detail. In the process of this review the Chair or primary IRB reviewer may contact the investigator, co-investigators, other IRB members, or outside sources as necessary to insure a thorough evaluation of risks and benefits of the proposed research.

The protocols undergoing initial review are presented and discussed individually by the IRB, as well as those protocols undergoing continuing review. After complete and individual discussion, each protocol
is voted upon for one of four possible dispositions. The Board may vote to approve, disapprove a study, to table a study, or to approve a study with explicit conditions. A study may be tabled either because the Board did not have sufficient time, or expertise, or appropriate personnel present (i.e., absence of prisoner advocate for a study involving prisoners) to vote on the study or because the Board needed substantive clarification or modifications regarding the protocol, or informed consent documents to determine whether to approve or disapprove the study. A study may be approved with explicit conditions when the convened IRB is able to stipulate specific revisions that require simple concurrence by the investigator. If the IRB approves a study with explicit conditions, then the primary IRB reviewer or Chair may approve the revised research protocol under an expedited review procedure to determine whether the investigator has incorporated the specified explicit conditions into his or her project:

"Approved" - Approved as written with no conditions.

"Approved with Explicit Conditions" - Approved with explicit minor changes or simple concurrence of the principal investigator (PI), that will be identified to the PI and must be completed and documented prior to beginning the research. For these conditions, the IRB Chair or designated reviewer can, upon reviewing the PI's response(s) to stipulations, approve the research on behalf of the IRB. If your study has received approval with Explicit Conditions, return one copy of the corrections to the IRB with any changes underlined or in bold.

"Tabled" - Generally, the protocol or consent/authorization form has deficiencies that prevent accurate determination of risks and benefits or requires significant clarifications, modifications or conditions that, when met or addressed, require full IRB review and approval of the PI's responses and revisions. The deficiencies will be specified to the PI, and on occasion the PI is asked to attend the full board meeting in order to clarify the points in question.

"Disapproved" - The protocol describes a research activity that is deemed to have risks which outweigh potential benefits or the protocol is significantly deficient in several major areas. A principal investigator has the right to appeal the disapproval of his research protocol to the Board and asked to have the decision reconsidered.

If the protocol disposition is "Approved" or "Approved with Explicit Conditions" and the protocol requests inclusion of a vulnerable population(s), special determinations for the vulnerable population(s) are performed at this time.

Following the presentation and discussion of protocols receiving either initial or continuing review, a listing of protocols reviewed and administratively approved for continuation, a listing of protocol modifications, a listing of adverse events reported, a listing of those protocols approved through expedited review procedures and other information relating to ongoing research activities are reported to the IRB. Protocols requesting significant modifications or of special interest to the IRB are discussed in detail, and voted upon by the convened IRB. The principal investigator is notified of the status of approval within 3 days of the IRB meeting. Letters are sent to the PI through campus mail and by email as necessary.

There are times when the risks associated with a particular protocol are such that continuing review should take place more frequently than annually. In these cases, the IRB will specify that the PI report to the IRB either at a shorter time interval or after a specified number of participants (e.g., after each
participant or after 3 participants) are enrolled. The PI's reports must describe the observed effects of the research activities and/or how the participant(s) responded to the research interventions. The determination will be recorded in the IRB minutes and reports forwarded to the IRB, by the IRB office, when they are submitted.

**Appealing an IRB Decision**

If the IRB makes a decision that an investigator believes to be unfair, unsubstantiated, or unduly restrictive on his/her proposed research, the investigator should first discuss the matter with the Chair of the IRB and the Human Protections Administrator. The investigator should be prepared to present reasons that he/she believes that the proposed research is in compliance with University policy and Federal regulations for the protection of human participants.

If the issue cannot be resolved satisfactorily by negotiation, the investigator may appeal the decision, in writing, to the IRB. In developing his/her appeal, the investigator is encouraged to seek the advice or opinion of an objective, qualified consultant (or consultants) to support the claim that the proposed research is in compliance with human participants policy and regulations.

The investigator must appear before the IRB to present his/her appeal and any supportive material or documentation obtained through consultation. Based upon this appeal, the IRB will issue a final recommendation on the proposed research.

**IRB Minutes**

The minutes of the prior meeting are distributed after each IRB meeting. Minutes include a list of all studies that were voted on at the subsequent meeting, as well as a list of all actions that were taken administratively during the previous month. Minutes include separate deliberations, actions, and votes for each protocol undergoing initial or continuing review by the convened IRB. The vote on all IRB actions include the number of persons voting for, against, and abstaining, in order to document the continued existence of a quorum. The minutes include the documentation of risk, as well as any potential conflict of interest that an IRB member may have with a particular protocol.

**Submission Schedule Requirements**

There is one IRB meeting per month. Meeting dates and submission deadlines for full board review are listed on the IRB website at [www.uni.edu/osp/research/irbmembers.htm](http://www.uni.edu/osp/research/irbmembers.htm). Protocols must be submitted to the IRB office before 5 p.m. of the deadline date listed. The submission packets must have all individual forms stapled and collated. The deadline for submission packets is approximately 14 days prior to the meeting date. An attempt is made to send the packets to the IRB members within 3-4 days of that deadline to allow adequate time for review of materials prior to the meeting.

**Changes in Protocols and Adverse Reactions**

The investigator is responsible for ensuring that any changes to the protocol are submitted to the IRB for review before the changes are incorporated into the research. Depending on the extent of the changes sought, this can be done by sending an email/letter/memo, signed by the responsible faculty member and referencing the protocol number and title, which describes the proposed changes. The
changes will be reviewed by the IRB Chairperson, or at the next regularly scheduled meeting of the IRB and the investigator will be notified of the results of the review. Investigators should note that only those procedures specifically approved by the IRB may be initiated. Any changes or additions, such as adding a new measure, review of academic or medical records, or contacting participants again for follow-up research, must have either been included in the original procedure and consent form or receive specific approval as a modification from the IRB.

New information, which would affect the potential risk to participants, must be brought to the IRB’s attention in a timely way. Any unexpected adverse reactions by participants to research interventions should be reported to the IRB immediately. New findings are unexpected problems whose nature, severity, and frequency are not described in the information provided to the IRB or to participants. Examples include unexpected injury or emotional stress, missteps in the consent documentation, or breaches of confidentiality. Adverse events should be reported to the IRB within 10 working days. Sometimes a study must be suspended to ensure participants' safety and well-being.

The report of the event should discuss:

- the facts of the case, including the date and a description of the participant;
- whether the event is related to the study's procedures or drugs or to the subject's underlying disease or condition;
- the steps that have been taken to address the problem;
- whether the event is likely to recur; and whether the event provides new information about the study's risks that should be conveyed to participants, in a revised consent form.

These reports usually receive expedited review, but in some cases the full IRB is involved.

**Continuing Review of Ongoing Research**

The federal rules mandate that ongoing research must be reviewed by the IRB at least once a year (except in the case of exempt research). Most protocols are approved for one year, although the review interval may be less if the IRB determines that it is necessary, for whatever reason, to review the protocol on a shorter review cycle.

Approximately 45 days before the end of the review interval, the investigator will receive a notification that the IRB approval is about to expire. A continuing review form plus a copy of the consent form currently in use should be submitted if the research is still active. This notification is meant to assist the investigator in securing timely renewal of human participants IRB approval. It is the responsibility of the investigator to see that ongoing research is submitted for review however, before the approval lapses. If IRB approval lapses, the investigator must suspend any ongoing research interventions with participants and must not recruit any additional participants. If a study is completed before one year has elapsed, the investigator should complete the protocol closure form and submit it to the Human Participants Review Committee.

**Non-Compliance with Institutional Review Board Decisions**

Non-compliance means significant failure by an investigator to abide by the University and Federal regulations protecting human participants in research. Instances of non-compliance would include beginning research before securing IRB approval, misuse or non-use of approved consent forms,
failure to secure IRB approval before introducing changes in an on-going protocol, and continuing to gather data from participants after IRB approval expires. Non-compliance with IRB guidelines is a violation of UNI’s Federal Wide Assurance (FWA00002159) and Federal regulations for the protection of human subjects. Incidents of non-compliance must be reported both to ensure the protection of the rights of human participants and to uphold the University of Northern Iowa Assurance to the Federal government.

Non-compliance presents a serious challenge to the IRB. Regardless of investigator intent, unapproved research involving human subjects places those subjects at an unacceptable risk. Any incident of non-compliance with IRB guidelines must be reported to the Chair of the IRB immediately.

Federal regulations (45 CFR 46.113) provide the IRB with the authority to suspend or terminate approval of research that is not being conducted in accordance with IRB requirements.

**Procedures For Allegation Of Non-Compliance And/Or Complaints**

The procedures for any reported allegation and/or complaint of investigator non-compliance related to the protection of human participants are as follows:

The Investigator is notified of the concern and advised that the IRB will conduct an inquiry to determine the validity of the concern. A letter or email describing the IRB’s concern will be prepared by the IRB Chair offering the investigator an opportunity to respond via email, in writing, at an informal conference, or at an IRB meeting. The Human Protections Administrator in consultation with the IRB Chair will specify a time period within which the investigator should respond and will advise the investigator in writing.

If the investigator offers a timely and satisfactory explanation for the concern, the process will be terminated and the investigator will be notified in writing. If the investigator offers an explanation that fails to satisfy the complaint, or if the investigator fails to respond within the specified time period, the full IRB will make a recommendation for further action.

**IRB Actions that may be taken:**

1. Require a response from the investigator with a plan for corrective actions
2. Initiate audits of the active protocols
3. Require that participants previously enrolled in the study be contacted and provided with additional information and/or re-consented
4. Terminate the study
5. Freeze sponsored research grant account
6. Determine that the data collected during non-compliance cannot be used for publication
7. Require that a statement be included with all publications or research reports indicating that the research was not approved by the IRB
8. Report to the sponsor, administrative officials, and governmental agencies, i.e., NIH, OHRP
9. Disqualify the PI from conducting research involving human participants at the University

In the case of serious or continuing non-compliance the IRB and the University will address the question of the investigator's fitness to conduct human participant research. The IRB will also take remedial action, as necessary, regarding the welfare of the participants and the research data gathered
in non-compliance. Further, the IRB will refer instances of serious non-compliance to the Department Chair, Institutional Official and Provost who must decide whether to impose disciplinary sanctions. The distinction between remedial action taken by an IRB and disciplinary action taken by an administrator is: Remedial action is action that the IRB takes or may require on behalf of present or future human participants in research; Disciplinary action, in this context, is a penalty imposed by administrators on an investigator for serious non-compliance with the regulations protecting human participants in research.

**Cooperative Research**

The University of Northern Iowa will ensure that any of its collaborating entities [i.e., those engaged in human participants research by virtue of subject accrual, transfer of identifiable information, and/or in exchange of something of value, such as material support (e.g., money or identifiable materials), co-authorship, intellectual property, or credits] engaged in the conduct of non-federally sponsored research involving human participants will possess mechanisms to protect human subjects that are at least equivalent to those procedures provided for in the ethical principles to which this institution is committed.

The University will comply with the requirements set forth in 45 CFR 46.114 regarding cooperative research projects. When research covered by this institution’s Federal Wide Assurance (FWA) is conducted at or in cooperation with another entity, all provisions of the MPA remain in effect for that research.

The University IRB may, at its discretion, enter into a joint review arrangement, rely upon the review of another qualified IRB that adheres to similar standards of human participants protections, or make similar arrangements for the purpose of meeting the IRB review requirements and obviating duplication of effort. Such arrangements must be (a) in writing, (b) approved and signed by the Institutional Official (or designee) and IRB Chair of the University, and (c) approved and signed by correlative officials of each of the cooperating institutions. These arrangements may be entered into on a case-by-case basis, if arrangement is needed for the review of a single research project. Or, for ongoing cooperative research, a more formal arrangement may be entered into-e.g., a memorandum of understanding detailing the joint review mechanism(s).

University of Northern Iowa research studies involving a collaborating institution must include a statement in the consent form indicating the existence of the collaborative relationship. Use of a single, consolidated informed consent form for such studies is strongly encouraged. In addition, copies of all correlative protocols and consent documents required at collaborating institutions must be kept on file at the University of Northern Iowa.

**Education and Training**

In accordance with Federal regulations, the University will ensure that the IRB Chairpersons, the IRB members, human participants investigators, and relevant administrative personnel complete appropriate education related to the protection of human participants before reviewing or conducting human participants research.

The Institutional Official, the Human Protections Administrator, the IRB Chairperson, IRB members must complete the NIH Human Research Protections web-based training (http://cme.nci.nih.gov/).
IRB members are also required to read and familiarize themselves with the Federal regulations, the Belmont Report, and the IRB Guidebook and must complete the CD-based IRB 101 training as part of their orientation program to the IRB review process.

Prior to the submission of a human participants review form for IRB review, the research investigator and all key personnel listed on the protocol must complete the NIH Human Research Protections web-based training program (http://cme.nci.nih.gov/). If the investigator is a student, the student’s faculty advisor must also complete the NIH training program. Documentation of alternative training programs may be considered upon request and review. Certification of completion of training programs conducted by the IRB will also be accepted. A copy of the Completion Certificate should be sent to the Human Protections Administrator (#213 East Bartlett Hall, UNI 0394).