

**NORTHERN ILLINOIS UNIVERSITY**  
**INSTITUTIONAL REVIEW BOARD**

**AMENDED POLICIES AND PROCEDURES PERTAINING TO RESEARCH**  
**INVOLVING THE USE OF HUMAN SUBJECTS**

April 2003

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## I. OVERVIEW

Northern Illinois University has the responsibility for protecting the rights and welfare of human subjects used in research projects conducted at this institution or under the direction of any employee or agent of this institution, whether funded or not, and regardless of the source of funding. In compliance with the Department of Health and Human Services (DHHS) regulations

for the Protection of Human Research Subjects (45 CFR 46, as amended), NIU has established duly constituted Institutional Review Boards to review all research involving the use of human subjects and to set forth institutional policy regarding such research. (See Appendices A and B for DHHS regulations and the Northern Illinois University Assurance of Compliance for regulatory and policy details.) These Boards are directly responsible to the Vice President for Research/Dean of the Graduate School.

All proposed projects that include activities which meet the federal definitions of research involving human subjects conducted by NIU faculty, staff, and/or students or sponsored in part or in whole by NIU must be reviewed and approved by an NIU Institutional Review Board (IRB) and/or its agents prior to the start of data collection. To qualify as human-subjects research, the project must involve living humans from or about whom the investigator obtains data or information (through intervention, interaction, or from privileged records or existing databases) that is intended to contribute to generalizable knowledge (typically via scholarly dissemination). This includes research conducted in conjunction with a student dissertation or thesis. It includes interviews, observation, educational tests, and secondary analysis of data previously collected for research or for non-research purposes as well as experimental trials. It includes subjects of both genders, all ages, and all conditions no matter where they reside.

Proposed activities that do not meet the federal definition of human-subjects research include the following:

a) the collection or study of existing data, documents, or records, for the purpose of conducting statistical analyses (such as a meta-analysis), critical reviews, or integrative research reviews **if** these sources are publicly available **and** 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;

b) data/information obtained only from the records of deceased individuals;

c) data collection intended to benefit **only** the subjects or organization involved **and** the results shared **only** with members of the organization, stakeholders, or funding entity and are not intended for dissemination via scholarly outlets;

d) data collection intended only for an internal evaluation of well-established programs typically for the purpose of quality improvement, and;

e) **anonymous** data collection from adults that poses no risk to participants, and is conducted solely as an evaluation or assessment component of a training seminar or workshop project.

This institution is guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" (the "Belmont Report"). These principles include:

1. Respect for persons (individuals should be treated as autonomous agents, subjects should enter into the research voluntarily and with adequate information, persons with diminished autonomy are entitled to protection);
2. Beneficence (maximize possible benefits of the research to the participants and to society while taking steps to minimize potential harm);
3. Justice (equitable distribution of the burdens and benefits of research).

The IRB encourages and promotes constructive communication among the research administrators, department chairs/directors, research investigators, clinical care staff, and institutional officials, as well as the human subjects, in order to maintain a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.

Correspondence

concerning human subjects research and requests for additional information should be directed to the IRB, in care of the Office of Research Compliance (ORC), Graduate School.

## II. DEFINITIONS

NIU has adopted the definitions included in the federal regulations to guide researchers and other interested parties in determining the necessity for review.

A. *RESEARCH*: "A systematic investigation designed to develop or contribute to generalizable knowledge." (45 CFR 46.102(d)). Research encompasses work that is conducted on or off campus and includes questionnaires, interviews, tests, observations, surveys, and other experiments, regardless of the content or routine nature of the topic and whether the work is preliminary in nature or a study proper. Activities that meet this definition may be funded or unfunded, or may be conducted as a component of another program not usually considered research.

In determining whether an activity needs IRB review, the focus is on the intended purpose of the activity. For example, classroom activities may include instructing students in research methodologies and techniques. If the sole purpose of the activity is to teach students research techniques or methodology and not to develop or contribute to generalizable knowledge, it is considered an educational exercise rather than research. However, if students will practice research methodologies on human beings, they should be educated in the ethical conduct of such activities and should be advised to obtain the informed consent of their practice subjects where such consent would be appropriate.

If the intent is to conduct quality improvement and quality assurance activities solely for maintaining or improving quality of services provided by an institution or organization, this, likewise, is not considered to be research. However, if the data collected are generalizable or are to be shared outside of the institution, other than with the client, through scholarly dissemination (e.g., discussion, presentation, publication, etc.), the activity qualifies as research. Sometimes, data from a program evaluation or quality improvement activity become of interest to the external community after they have been analyzed. In these cases, the research use of the data collected for another purpose must be reviewed. If a project includes multiple components and at least one of those components is designed to generate generalizable knowledge, then the entire project is classified as research unless the components are separable.

In some situations, what began as a non-research activity (e.g., education, program evaluation, surveillance, therapy, etc.) may evolve into a research project. In such a case, the researchers are obligated to submit the research activity for appropriate review as soon as the intent of the data collection or analysis changes. Often the research activity for review consists of secondary analysis of data/information collected originally for another purpose. Pilot studies and preliminary field work otherwise meeting the federal

definitions are considered to be research activities and should be reviewed prior to initiation.

B. *HUMAN SUBJECT*: "A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." (45 CFR 46.102(f)). Women and members of minority groups and their subpopulations must be included in all biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the IRB that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In some types of research *subjects* might be more appropriately described using other terms (e.g., participants, informants, conversational partners, volunteers, etc.) but this definition is still applicable.

C. *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.

D. *INTERACTION*: includes communication or interpersonal contact between investigator and subject.

E. *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) as well as information provided specifically in response to data collection.

F. *GENERALIZABLE KNOWLEDGE*: Generalizable knowledge means new information that has relevance beyond the population or program from which it was collected, or information that is intended for dissemination in any format. Knowledge that can be generalized is collected under systematic procedures that reduce bias, allowing the knowledge to be applied to populations and settings different from the ones from which it was collected.

G. *MINIMAL RISK*: means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

H. *ASSENT*: a minor's **explicit** affirmative agreement, oral or written, to participate in research. Failure to object cannot be construed as assent.

I. *LEGALLY AUTHORIZED REPRESENTATIVE*: "...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." (45 CFR 46.102(c)).

J. *RESEARCH PROTOCOL*: A research protocol is a written description of, and scientific rationale for, a proposed research activity. Of primary concern are the human subject protection issues that are relevant to the study. Protocols must be submitted to the IRB using the current application form available on the ORC website and should include a description of the project using non-technical, lay terminology, the potential risks to the participants and the potential benefits to be gained from the research, participant recruitment and selection, the informed consent process to be used, and a description of how participant anonymity or confidentiality will be protected. If potentially vulnerable subjects are to be enrolled, appropriate additional safeguards should be described. Potentially vulnerable subjects may include the elderly, prisoners, children, cognitively impaired individuals, or people who are economically or educationally disadvantaged.

K. *PROGRAM EVALUATION*: When the purpose is to assess the success of an established program in achieving its objectives in a specific population and the information gained from the evaluation will be used to provide feedback to that program, the evaluation, referred to as program evaluation, is non-research. In the non-research scenario, the evaluation is used as a management tool to monitor and improve the program. The evaluation activity is often a component of the regular, ongoing program. Information learned from the evaluation has immediate benefit for the program and/or the clients receiving the services or interventions. The information is often not generalizable beyond the individual program. Interventions and services that are evaluated are never experimental or new; they are known (either from empirical data or through consensus) to be effective. Evaluation of new or experimental programs is considered to be research and requires IRB review.

L. *ANONYMITY*: Pertains to data or information having no known source or having no name or identity associated with it. For research data to truly be considered anonymous, it must be impossible to trace them back to their source (the individual who provided them). Substitution of a code number, initials, pseudonym, etc. for the subject's name does not automatically anonymize the data if a mechanism exists whereby the data can be linked to the individual subject (e.g., a master list or decoding pattern). Investigators should also be aware of situations in which there is a possibility of deductive identification of otherwise anonymous subjects on the basis of separate elements of data (e.g., birthdate, occupation, and zip code). In these situations subjects and information can only be protected by confidentiality not anonymity.

M. *CONFIDENTIALITY*: Pertains to the treatment of information that an individual has disclosed in a relationship of trust with the expectation that his/her participation and/or information will not be divulged to others without permission in ways that are inconsistent with the understanding of the original consent. The measures taken by an investigator to protect confidentiality should be commensurate with the potential risk to research subjects that could result from a breach of confidentiality.

### III. SUBMISSION AND REVIEW OF APPLICATIONS

The IRB review process begins with the preparation, by the investigator, of the application form titled *Institutional Review of Research Involving Human Subjects*. The preface to the application form, the supplemental Screening Form, is intended to assist the researcher and departmental reviewer in determining whether or not an activity involving human beings requires IRB review. In the case of projects that do *not* qualify as needing any level of IRB review, the completed application will be kept on file according to procedures developed within each department and a copy of only the Screening Form will be forwarded to and kept on file in the Office of Research Compliance (ORC). For projects that clearly meet the regulatory definitions of research with human subjects, the Screening Form need not be completed and the investigator should complete and submit only the main *Institutional Review of Research Involving Human Subjects* application form (along with appropriate supporting material). Applications for all projects qualifying for IRB review must be submitted from departments, centers, units, etc., to the Office of Research Compliance (ORC). The ORC staff will screen the application for completeness and route the application to the appropriate IRB reviewer(s). Investigators submitting incomplete applications to the Office of Research Compliance will be notified immediately of the missing materials or

information and will be given five working days to provide what was omitted. The project advisor (for student projects) and Department Chair/Director/Designee will also be notified of the deficiency. If the requested information is not provided within five days (unless appropriate alternative arrangements are made) the application will be considered void and the investigator will be required to submit a new, complete application for review and approval prior to initiating the research.

Proposed research involving the use of human subjects is designated as qualifying for one of three levels of IRB review: Administrative Review, Subcommittee Review, and Full Board Review. These categories are assigned according to the level of known or potential risk to the subjects, the degree of confidentiality, the use of deception, etc. (In the instance of secondary analysis of data previously collected, the primary research does not need to be re-reviewed by the IRB.) The three levels are described as follows:

A. ADMINISTRATIVE REVIEW: Administrative Review is used to: (a) confirm whether the project meets the federal definitions of *research with human subjects* (see Section II, above) and (b) determine whether the project meets the criteria for any of the federally-specified exempt categories. (See 45 CFR 46.101(b)(1-6)). This review typically is the responsibility of the IRB Chair. Studies in this category are usually processed within 5-7 business days after receipt in the ORC office, assuming the application is complete upon receipt. The determination of the IRB Chair will be conveyed, in writing, to the researcher and the department upon completion of review.

In order to be considered for Administrative Review, the research must be covered in one or more of the following categories:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special educational 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.

NOTE: The Category 2 exemptions for survey and interview procedures do not apply to survey or interviews where the subjects are minors.

3. Research involving the collection or study of existing data, documents, 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.
4. 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 alternative to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
5. 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.

B. SUBCOMMITTEE REVIEW: The eligibility of some research for Subcommittee Review is in no way intended to negate or modify the policies of this institution or the other requirements of 45 CFR 46. The IRB may use the Subcommittee Review procedure to review minor changes in previously approved research during the period for which approval is authorized. The only other research for which the IRB may use a Subcommittee Review procedure is that which involves no more than minimal risk to the subjects and in which the only involvement of human subjects will be in one or more of the following categories designated as expedited in 45 CFR 46.110:

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

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children<sup>1[1]</sup>, 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.

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<sup>1[1]</sup>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 46.401(a).

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.)
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). (This rule applies if the data are not anonymous)
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.
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.

It should be noted that *expedited* does not necessarily mean *fast track*. Proposals evaluated at the subcommittee level, barring complications, are typically reviewed within 7 to 10 business days. Subcommittee Review shall be conducted by the IRB chair or his/her designee and by one or more of the IRB members designated by the chair to conduct the review. The IRB member(s) conducting the review may exercise all of the authorities of the IRB except that the reviewer(s) shall refer any research protocol that the reviewer(s) would have disapproved to the full committee for review. The reviewer(s) may also refer other research protocols to the full committee whenever the reviewer(s) believes that full committee review is warranted.

When the Subcommittee Review procedure is used, the IRB chair or member(s) conducting the review shall inform IRB members of research protocols which have been approved under this procedure. At a convened IRB meeting, any member may request that an activity that has been approved under the Subcommittee Review procedure be reviewed by the IRB in accordance with Full Board Review procedures. A vote of the members shall be taken concerning the request and the majority shall decide the issue. The determination of the IRB will be conveyed to the researcher and the department following the meeting.

C. **FULL BOARD REVIEW:** When the IRB chair has received a research proposal involving more than minimal risk to the subjects or that does not fall within the Administrative (exempt) or Subcommittee (expedited) review categories, the proposal is referred for review by the IRB at a convened meeting.

The IRB shall have the responsibility to review and the authority to approve, require modification of, or disapprove all activities or proposed changes in research based on the IRB's determinations that the following requirements are satisfied:

1. Risks to subjects are minimized:

- (a) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
- (b) 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 knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB shall 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 shall not consider long-range effects of applying knowledge gained in the research 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 shall take into account the purposes of the research, the setting in which the research will be conducted, and the population from which subjects will be recruited.
  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 45 CFR 46.116 and *The Belmont Report*.
  5. Informed consent will be appropriately documented in accordance with, and to the extent required by 45 CFR 46.116 and 46.117.
  6. Where appropriate, the research plan makes adequate provision for monitoring the data collection to insure the safety of subjects.
  7. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
  8. Additional safeguards have been included in the study to protect the rights and welfare of subjects likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

Research protocols scheduled for review shall be distributed by ORC staff to all members of the IRB approximately one week prior to the meeting. When it is determined that consultants or experts will be required to advise the IRB in its review of a protocol, the research protocol shall also be distributed to the consultants or experts prior to the meeting.

A majority of the voting membership of the IRB constitutes a quorum and is required in order to convene a meeting for the review of research protocols. An IRB member whose concerns are primarily in non-scientific areas must be present at the convened meeting before the IRB can conduct its review of research. For a research protocol to be approved it must receive the approval of a majority of those voting members present at the convened meeting. No IRB member may participate in the IRB's initial or continuing review of or vote on any project in which the member has an interest, except to provide information requested by the IRB. The determination of the IRB will be conveyed, in writing, to the researcher and the department following the meeting.

Research protocols are typically approved for a period not to exceed 365 days from the original date of review. In some cases, such as projects that are especially complex or present high-risk to subjects or projects that are proposed by researchers with a history of repeated noncompliance, the IRB may elect to approve the project for a period of less than 365 days.

In cases where research activities were initially approved under Subcommittee Review procedures and subsequently reviewed by Full Review procedures, the decisions reached at the convened meeting shall supersede any decisions made through the Subcommittee Review.

#### IV. REVIEW PROCEDURES AND RESPONSIBILITIES

##### **University Responsibilities**

NIU's human subjects protection program encompasses all aspects of the university community involved with human subjects research at any level and includes investigators, the IRB, as well as the university administration. Because the primary concern of NIU's human subjects protection program is protecting the rights and welfare of the individuals participating in research, it is reasonable to expect that the university community would respect investigators' obligations to appropriately protect the data/information obtained from research participants and support their efforts to do so.

The university will provide adequate administrative support and oversight for the activities of the IRB, including the preparation and maintenance of adequate documentation of IRB activities. The university will also provide adequate meeting space for the IRB.

Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the university. However, university officials may not approve the research if it has been disapproved by the IRB.

### **Responsibilities of the IRB:**

All research activities involving human subjects which are sponsored by NIU, or are conducted by or under the direction of any employee or agent of the university in connection with his/her university responsibilities are subject to IRB review.

The IRB establishes and implements policies and procedures for the review of research involving human subjects. These policies and procedures detail the mechanisms to be used for the initial review of newly proposed research protocols, the review of proposed amendments to previously-approved protocols, review of requests for continuation of approval, and the investigation of unexpected or adverse events (defined as harm to a subject not previously identified as a risk) and/or possible noncompliance by any person covered by this policy, including the suspension or termination of approved protocols and reporting to necessary federal offices/agencies.

The IRB considers the following factors when approval is sought for a research project:

1. Risks to the subjects are minimized,
2. Risks to the subjects are reasonable in relation to the anticipated benefits,
3. Selection of the subjects is equitable,
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative,

5. Informed consent will be documented,
6. When appropriate, the research plan makes adequate provision for monitoring the data collection to ensure the safety of the subjects,
7. When appropriate, adequate provisions are in place to protect the privacy of subjects and to maintain the confidentiality of data, and
8. Additional safeguards have been included in the study to protect the rights and welfare of subjects likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

### **Responsibilities of the IRB Members:**

New IRB members are expected to participate in an orientation session with ORC staff before being eligible to sit as a voting member at a convened meeting and to complete one additional appropriate educational activity (e.g., attending a conference or workshop, completing a CD-ROM or online tutorial, viewing a videotape, or reading a book relevant to IRB review of research) during their first six months of membership. Members are expected to complete at least one educational activity relevant to IRB review of research per year thereafter for the duration of their term on the IRB.

IRB members are expected to attend all meetings unless they have a compelling reason to be absent and have notified the ORC staff of their pending absence. IRB members are expected to read all application materials provided before the scheduled meetings and to come to meetings prepared to discuss the applications.

Each IRB member, other than the Chair and Vice Chair, is expected to serve in the Subcommittee Review process on a monthly, rotating basis. The designated monthly reviewer is responsible for reviewing protocols that qualify for expedited review and those that are accompanied by proposals for external funding regardless of review category. Members serving in this review capacity should strive for 48-hour turnaround time on application review and, in the event that this is not feasible, are expected to notify ORC staff so that alternative arrangements can be made to ensure that review takes place in a timely fashion.

IRB members agree to make themselves available, upon request, to consult with other members, ORC staff, and researchers on issues relevant to the review of specific protocols.

### **Responsibilities of Department Chairs/Directors or Designated Reviewers:**

The primary responsibility of the Department Chair/Director/Designated Reviewer with regard to applications for IRB approval is to conduct the initial review of research protocols:

- for ethical considerations;
- to determine that the research has scientific merit
- to determine that the investigators are qualified to conduct the research;
- to ensure that the protocol conforms to any specific requirements that the University or State of Illinois may impose as well as federal copyright laws;
- to assure that the application is complete;
- to make the initial determination of review category (meets definitions of *research with human subjects* and requires Administrative, Subcommittee, or Full Review).

Because the Department Chair/Director/Designated Reviewer is generally knowledgeable about the discipline(s) within his/her department, it is appropriate that this person be the one responsible for conducting a thorough preliminary review of research protocols before submission to the IRB. This is the primary location for determination of *scientific* merit of the proposed research and that the design and procedures are appropriate in order for the IRB to adequately evaluate the potential risks and/or benefits to the participants. In addition, Federal regulations prohibit the investigator from making the determination of review category for his/her own project. When the Department Chair/Director/Designee is directly involved with a project in need of review, the review should be conducted by another individual who has no relationship to the project, who has had appropriate reviewer training, and who has the authority to conduct the review (e.g., College Dean).

Because of their key role in the review process, Authorized Departmental Reviewers (i.e., Department Chairs, Directors, or Designated Reviewers), are expected to participate in an orientation session with ORC staff in order to be eligible to review IRB applications submitted from their department. They are also required to document the completion of one additional appropriate educational activity (e.g., attending a conference or workshop, completing a CD-ROM or online tutorial, viewing a videotape, or reading a publication) relevant to IRB review of research per year thereafter for the duration of their term as Authorized Departmental Reviewer.

Departmental Reviewers are expected to maintain a log of applications that have been reviewed at the departmental level. This log should contain dated entries of when applications are received from investigators and forwarded to the ORC, departmental determination of review category, and any other information the departmental reviewer may find to be helpful in the review process. The ORC staff may periodically request to review these documents to assure consistency with NIU and federal policies.

Research investigators and Department Chairs/Directors/Designated Reviewers are responsible for insuring that all applications involving humans as potential subjects (regardless of review category) are submitted to the IRB via the Office of Research Compliance (ORC). No data collection may begin in any project without formal notice of approval or designation that the research does not fit the regulatory definitions of *research with human subjects*. Screening Forms and applications that have been determined by departmental review to not meet these regulatory definitions shall be kept on file within the department and the Departmental Reviewer shall notify the ORC of this determination by forwarding a copy of the Screening Form to the ORC.

Research investigators and Chairs/Directors/Designated Reviewers are responsible for reporting promptly to the IRB, via the ORC, any serious or continuing noncompliance with federal and/or university regulations. In turn, the University is required to report such noncompliance to the federal Office of Human Research Protections (OHRP).

The Department Chair/Director is responsible for nominating individuals for IRB membership. The procedure for selecting nominees is up to the discretion of the department(s) involved. Departments should use a rank ordering when submitting more than one nomination. Nominations are requested by and should be submitted to the Vice President for Research. Members are selected based upon expertise in a general research area (e.g., education, psychology, kinesiology, physiology, or social science research).

## **Responsibilities of the Investigator:**

The primary responsibility of the investigator is to protect the research participants by following the ethical principles of *The Belmont Report* as well as any set forth by professional organizations relevant to his/her academic discipline. It is the responsibility of the researcher to know and comply with the review procedures of the IRB. Should the researcher be a student matriculating at NIU, the student's academic or dissertation/thesis advisor assumes primary responsibility for the proposed activity. The advisor is to familiarize the student with his/her obligation vis-à-vis the ethical protection of the subject(s) from risks incurred as a result of participating in the research.

Because it is the investigator who directly interacts with the research participants and/or their information, it is reasonable to expect investigators to possess a level of knowledge and understanding that will result in behavior that protects the rights and welfare of research participants. The *Belmont* principle of Beneficence requires that competent researchers design ethical research, protect human research participants from risk, and perform continuing risk/benefit assessments. In addition, the *Belmont* principle of Respect for Persons requires that investigators implement the informed consent process and safeguard subject privacy. Guidance from OHRP indicates that research investigators at Assured institutions “must complete appropriate institutional training before conducting human subject research.” Additionally, National Institutes of Health (NIH) policy stipulates that investigators receiving NIH funding must receive required education in the protection of human subjects. Investigators seeking NIH support are required to provide, for all individuals listed as *key personnel* in the proposed research, a description of education completed in the protection of human subjects. Primary investigators of non-NIH projects are expected to provide the same information for all personnel listed on the NIU application form. Appropriate training might include, for example, completing an online or CD-ROM tutorial, attending a conference or workshop, discussing relevant ethical principles in a research methods course or with a mentor, viewing a videotape, or reading a publication relevant to IRB review of research. The principle investigator is responsible for assuring that all research staff associated with the project have completed appropriate human-subjects training.

Research investigators in consultation with their department chair/director or designee shall make a determination as to whether research will involve human subjects as defined

above by using the Screening Form that is the preface to the application form. When it is still not clear whether the research involves human subjects, researchers should seek assistance from the IRB chair or the ORC staff in the Graduate School in making this determination.

For all human subjects research, approval must be obtained prior to the start of data collection. Approval is obtained via submission of the "Institutional Review of Research Involving the Use of Human Subjects" application form. The application is to be completed by the researcher(s) and all required signatures obtained (i.e., applicant and authorized departmental reviewer for all projects; project advisor for student projects) prior to submission to the ORC. (Graduate students should seek assistance from their academic advisors when preparing applications.) The application should be submitted after the research procedures have been determined but before any data have been collected, and in a timely manner that will permit dialog between the ORC/IRB and the investigator without undue time pressure for either party. For externally-funded projects, the IRB is required to review a copy of the contract or grant proposal along with the IRB application; it is the responsibility of the investigator to supply a copy of any such documents when submitting an IRB application.

For the section of the form calling for a description of the study, researchers should be sure to clearly state the purpose of the study, including a description of the hypothesis or research question, and provide sufficient detail, in nontechnical terms, so that the IRB may evaluate the risks, if any, to the subject. Careful attention to detail and the use of non-jargon terminology is expected from researchers when completing the application form. Assurance from the investigator that there is no risk to the subjects, no matter how strong, will not substitute for a description of the transaction(s). A few studies may have "no foreseeable risks," however, researchers must consider not only physical risks, but also economic, ethical, legal, political, psychological/emotional, social, and breach of confidentiality risks.

The form also calls for details regarding informed consent procedures (see the section entitled "Informed Consent Procedures" below), and assent for minors (see section entitled "Additional Protections for Children and Other Special Populations"). Investigators are responsible for documenting the informed consent procedures (also assent and permission procedures, if applicable) and for retaining the consent documents signed by human research subjects in a repository approved by the IRB for three years after conclusion of the study.

If surveys, questionnaires, interview questions, etc., have been submitted in draft form, the investigator is responsible for submitting finalized versions of these materials to the ORC prior to the start of data collection.

Universal blood and body fluid precautions (also known as "universal precautions") recommended by the Centers for Disease Control and Prevention (CDC) must be used in all research protocols in which blood or other body fluid specimens are collected. Compliance with CDC guidelines should be addressed in the description of the study that is submitted to the IRB. Such activities may also require review and approval by the Institutional Biosafety Committee (IBC).

For projects conducted at or in cooperation with another entity by NIU administrators, faculty, staff, or students, the NIU IRB may accept the review of another institution's IRB, provided that said IRB has on file an approved assurance of compliance with the DHHS. Such acceptance must be in writing, approved and signed by NIU's IRB chair, and approved and signed by correlative officials of each of the other cooperating institutions. For grant proposals, a copy of the agreement must be forwarded to the DHHS Office for Human Research Protections (OHRP).

During and after data collection, the researcher is responsible for maintaining the confidentiality of research data/information:

- at a level commensurate with the sensitivity of the data and the potential risk to subjects posed by a breach of that confidentiality; and
- in a manner approved by the IRB.

Because researchers often need to balance this responsibility with the university's administrative needs (e.g., equipment inventory, chemical storage, etc.), it is recommended that researchers label locations (e.g., file cabinets or drawers) where protected human-subjects data are stored as *Confidential*. Implicit in its labeling as confidential, the owner attests that no state equipment, chemicals (or anything else one might think of which a department might need to report on) are present in the storage unit and that any locked file drawer labeled *Confidential* would not be examined or asked to be examined. In this way, the researchers' obligations to maintain appropriate confidentiality of protected research data need not conflict with maintaining necessary access to state facilities by state employees in the conduct of their official duties.

Research investigators are responsible for reporting the progress of research projects originally reviewed and approved by Subcommittee or Full Board Review to the IRB no less than once per year. This is typically done during the application process for continuation of project approval (a.k.a., Continuing Review). If the project has been approved by Administrative Review, it needs no further review unless the investigator intends to modify the protocol.

Research investigators are also responsible for reporting promptly, directly or through their department chairs/directors or designees, to the IRB any injuries or any unanticipated problems that involve human research subjects or others involved in the research project. The “Adverse Event Reporting Form” (available for download from the ORC website) may be used for this purpose or the investigator may simply write a letter to the IRB detailing the event.

If amendment of the approved protocol should become necessary, the investigator is responsible for seeking IRB approval for any modifications prior to their implementation except where the immediate safety of a subject is of concern. When participant safety precipitates the need for an immediate change, the IRB must be informed as promptly as possible. The ORC should be immediately notified of proposed changes in a research activity. Changes in research during the period for which IRB approval has already been given require IRB review and approval before they can be implemented, except when the change is necessary to eliminate apparent immediate hazards to the subject.

Researchers are responsible for maintaining continuous approval of research until data analysis is complete and all identifiers have been removed from stored data (unless the IRB has approved appropriate measures for the archiving of identifiable data). To obtain continuation of approval, beyond the original approval period of a project that has no changes to the protocol, the researcher should submit a "Continuation of Approval" form to the IRB via the ORC. In order to amend the original protocol at the time of continuation, the investigator must append an explanation of and justification for the requested changes to the “Continuation of Approval” form. Approval must be obtained in writing from the IRB before the researcher may continue data collection past the date originally approved or before implementing any project amendments. Continuing review is required until the project is completed or until the investigator no longer retains any identifiers that could link the data to the subjects. Identifiable data may be archived for future use provided the research participants consented to their data being used in future research or the subjects provide appropriate consent for the archival, and the investigator continues to protect the confidentiality of the data to the satisfaction of the IRB.

Archived data may be *reactivated* by obtaining IRB approval via the submission of a new “Institutional Review of Research Involving Human Subjects” application form.

Researchers should submit the “Application for Continuation of Approval of Research Involving the Use of Human Subjects” form (a.k.a. “Continuation of Approval”) in a timely manner to avoid interruption of their data collection. Data collection must stop at the conclusion of the approval period unless continuation of approval is granted by the IRB. As part of the continuing review process, the investigator is expected to provide a progress report to the IRB. This information can be provided on or appended to the “Continuation of Approval” form. The progress report should include the following information:

1. number of subjects accrued;
2. adverse events and unforeseen problems\*;
3. withdrawals and dropouts\*;
4. subject complaints\*;
5. summary of recent literature relevant to the research published since the last progress report that might impact subject risk;
6. request for amendments, if any, prior to their implementation;
7. changes in sponsor or study personnel including verification of training of new personnel;
8. any other information the investigator believes to be relevant.

\* The number of subjects affected as well as an explanation should be provided if this event has occurred.

The IRB may also request verification from sources in addition to the investigator that no material changes have occurred since previous IRB review if the project is especially complex or presents high-risk to subjects or if the project is conducted by a researcher with a history of repeated noncompliance.

**Investigational New Drugs:** The research investigators shall be responsible for notifying the Food and Drug Administration (FDA) and the IRB whenever it is anticipated that an investigational new drug or device exemption will be required. The IRB chair shall identify the test article (i.e., drug biologic or device) in the certification to the DHHS when the proposal involves a test article and state whether the 30-day interval required

for test articles has elapsed or was waived by the FDA. If the 30-day interval has expired, the IRB chair shall state in the certification to HHS whether the FDA has requested that the sponsor continue to withhold or restrict the use of the test article for application in human subjects. If the 30-day interval has

not expired and a waiver has not been issued, the IRB chair shall send a statement to the DHHS upon expiration of the interval.

## V. INFORMED CONSENT PROCEDURES

It is the researcher's obligation to obtain legally effective informed consent of the subject or the subject's legally authorized representative prior to the start of data collection. In addition, the researcher must also solicit the assent of any minor subject capable of assenting. To be legally effective, informed consent should:

1. be in language understandable to the subject or the representative;
2. be obtained under circumstances that offer the subject or the representative sufficient opportunity to consider whether the subject should or should not participate; and
3. not include 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 research investigator, the sponsor, the institution or its agents from liability for negligence.

Standard informed consent includes:

1. a statement that the project 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/or 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 (e.g, investigator; also advisor if student project) and research subjects' rights (e.g., ORC at 815-753-8588), and whom to contact in the event of a research-related injury to the subject (e.g., investigator/advisor, physician, counseling referral, etc);
8. a statement that participation is voluntary, and refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled; and
9. a statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. Note: Students involved in the research as subjects should be assured that their participation (or non-participation) will not impact their grade in any course. Where participation in a research project is one option for earning class points, students must be told under what conditions they will have been deemed to have earned those points (e.g, upon completion of all subject activities).
10. parental informed consent for minors must include a place to refuse participation, or a notation that failure to return the form constitutes lack of consent.

For projects that have been approved by Administrative Review, having qualified as exempt under 45 CFR 46.101(b), informed consent may be obtained either orally or in writing and may include only those elements from the listing above deemed appropriate by the investigator.

Informed consent documents given to subjects participating in research approved by either the Subcommittee or Full-Board Review processes are required to bear the approval stamp of the NIU IRB. The stamped document is the only consent form that may be photocopied for distribution to study participants. The original date-stamped consent form is returned to the investigator along with the project approval letter. A copy of the stamped form is kept on file in the ORC.

Continuing review of projects initially approved by either the Subcommittee or Full-Board Review processes is required at least annually until all identifiers that could link the subjects to the collected data have been removed or until the data are archived in a manner approved by the NIU IRB. For each protocol, continuing review will be conducted by the same procedure as the original review unless the PI wishes to amend the protocol in such a way that review by a different procedure is warranted or unless a project that was originally reviewed by Full-Board procedures qualifies for Subcommittee Review under expedited review category 8 (see Section IIIB of this Policy document.). If the project will continue beyond the date stamped on the form, a fresh, unstamped copy of the consent form should be provided when continuation of IRB approval is sought (this should accompany the "Application for Continuation of Approval of Research Involving the Use of Human Subjects" form). Upon completion of the continuing review process the consent form bearing the updated stamp will be sent to the investigator with the project approval letter. Again, the research participants are to be given photocopies of this date-stamped consent form.

If modifications to the form are needed the investigator should contact the Office of Research Compliance for assistance. Any revision or amendment to a study protocol or to an informed consent document must be approved by the IRB before the requested changes can be implemented unless subject safety is an immediate concern. The investigator should provide three versions of the informed consent document:

- the version that had original IRB approval,
- the version incorporating the proposed revisions with the revisions highlighted,
- the version incorporating the proposed revisions without highlighting.

The revised version without highlighting will then be date stamped and returned to the investigator along with the letter from the IRB chair approving the requested revisions.

Video/Audiotaping Procedures: Projects involving the use of videotaping or audiotaping must make specific mention of these in the consent documents including information about storage of tapes and how and when the tapes will be destroyed. The subject must have the choice of whether to participate in the video or audiotaping procedures. This consent is separate and distinct from consent to participate in the project, therefore, separate signature and date lines are required. If the IRB has approved an oral consent procedure (see "Waiver of Written Consent", below) the investigator may tape the consent process.

Additional Consent Requirements: When called for by the IRB, the research investigator must provide additional elements of information to the subject, including the possibility of currently unforeseeable risks; 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; a statement that significant new findings developed during the course of the research which may relate the subject's willingness to continue participation will be provided to the subject; and the approximate number of subjects involved in the study.

Documentation of Informed Consent: Researchers shall be responsible for ensuring that informed consent is 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, unless this requirement is specifically waived by the IRB. Each person signing the written consent form is given a

copy of that form. A written consent form should include those standard elements listed above, and contain signature and date lines. This form may be read to the subject or the subject's legally authorized representative, but in any event, the research investigator shall give either the subject or the representative adequate opportunity to read the form before signing it.

A "short form" in which the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative may also be used. When the "short form" is used, researchers should ensure that a copy of the short form is given to the subject or the representative, and that a written summary of what is to be said to the subject or the

representative receives the prior approval of the IRB. Furthermore, a witness should be present at the oral consent discussion, and the subject (or representative), the witness, and the researcher (or person obtaining consent) should sign the short form.

Waiver of Written Informed Consent: The IRB may waive the requirement for signed consent forms (but not consent *per se*) if it is found that:

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; 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.

Waiver or Alteration of the Required Elements of Informed Consent: In cases where the research or subject well-being would be jeopardized by full consent procedures, all or some consent elements may be waived by the IRB if it is found that **all four** of the following conditions are met:

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

When preparing the justification for either type of waiver described above, it must be understood that the risk to subjects is not in, for example, answering the telephone, carrying on a conversation, or completing a written questionnaire, but in the content of the questions and possible answers. The waiver of all elements of consent is intended to be a very rare occurrence. Waiving the requirement for a signed, written form, or for some of the elements of informed consent does not waive the requirement that subjects be informed of the nature of the research nor that their consent (or the permission of their legally authorized representative whenever appropriate) be obtained.

Requests for a full or partial waiver of informed consent procedures must be accompanied by sufficient justification. In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. Requests should be submitted using the "Request for Variation of Consent Attachment" along with the "Institutional Review of Research Involving the Use of Human Subjects" form.

## VI. ADDITIONAL PROTECTIONS FOR CHILDREN AND OTHER SPECIAL POPULATIONS

The IRB, in compliance with federal regulations, gives special consideration to proposed research involving: prisoners, children, persons with physical or mental handicaps, fetuses, pregnant women, in-vitro fertilization of human ova, and other potentially vulnerable groups. The additional regulations pertaining to these protected groups are located in Subpart B of the regulations (45 CFR 46, as amended).

Of particular concern at NIU is research conducted involving children as subjects. Parental permission (as well as IRB approval) must be obtained prior to beginning any research project which alters a child's routine or behavior. This includes research conducted in classroom settings, such as educational tests, surveys, etc. Parental permission may be waived only when the child is legally designated an emancipated minor or when it is determined by the IRB that parental permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children). For research conducted in settings in which general blanket participation forms have been signed by legally authorized representatives, (i.e., schools, classrooms, etc.), specific permission of the representative and assent of the child must still be obtained for each project conducted with these subjects unless there will be no manipulation of the subject's behavior or disruption of the normal routine of the individuals in these settings. Furthermore, verbal assent must be obtained from the minor unless the IRB determines that the capability of some or all of the minors is so limited that they cannot reasonably give assent. Information on the requirements for developing and implementing an age-appropriate assent process for minors are available from the Office of Research Compliance (ORC).

## VII. COMPLIANCE WITH IRB DECISIONS

The IRB, via the ORC, shall keep research investigators aware of decisions and administrative processing affecting their respective protocols and shall return all disapproved protocols to the research investigators and to the department chair. Research investigators shall be responsible for complying with all IRB decisions, conditions and requirements.

If the IRB becomes aware of research about to be conducted with human subjects, and if the research has not been brought to the attention of the IRB by the investigator(s), the investigator(s) will be asked to seek IRB approval before the start of data collection. If the investigator(s) does not respond within five business days of notification of noncompliance, the investigator(s) will be immediately informed that the research cannot proceed, or must be suspended, and will be asked to contact the signatory IRB chair or Office of Research Compliance immediately. The department chair/director or designee will also be notified of the noncompliance and asked to take appropriate action. The department chair/director or designee will be asked to report the action taken and the results to the IRB within one week. If no response is received with that week, the IRB chair will contact the department chair/director or designee by telephone. If no resolution of the problem has occurred, the IRB chair will, if s/he deems it necessary, inform the Vice President for Research of the situation and convey the recommendation(s) of the IRB for further action, if any.

No mechanism exists, under 45 CFR 46, for retroactive IRB approval (or disapproval) of a project. Therefore, if the IRB becomes aware of research that has already been conducted without prospective IRB review and approval, the full IRB will investigate the project and report its findings and recommendations to the Vice President for Research who would then consider the IRB's recommendations in determining what action will be taken. In considering the project the IRB:

- **will** determine what level of risk and category of review (Administrative, Subcommittee, or Full) would have been assigned to the project had the application been submitted and processed in the proper sequence (i.e., prior to data collection).
- **will** determine whether the subjects were harmed in any way or if their rights and/or welfare were infringed.
- **may** make a recommendation to the Vice President for Research as to whether or not the investigators should be allowed to make use of the data.
- **may** make a recommendation to the Vice President for Research that notification be provided to the funding agency and/or the appropriate publication outlet (journal or organization to which a manuscript or abstract has been submitted, thesis/dissertation office, etc.) that the data were collected without IRB approval. If the data were collected for a thesis or dissertation, the methods section must contain a statement that the data were collected without IRB approval.

Appeals of IRB decisions should be made in writing to the IRB, via the ORC. The IRB will review the appeal at the next regularly convened meeting. Should a researcher wish,

the appeal may be made in person. For a schedule of meetings, the Office of Research Compliance should be contacted.

In the event of serious or continuing noncompliance with NIU Policy, the terms of NIU's Assurance of Compliance with DHHS, or the requirements or determinations of the IRB (e.g., deliberately conducting research without IRB approval, failure to report adverse events or unanticipated problems involving risks to subjects or others to the IRB, etc.) the IRB will first gather information regarding the allegation(s) of noncompliance and attempt to resolve the situation with the cooperation of the investigator(s) involved. If reasonable attempts to rectify the situation fail, the IRB will make an informed recommendation, referring the case to the Vice President for Research for final resolution. When appropriate and upon the recommendation of the IRB, the IRB Chair and/or the Vice President for Research will report the situation to OHRP.

#### VIII. PROCEDURES FOR REVIEW OF EXTERNALLY FUNDED PROJECTS

Researchers should be aware that some agencies require institutional approval of Human Subjects research at the submission stage of a grant proposal and should allow enough time for the Institutional Review Board (IRB) to review and approve their protocol before the grant submission deadline. More often, federal and private agencies require IRB approval before awarding a grant. A copy of the full grant should be attached to the IRB protocol.

NIU may be required to certify to the funding agency, for research involving human subjects, that the institution is operating under an approved Assurance and provide certification that an appropriate Institutional Review Board has, within 12 months of the budget period start date, reviewed and approved the proposed activity in accordance with the regulatory requirements consistent with 45 CFR Part 46. The Chair of the IRB will provide a letter of certification for submission to the funding agency at the request of the Office of Sponsored Projects (OSP).

During the course of a research project, subsequent supplement certification to the agency may be required when:

1. involvement of human subjects in a project is proposed and the activity previously had only indefinite plans or no plans for the involvement of human subjects, or
2. it is proposed to change the involvement of human subjects and that involvement is significantly different from that which was initially approved by the IRB.

Under no circumstances will approval of a grant account be initiated by OSP or an account opened by Grants Fiscal Administration for an externally funded project involving Human Subjects research before the investigator has obtained IRB approval. To avoid delays in the processing of awards at the agency and on an institutional level, researchers should ensure the timely review of their Human Subjects research protocols by the IRB at first hint of funding approval. If final details regarding all elements of the protocol are not available because they may be developed as part of the research project, a provisional protocol should be filed and approved by the IRB, allowing for the opening of a grant account. When final details are available, the provisional protocol should be modified and re-approved by the IRB prior to data collection.

## IX. IRB MEMBERSHIP

According to the DHHS regulations, the IRB is made up of at least five individuals, one of whom must not be affiliated with the University in any way. The members must be of varied background, including consideration of the gender and racial and cultural backgrounds of members 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. The IRB members must also possess sufficient expertise to address issues pertinent to research involving the use of human subjects. The 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.

The IRB membership is appointed by the Vice President for Research and is subject to approval by the University President. Members are appointed to three-year, renewable terms, with no term limits. Should a member resign, another individual with comparable expertise shall be selected as a replacement (see selection procedures below) to serve the remainder of the term.

The NIU IRBs will each consist of the following members:

Representative of the Vice President for Research of the Graduate School, chair

Representative from the University Health Service, physician

Representative from the Office of Sponsored Projects (nonvoting member)

Faculty member, Psychological Expertise

Faculty member, Educational Expertise

Faculty member, Physiological Expertise

Faculty member, Kinesiology Expertise

Faculty member, Social Science Expertise

Faculty member at-large

Community member (not affiliated with NIU)

Selection of Faculty Members with Specific Expertise: At least two months prior to the resignation or completion of term of one of the five faculty members with specific expertise, the IRB, via the ORC, will notify the Vice President for Research to solicit nominations from departments listed under the appropriate category.

The procedure for selecting nominees is up to the discretion of the department(s) involved, though departments are advised to ascertain whether individuals are interested in serving prior to submitting nominations to the Vice President for Research. No less than two nominations from within each category may be submitted to the Vice President for Research; no maximum number of nominations has been set (though departments submitting more than two nominations are asked to rank them). Should the Vice President for Research receive fewer than two nominations from within each category, a second call for nominations must be issued. The Vice President for Research then appoints faculty members from among the nominees. The new members serve terms of three years. (Note: Persons nominated, but not appointed as a "Faculty Member with Specific Expertise" are to be considered as nominees for the selection of the next "Faculty Member-at-Large.")

Selection of Faculty Member-At-Large: Selection of the faculty member at-large is without restriction to departmental affiliation. To solicit general nominations for the at-large member, the Vice President for Research must announce the availability of the position to the campus. Again, the procedure for selecting nominees is up to the discretion of the department(s) involved. Departments should use a rank ordering when submitting more than one nomination. The Vice President for Research then appoints the faculty member-at-large from among the nominees, including those individuals nominated, but not appointed, as "faculty member with specific expertise." The faculty member-at-large serves for a period of three years.

Based on departmental representation vis-à-vis human subjects applications in recent years, the categories listed below have been suggested. The categories are by no means fixed, and may be modified as appropriate. Further, it is recognized that the IRB will be comprised of members having expertise in qualitative and quantitative research methodologies.

<u>Educational</u>	<u>Psychological</u>	<u>Kinesiology</u>	<u>Physiological</u>	<u>Social</u>
<u>Science</u>				
CAHE	Psychology	Kinesiology &	Biological Sciences	Anthropology
EPF		Physical Education	Nursing	Communications
ETRA			Allied Health	History

TLRN

Sociology

Professions

Communicative

Political

Disorders

Science

In the event of short-term absence, members of each IRB will serve as alternates for their expertise counterpart on the other IRB. An additional alternate may need to be appointed as an “interim” member in the event of the long-term absence of a member (e.g., due to extended illness, sabbatical leave, etc.). Appointment of alternate “interim” members will follow the same procedures used for appointment of regular members.

Should any member fail to meet the expectations of IRB membership, the IRB chair will attempt to rectify the situation by discussing the matter with the member. If the situation does not improve in an acceptable time frame, then the member will be given the option of resigning voluntarily. If all attempts to remedy the situation are unsuccessful the IRB chair, in consultation with the ORC, may recommend to the Vice President for Research that the individual’s membership status be reviewed. The Vice Provost for Research, with the concurrence of the University President, will make the final decision regarding the individual’s membership status on the IRB.

## X. ADDITIONAL RESPONSIBILITIES OF THE IRB

The IRB reports directly to the Vice President for Research at Northern Illinois University and, through that person, to the President. Convened meetings of each IRB shall occur: (1) Once a month; or (2) at the call of the Chair when the Chair judges the meeting to be necessary or advantageous; or (3) at the call of the Chair upon the receipt of a joint written request of three or more members.

The IRB, with the assistance of the ORC, 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 consent documents, progress reports submitted by research investigators (as part of continuing review or otherwise) and reports of adverse events involving subjects.
2. Minutes of IRB meetings which shall be in sufficient detail to show the names of attendees 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; a written summary of the discussion of controverted issues and their resolution; and dissenting reports and opinions. If a member in attendance has a conflicting interest regarding any project, minutes shall show that this member did not participate in the review, except to provide information requested by the IRB.
3. Records of continuing review activities.
4. Copies of all correspondence between the IRB and the researchers.
5. A list of IRB members as required by 45 CFR 46.103(b)(3).
6. Written procedures for the IRB as required by 45 CFR 46.103(b)(4).
7. Statements of significant new findings provided to subjects, as required by 45 CFR 46.116(b)(5).
8. Official correspondence with OHRP.

The IRB shall provide for the maintenance of records relating to a specific research activity for at least 3 years after termination of the last IRB approval period for the activity. IRB records shall be accessible for inspection and copying by authorized representatives of HHS at reasonable times and in a reasonable manner, or shall be copied and forwarded to HHS when requested by authorized HHS representatives. Researchers are encouraged to retain personal copies of their applications, correspondence, etc. as well.

The IRB chair shall be responsible for promptly reporting information to the IRB, and, as appropriate, to the Vice President for Research for notification to the OHRP and/or appropriate department or agency heads (i) any instances of adverse events involving subjects and unanticipated problems involving risks to subjects or others involved in the research, and (ii) information concerning the IRB's reasons for the termination or suspension of IRB approval. Changes in IRB membership shall be reported to the OHRP at least annually.

Amendment of policy and procedures, as needed by the Vice President for Research, may be recommended at any time by the IRB. Proposed amendments shall be submitted to the full board for review, and must be approved by a majority of a convened meeting or by written vote following sufficient opportunity for questions and discussion. Approved amendments shall then be forwarded to the Vice President for Research for review and final approval.

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