
IRB Handbook

**POLICIES AND PROCEDURES FOR RESEARCH INVOLVING
HUMAN SUBJECTS**

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[See OSP website for IRB Application Forms]

ABBREVIATIONS

CFR	Code of Federal Regulations
DHHS	Department of Health and Human Services
IRB	Institutional Review Board
NEIU	Northeastern Illinois University
OSP	Office of Sponsored Programs

DEFINITION OF TERMS USED IN RESEARCH

Adverse effect: An unintended, but not necessarily unexpected, result of therapy or other intervention that is unpleasant or dangerous.

Certification: The official notification by the University that a research project or activity involving human subjects has been approved by the IRB.

Children (minors): 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.

Clinical investigation: Any experiment that involves a test article and one or more human subjects.

Compensation: Payment or medical care provided to subjects injured in research; does not refer to payment (remuneration) for participation in research.

Confidentiality: Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.

Cooperative research projects: Those projects normally supported through grants, contracts, or similar arrangements, which involve institutions in addition to the grantee or prime contractor (such as a contractor with the grantee, or a subcontractor with the prime contractor).

Device (medical): Therapeutic, diagnostic or prosthetic articles which do not interact chemically with the body (e.g., pacemakers, intrauterine contraceptive devices, diagnostic test kits, crutches, artificial joints).

Emancipated minors: Individuals who are considered to have reached maturity through marriage, parenthood, financial independence, or other means, depending on state law. (Contact IRB Executive Secretary for Illinois Statute.)

Emergency use: The use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval.

Guardian: An individual who is authorized under applicable state or local law to consent on behalf of another person (i.e., children) to general medical care.

Human subject: A living individual about whom an investigator (professional or student) conducting research obtains: a) data through intervention or interaction with the individual, or b) identifiable, private information.

Informed consent: The knowing, legally effective consent of any individual or the individual's legally authorized representative. Such consent can be obtained only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

Interaction: The communication or interpersonal contact between investigator and subject.

Intervention: Includes both physical procedures by which data are gathered (i.e., venipuncture) and manipulation of the subject or the subject's environment that are performed for research purposes.

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 research procedure(s).

Minimal risk: Probability and magnitude of physical or psychological harm that does not exceed those encountered in ordinary, everyday life or in the performance of routine medical or psychological examinations.

Parent: A child's biological or adoptive parent.

Permission: The agreement of parent(s) or guardian to the participation of their child or ward in research.

Principal Investigator: The scientist or scholar with primary responsibility for the design and conduct of a research project.

Private Information: either about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place or information that has been provided for specific purposes by an individual which that individual can reasonably expect will not be made public, (i.e., a medical record.)

Remuneration: Payment for participation in research. (NOTE: The use of the term "compensation" is confined to payment or provision of care for research-related injuries.)

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

STATEMENT OF PRINCIPLES

Northeastern Illinois University is committed to the pursuit of excellence in teaching, research, and public service. Concomitantly, the University seeks to adequately protect every person who may be involved in research and training projects. The University 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).

The University acknowledges that it bears full responsibility for the performance of all research involving human subjects and gives assurance that it will comply with the Department of Health and Human Services (DHHS) regulations for the protection of human subjects (45 Code of Federal Regulations 46) and relevant FDA regulations. The University will comply with the policies set forth in 45 CFR 46 which provide additional protection pertaining to: 1) research, development, and related activities involving fetuses, pregnant women, and *in vitro* fertilization of human ova; 2) prisoners involved in research; 3) research that involves children, individuals institutionalized as mentally disabled and other potentially vulnerable groups; and 4) cooperative research projects.

Unless specifically exempted by 45 CFR 46, all research involving human subjects will be reviewed and approved by an established IRB. Thus, the following principles are affirmed and apply to research, regardless of the status of the researcher, wherein any property or facility of this institution is utilized. (Property is interpreted to include any University non-public information whether this information is utilized in and of itself or is utilized for contacting subjects or prospective subjects.):

1. Since the participation of humans in research and training projects may raise fundamental ethical and civil rights questions, no distinctions in the monitoring of projects will be drawn between funded and unfunded projects, sponsored and unsponsored projects, or between projects carried out by students, faculty, or other University employees, on-campus or off-campus, in the United States or overseas.
2. All activities involving humans as subjects must provide for the safety, health and welfare of every individual. Rights, including the right of privacy, must not be infringed.
3. The direct or potential benefits to the subject, or the importance of the knowledge to be gained, must outweigh the inherent risks to the individual.
4. Participation in projects must be voluntary and informed consent must be obtained from all subjects, unless this requirement is specifically waived by the IRB. Methods that are

in accordance with the requirements of 45 CFR 46.116 and 45 CFR 46.117 and are adequate and appropriate to the risks of the project must be used to obtain the subject's informed consent.

5. Consent should be obtained whenever possible from the participants themselves. If a subject is not legally or physically capable of giving informed consent, a legally authorized representative may do so. Careful consideration shall be given to the representative's depth of interest and concern with the subject's rights and welfare. Children, for example, may not be exposed to risk except for the child's benefit.
6. An individual does not abdicate any rights by consenting to be a research subject. A subject has the right to withdraw from a research project at any time or can refuse to participate without loss of benefits to which the subject would otherwise be entitled. Further, a subject has the right to receive appropriate professional care, to enjoy privacy and confidentiality in the use of personal information and to be free from undue embarrassment, discomfort, anxiety, and harassment.
7. Safeguarding information about an individual that has been obtained in the course of an investigation is a primary obligation of the investigator. When the investigator is a student, responsibility for the conduct of the research and the supervision of human subjects lies with the faculty sponsor. Such information shall not be communicated to others unless the following conditions are met:
 - a. Explicit permission for the release of identifying data is given by the individual.
 - b. Information about individuals may be discussed only for professional purposes and only with persons clearly concerned with the project. Written and oral reports should present only data germane to the purposes of the project, and every effort should be made to avoid invasion of privacy.
 - c. Provisions must also be made for the maintenance of confidentiality in the preservation and ultimate disposition of any data collected. Adequate security measures must be described to the IRB and carried out by the principal investigator until the records are destroyed. Records which contain personal information shall be destroyed as soon as possible in keeping with the long-range goals of the project and records retention requirements.
8. Projects will be given initial and continuing review by the IRB as set forth in Section VI.

All members of the University community involved in investigation and training are responsible for continual monitoring to assure compliance of their research with these principles. Projects shall have appropriate administrative overview carried out at least annually to insure that the procedures designed for the protection of the rights and welfare of human subjects are being effectively applied and are in compliance with the requirements of 45 CFR 46.

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

10. In all cases, the investigator should show practical regard for the Northeastern Illinois University community, recognizing that violations of the ethical and legal standards incorporated in this statement of principles could impugn the investigator's own name and the reputation of the University (e.g., concerning confidentiality, informed consent, debriefing, and regard for the health, safety, and welfare of all human subjects). The investigator does not abdicate ethical and legal responsibility merely by complying with this protocol. It is always the responsibility of the investigator to obtain clearance from the IRB prior to the initiation of any research activity involving the use of human subjects. Failure to do so may result in personal restrictions on the research activities of such individual, as well as potentially endanger all federal funding to the University.

IRB OFFICE OF RECORD

The Office of Academic Affairs will serve as the Office of Record for the IRB. An appointed Executive Secretary shall be responsible for administering Board activities. The Executive Secretary shall:

- receive all protocols, review for completeness and conformity to IRB requirements and forward to the IRB Chairperson;
- prepare and maintain adequate documentation of IRB activities, maintain records three to five years or as required by regulations, and have records accessible for inspection by DHHS authorized representatives when requested;
- notify research investigators in writing of the IRB's decisions, conditions, requirements;
- report information as appropriate to the OPRR, FDA, IRB, research investigators and other University personnel on issues dealing with changes in regulations and new requirements;
- notify the President's Office, DHHS, OPRR, and sponsor of any cases of injury, breaches of trust, fraudulent research, unanticipated problems, serious or continuing noncompliance by research investigators with IRB requirements, and suspension or termination of IRB approval as notice of such cases is received.

IRB MEMBERSHIP AND INSTITUTIONAL RESPONSIBILITIES

The University has established and will maintain an Institutional Review Board. The IRB has the responsibility and authority to review, approve, disapprove or require changes in appropriate research activities involving human subjects. The Board will review invasive protocols involving test articles and medical research, and it will also review non-invasive protocols involving social and behavioral research.

The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

The IRB shall include:

- at least one member whose primary concerns are in scientific areas;
- at least one member whose primary concerns are in nonscientific areas;
- 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 member of the IRB 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.

Total membership must encompass at least five members. Members shall be selected according to the University's research needs but shall include at least one member whose primary concern is a non-scientific area and one non-University affiliated member whose immediate family is not affiliated with the University. The five members may not consist entirely of women or men or entirely of members of one profession. The university shall provide the

Board with access to legal counsel as needed.

The Board may, at its discretion, invite individuals who have competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the Board. These individuals shall not have voting rights and shall receive copies of research protocols prior to the meeting of review.

Appointments to the Board shall be made by the Provost of the University.

Any member who fails to attend four consecutive called or scheduled meetings of the IRB or who fails to attend more than fifty percent of the IRB meetings in any twelve-month period will be removed from the IRB and a replacement designated to fill the remainder of the removed member's appointment term.

The college dean and department chair will be responsible for insuring that research by individuals (faculty, students, or employees) is conducted according to human subjects guidelines. The Provost will name one college dean in the case of non-faculty researchers. The college or department may set up any internal screening procedures that are determined to be necessary to assure adequate internal review. Upon request by the IRB, the college dean, department chair, or director may be asked to supply additional expertise or information to aide the Board in its review process.

IRB meetings shall be recorded. The Minutes shall be in sufficient detail to show the names of those in attendance; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; and the basis for requiring changes in or disapproving research. In lieu of a written summary of the discussion of controvertible issues and their resolution and dissenting reports and opinions, meetings will be tape recorded. To assure consideration of an application by the IRB in any given month, the principal investigator must initially submit a completed application to the IRB Executive Secretary no later than forty-five days prior to the start of the research. This will allow sufficient time for an IRB meeting to be called and held.

All research projects involving the use of human subjects must be submitted to the IRB for approval. If it is unclear whether the proposed research involves human subjects, the investigator should seek assistance from the IRB Executive Secretary. Applications shall be submitted well in advance of either the proposal submission deadline when the proposal is to

be submitted (if being submitted to an external funding agency) or when the research is to begin. If external funding is being sought, one copy of the complete proposal must be submitted along with the IRB application. The IRB Executive Secretary will log in and review the application material for procedural omissions prior to submitting it to the IRB Chairperson or designee. The IRB Chairperson shall review the protocol prior to its consideration by the Full Board in an attempt to identify any items that need clarification or modification in order for the IRB to act on the application. All applications shall be distributed to the Full Board for review prior to the next scheduled meeting.

A majority of the members of the IRB, including at least one member whose primary concerns are in non-scientific areas, must be present at a meeting in order to conduct business. Final approval by the IRB shall then require a majority vote by members present. If the IRB is agreed that the proposed research protects human subjects in accordance with established standards, its conclusion shall constitute certification of approval. A letter of approval shall be sent to the investigator.

The IRB shall proceed to weigh the following primary factors:

1. That 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 the subjects will be recruited.
2. That the rights and welfare of the subjects will be adequately protected. Each project shall be scrutinized with the interests of the subjects foremost in consideration. No procedures shall be followed that would result in unnecessary or unacceptable risks to the subjects. Appropriate safeguards and emergency measures must be provided. The IRB is concerned with the maintenance of proper records and the protection of anonymity and confidentiality of all data collected. Furthermore, the IRB shall attempt to minimize personal embarrassment, mental anguish, and questions of conscience resulting from participation in a study. In short, the IRB shall make every effort to ascertain that both the mental and physical well-being of the subjects are adequately protected.
3. That the risks to the subjects are reasonable in relation to anticipated benefits. The project protocol will be evaluated to determine if the risks to subjects are reasonable in relation to the anticipated benefits, if any, to the subject and the importance of the knowledge that may reasonably be expected to result. The IRB expects that human subjects will not be utilized in projects which are poorly designed. However, the responsibility for monitoring research

design quality lies primarily with the appropriate college dean, department chair, director, principal investigator or faculty sponsor.

4. That the informed consent of subjects will be obtained by adequate and appropriate methods (described in Section X). All subjects will be fully informed by the investigator of the procedures to be followed, including discomforts, risks, and possible benefits. Risks must be well defined in terms understandable by the subjects. Informed consent must be obtained from all subjects, unless specifically waived by the IRB in accordance with 45 CFR 46.117 (c) (1) or (2).

An exempt or expedited review procedure is possible for those applications which involve no more than minimal risk to subjects and also either fall under one of the research categories eligible for expedited review (see Section VIII) or fall under the categories exempted by federal regulations (see Section VII). Final determination as to whether a specific project is exempt from IRB review or is eligible for expedited review can only be made by the IRB Chairperson or by one or more of the experienced IRB members designated by the Chairperson. For information as to whether or not a given research project falls under either of these category definitions contact the IRB Executive Secretary.

An expedited review procedure is also possible for minor changes in previously approved research during the period for which approval is authorized.

The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's decisions, conditions, and requirements or that has been associated with unexpected serious harm to subjects. The authority is absolute; however, any investigator receiving an adverse ruling shall have the right of reconsideration. A second adverse ruling will be final.

The IRB shall respect the sponsor's need to maintain confidentiality of certain information about products under development. Members and staff shall be aware that information submitted for review may be confidential, trade secret, and of commercial interest and should recognize the need for maintaining a sponsor's confidentiality.

A certification of IRB approval, if required by an external funding agency or if requested by the investigator, shall be made in the form required by the agency and, as applicable, either submitted to the agency or returned to the investigator.

After protocol approval, research investigators are responsible for complying with all IRB decisions, conditions, and requirements.

Research investigators, department chairs, and any other person directly knowledgeable of the research activities are responsible for reporting promptly to the IRB and OSP any serious or continuing noncompliance with the requirements of the NEIU IRB Handbook or the determinations of the IRB.

REVIEW PROCEDURES AND CRITERIA FOR APPROVAL

The investigator will be asked to meet with the IRB to answer any questions that might arise. No individual involved in the conduct and/or supervision of the research project shall participate in its review, except to provide information to the IRB. Even if the consensus of the IRB is favorable, it may elect to impose some additional restrictions or recommendations under which the project shall be conducted.

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

Adverse effects or injuries to subjects or any unanticipated problems which involve risks to the subjects or others must be reported immediately to the IRB Executive Secretary, OSP, and the appropriate department head by the responsible investigator. The investigator shall submit to the sponsor and to the IRB a report of any unanticipated adverse effect occurring during an investigation as soon as possible, but in no event later than ten working days after the investigator first learns of the effect. Reports to the IRB shall be documented by memorandum to which a copy of the subject's case history report. (Adverse Event Form)

Change in Procedures proposed in the research protocol during the period for which IRB approval has already been given may not be initiated by the investigator without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects. In the latter case, the investigator should promptly inform the IRB of the change following its implementation. The IRB will review the change in the study to determine that it is, in fact, consistent with ensuring the continued welfare of the subjects. A change in procedures should be reported on IRB Amendment Form .

Continuing Review after initial approval of a protocol is required at least annually. The IRB shall indicate the minimum intervals between re-evaluation of the project so that continued acceptance of the protocol is assured. Routine projects will be reviewed at yearly intervals; more complex and potentially dangerous projects will be reviewed at a frequency commensurate with the related risks. Projects that are determined to be exempt shall not require additional review. Renewal projects should include a progress report as well as a detail

of any new information that has come to light since the last IRB review. Projects may also be re-evaluated if subjects involved in the research lodge a complaint with the IRB or the investigator reports problems with the research. In the latter case, the IRB may elect to review the data accumulated by the investigator and may interview both the investigational staff and persons under risk. Continuing review of a study may not be conducted through an expedited review procedure, unless the study was initially reviewed by expedited review. A progress report for continuing review must be submitted on IRB Form.

Final Reports are required when a protocol is closed for any reason. A final report covering the period of time since the last IRB review and approval must be submitted by the investigator for IRB review. Investigators who do not submit a final report when a protocol is closed shall be notified that the Board will not accept any new protocols in which they are involved until a final report is submitted for the closed study. A final progress report must be submitted on IRB Final Report Form.

Definite plans not set -- certain proposals may be submitted knowing human subjects are to be involved with the project, even though definite plans for this involvement remain inconclusive. Such proposals shall be reviewed and certified in the same manner as more complete applications with the obligation that later review and approval will be required as more complete plans are made, but before the period during which human subjects would be utilized. In the case of an externally funded project, this later review and approval must precede the beginning of any grant budget period during which human subjects would be utilized.

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

Special classes of subjects require additional protection. DHHS has issued specific regulations governing research with the following special classes of subjects:

1. biomedical and behavioral research involving children;
2. the mentally disabled;
3. prisoners;
4. fetuses and human in vitro fertilization;
5. pregnant and lactating women.

Investigators initiating a project including one or more of the special classes as subjects should be knowledgeable of the appropriate regulations. Use the appropriate Appendix to report use to the IRB.

EXEMPTED REVIEW

The University has adopted five categories of research as exempt from continuing IRB review based upon DHHS regulations published in the Federal Register on June 18, 1991. In order to establish an individual research project as exempt, an investigator must complete an IRB application. On the IRB application, the investigator should indicate the number of the category under which an exemption is claimed. Final determination as to whether or not a research project is exempt rests with the IRB Chairperson or designee.

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

The following categories of exemption have been adopted by DHHS and Northeastern Illinois University:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
 - a. research on regular and special education instructional strategies, or
 - b. 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), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
3. Research involving survey or interviewing procedures, except where all of the following conditions exist:
 - a. responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subject,
 - b. the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and

- c. the research deals with sensitive aspect of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.

- 4. Research involving the observation (including observation by participants) of public behavior, except where all of the following conditions exist:
 - a. observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects,
 - b. the observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and
 - c. the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

- 5. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. (Investigators must include with the IRB application a letter of approval for use or supply of the information material or specimens.)

EXPEDITED REVIEW

DHHS regulations recognize that there are certain categories of research which involve procedures which pose no more than minimal risks to subjects and for which clear standards can be set. Accordingly, research projects which fall under one of the categories listed below shall be reviewed by the Expedited Review Subcommittee, which shall consist of the IRB Chairperson and/or one or more experienced IRB member(s) selected by the Chair.

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

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

Investigators should be aware that even though applications for expedited review are less complicated to review, the expedited review process may be no faster than the full review procedure. When a research project has been approved under expedited review, a letter of tentative approval will be sent to the principal investigator and will state that formal approval is pending Full Board review at the next convened meeting. The investigator will not have to attend the Board meeting to present the protocol.

Listed below are eleven categories subject to expedited review. Expedited review shall be given only for research protocols that fall under one of these categories:

1. Collection of: hair, nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction;
2. Collection for analysis of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor;
3. Recording of data from subjects eighteen years of age or older using noninvasive

procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. (These procedures include weighing, testing sensory acuity, electrocardiogram, electroencephalogram, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range, (i.e., x-rays, microwaves.);

4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects eighteen years of age or older who are in good health and not pregnant;
5. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
6. Voice recordings made for research purposes such as investigations of speech defects;
7. Moderate exercise by healthy volunteers;
8. The study of existing data, documents, records, pathological specimens or diagnostic specimens;
9. Research on individual or group behavior or characteristics of individual, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects;
10. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required;
11. Minor changes in procedures (i.e., revisions, amendments, modifications, title change) to existing approved studies.

INFORMED CONSENT

Informed consent is a process, not just a piece of paper. A written informed consent documents this process, but cannot serve as a substitute for it. No subject may be involved in research without the legally effective informed consent of the subject or the subject's legally authorized representative. This consent shall be sought under circumstances that provide sufficient opportunities for the subject to freely consider whether or not to participate. Particular attention should be paid to minimizing the possibility of coercion or undue influence. The IRB shall have the authority to observe or have a third party observe the consent process and the research.

The information given to the subject, or the subject's legally authorized representative must be in simple, easily understood language. If the subject population is not English speaking, the informed consent must be presented in whatever language is appropriate.

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

The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws requiring additional information to be disclosed in order for informed consent to be legally effective.

Written documentation of the consent process (i.e. a cover letter or cover sheet) is always required unless specifically waived by the IRB. The consent document should be signed by the subject or the subject's legally authorized representative unless this requirement is waived by the IRB. A waiver of the written informed consent requirement will be granted only if the investigator can provide adequate justification for the request.

If the subject is a minor, written parental/legal guardian consent is required unless this requirement is waived by the IRB. In addition to obtaining parental consent, the investigator must obtain the assent of the child unless the child is incapable of giving assent and the IRB has waived the requirement.

If the only record linking the subject to the research or data is the written, signed informed consent, its use may be waived by the IRB. However, a statement describing the procedures

and objectives of the research shall still be supplied to the subjects in a written format. An example of such a project would be the analysis of a questionnaire which is distributed and returned anonymously through the mail. A cover letter should include all the elements of informed consent listed in this section.

If informed consent is to be obtained orally, a "short form" written consent document stating that the elements of informed consent have been presented orally may be signed by the subject or the subject's legally authorized representative. A written summary of what the subject will be told must be provided to the IRB for review and approval and there must be a witness to the oral presentation. The witness must sign the "short form" and the written summary and then receive copies of both documents. The person obtaining consent must sign a copy of the summary. Where informed consent is obtained by means other than a written form, the investigator is responsible for documenting and maintaining records of the procedures used and response of each subject.

Research investigators are responsible for securing and keeping informed consent forms for a period not less than three years after completion of the research. If the principal investigator is a student, the faculty sponsor is responsible for the maintenance and retention of such records. If the principal investigator or faculty sponsor leaves the University, this responsibility is given to a co-investigator. Otherwise, the IRB Chairperson will determine the appropriate disposition.

Unless waived by the IRB, the following information shall be supplied in all written informed consents:

1. "Informed Consent Form" heading.
2. Identification of responsible institution(s) (i.e. Northeastern Illinois University), college, department, principal and co-investigator(s), title of project.
3. Purpose of Project (Study) A statement that the study involves research (and or an investigational test article), the name of any sponsoring or funding source supporting the research, an explanation of the scope, aims and purposes of the research, the approximate number of subjects involved in study and an explanation of the expected duration of the subject's participation.
4. Procedures Involved A description of the procedures to be followed, and identification of any procedures which are experimental.

5. Risks, Discomforts or Side Effects A description of any reasonably foreseeable risks or discomforts to the subject (including likely results if an experimental treatment should prove ineffective). If the risk potential is currently unknown or unmeasurable, a statement to that effect will be required. A statement, if applicable, that the particular treatment or procedure may involve risks to the subject or to the embryo or fetus if the subject is or may become pregnant.
6. Possible Benefits Description of any benefits to the subject or to others which may reasonably be expected from the research.
7. Alternative Procedures or Treatment A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
8. Participation as a Research Subject:
 - a. Decision By Subject A statement that participation is voluntary and that refusal to participate or a subsequent decision to discontinue participation will not result in penalty or loss of benefits to which the subject is otherwise entitled. Describe the consequences, if any, that would accompany a decision to withdraw from the research and procedures for orderly termination of participation by the subject.
 - b. Terminated by Investigator A statement to inform subjects of the anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
 - c. New Information A statement that any new information developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
 - d. Additional Costs to Subject Either a disclosure of any additional costs to the subject that may result from participation in the research study or a statement that there will be no additional costs to the subjects if they participate in the research study.
 - e. Remuneration If subjects are to be offered payments as an inducement to participation, this information must be clearly stated on the consent form and include the payment policy under various contingencies (one-time fee, per visit, drop-out for medical reason, etc.).
9. Confidentiality A statement describing the extent, if any, to which confidentiality of records

identifying the subject will be maintained.

10. Contact for Questions An offer to answer any questions the subject (or the subject's representative) might have about: a) the research, b) the research subject's rights, or c) a research-related injury to the subject. This statement should include the name, address and telephone number (day and night) of the principal and/or co-investigators as the contact point if questions or problems should occur.
11. Compensation for Injury For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained. In partial compliance with this element of consent, the IRB requires that all consent forms for protocols involving NEIU affiliated investigators include the following statement (by NEIU General Counsel) unless subjects are "not at risk" as determined by the IRB under either exempted, expedited or Full Board Review:

"I understand that in the event of injury resulting from research procedures, medical treatment for injuries or illness may not be available from Northeastern Illinois University. Money damages are available to the extent specified in Illinois Statute 505.8. A copy of such Statute is available upon request to the Office of Sponsored Programs, NEIU. In the event I am injured, I have been informed to notify the NEIU _____ at Northeastern Illinois University."

(The above statement may be modified for subject population, i.e., my child is injured.)

12. Subject's Consent The following statement must be inserted above the signature line in ALL written informed consents:

"I have read the above information about this study and have been able to express questions and concerns which have been satisfactorily responded to by the research investigator and/or his/her staff. I believe I understand the purpose of the study as well as the potential risks that are involved. I understand that I will be given a copy of my signed consent to participate in this study. I hereby give my informed and free consent to be a participant in

this study."

(The above statement may be modified for subject population.)

13. IRB Approval Statement The following statement must be included in ALL written informed consents (including cover letters). Insert at the bottom margin of the form, letter, or portion of the form that is to be retained by the subject:

THIS RESEARCH PROJECT/STUDY HAS BEEN REVIEWED BY NORTHEASTERN
ILLINOIS UNIVERSITY INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION
OF HUMAN SUBJECTS, PHONE:

* * * * *

An informed consent template is available on the OSP website.

Investigators are advised not to accept a consent form supplied by the sponsoring agency, or anyone else, without critical review to assure that it conforms to the IRB guidelines.

Example B: Cover letter for mailed questionnaire when use of an informed consent could present risk in otherwise risk-free project.