

September 15, 1999

ADMINISTRATIVE MEMORANDUM NO. 79

To: Vice Presidents, Deans, Directors, Department Chairs, and Other
Administrative Officials

From: Salme H. Steinberg, President

Subject: Policy Statement on Use of Human Subjects in Research

Preamble

This is a brief summary of the policy of Northeastern Illinois University regarding research involving the use of human subjects. The Northeastern Illinois University Institutional Review Board (IRB) Handbook on Policies and Procedures for Research Involving Human Subjects should be consulted for a full statement of university policy and procedures. Copies of this Handbook are available through the Office of Sponsored Programs. It is the responsibility of all NEIU faculty, staff and students proposing research which falls under this policy to adhere to the requirements of the NEIU IRB Handbook. While many proposed research projects involving the use of human subjects will fall under one of the categories exempted from review or qualified for expedited review under federal regulations, all NEIU investigators proposing any research involving the use of human subjects must submit applications for approval of that research to the NEIU IRB (regardless of whether that research is funded or unfunded, or if funded, the source of that funding).

Applications are available from the Office of Sponsored Programs and completed applications should be submitted to that office. If it is determined that, based on the criteria outlined in the NEIU IRB Handbook, the proposed research falls under one of the categories exempted from review or qualified for expedited review, the investigator will be promptly notified of this fact. Any proposed use of NEIU students as subjects of research must also have preliminary approval from the Office of the Provost prior to the submission of an application.

1. General Principles

Northeastern Illinois University is committed to the pursuit of excellence in teaching, research, and public service as well as to the principles of academic freedom and shared governance. At the same time, 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)¹. In addition, 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. In order to carry out this responsibility, individual university faculty, staff and student researchers will also be held responsible for compliance with these regulations and with university policy governing the use of human subjects in research.

2. To advance the above goals and in compliance with the federal regulations referenced above, the Provost shall appoint a Human Subjects Institutional Review Board ("IRB"). The IRB is responsible for reviewing and monitoring research involving human subjects conducted by faculty, students, and investigators seeking access to human subjects under the auspices of the University. The IRB has the authority to prohibit research that does not meet the standards of ethical research practices. It also has the authority to suspend or terminate approval of research that is not being conducted according to such standards. All research which involves human subjects must be reviewed by NEIU's IRB. IRB approval and IRB certification are necessary prior to initiation of any such project. Continuing research projects are subject to continuing review. The IRB may monitor research at intervals appropriate to the degree of risks to study subjects. In addition, NEIU's IRB shall:
 - A. Develop written policy, procedures, and guidelines to protect human subjects.
 - B. Provide prior review and formal written approval and written certification of research proposals which have been found to be nonexempt.

Approval constitutes a written finding that all of the following conditions are met:

1. Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risks and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and relative importance of knowledge that may be reasonably expected to result.

¹ The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, DHEW Publication No. (OS) 78-0012 (1978).

3. Rights and welfare of subjects are protected and selection of subjects is equitable with the IRB being particularly cognizant of the special problems of research involving vulnerable populations.
 4. Informed consent is sought from each subject and/or the subject's legally authorized representative and is documented as required by law.
 5. Where appropriate, research plans make adequate provision for monitoring the data collected to insure the safety of subjects.
 6. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
 7. Where any of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of such subjects.
- C. Monitor ongoing research as dictated by funding sources or other needs with respect to human subjects' rights.
- D. Upon request, provide advice to researchers on issues concerning the treatment of human subjects.

3. Board Membership and Terms

The IRB shall be composed of from five to seven regular members and three to five alternate members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by this institution, and sufficiently qualified by expertise and diversity (including consideration of race, gender, and cultural backgrounds) to provide the IRB with the professional competence necessary to review the type of research activities which come before it. In particular, the following requirements shall be met:

- A. The IRB may not consist entirely of members from one academic discipline or profession. It must include both men and women.
- B. At least one member of the IRB shall be a person whose primary expertise or concerns are in a scientific area and one in a nonscientific area.
- C. At least one member of the IRB shall be a person who is not affiliated with the institution, or is not part of the immediate family of a person who is affiliated with the institution.
- D. The IRB may invite individuals with competence in special areas to assist

in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

- E. Members of the IRB are prohibited from participating in the review of research proposals if there is any conflict of interest.

Appointments to the IRB shall be made by the Provost, who has ultimate responsibility for the university's compliance with the above referenced ethical principles and legal requirements. Appointments shall normally be for two years, with terms staggered to allow for some continuity of membership. Appointments may be repeated, but attention will be given to the need to bring in new members from time to time. The Associate Provost will serve as an ex-officio non-voting member of the IRB and as liaison between the IRB and the Office of the Provost.

The Director of Sponsored Programs will serve as an ex-officio, non-voting member of the IRB and as Executive Secretary to the IRB. The Affirmative Action Officer will serve as a continuing resource person for the IRB.

The IRB will establish a schedule of meeting times for review of applications. This schedule will be made known to the university community through appropriate methods. It is the responsibility of investigators to submit research proposal applications in a timely manner in accordance with this schedule.

A formal written report shall be made at the end of each fiscal year by Sponsored Programs to the Provost concerning IRB activities during that fiscal year.