



ACADEMIC ALERT #2003-10

DATE: April, 2003
DECISION: National-Louis University Office of the Provost

**Revised National-Louis University Human Subjects Research Policy
AP: 303 (041790)**

Rationale

The original National-Louis University Human Subjects Research Policy effective April 17, 1990 was not specific enough in providing guidelines for the types of research activities which are subject to review. This revision of the policy provides that specificity.

**Revised by Institutional Research Review Board (IRRB): January 22, 2003
Approved by Faculty Senate: March 19, 2003**

IMPLEMENTATION DATE: March 19, 2003

CONTACT: Carol R. Melnick, Chair of IRRB, extension 3683

SIGNATURE

**Carol R. Melnick, Ph.D.
Vice Provost**

National-Louis University Human Subjects Research Policy

AP: 303 (041790)

Recommended:	Faculty Senate	Date: March 7, 1990
Approved:	President's Cabinet	Date: April 17, 1990
Revised:	Institutional Research Review Board	Date: January 22, 2003
Revision Approved:	Faculty Senate	Date: March 19, 2003

EFFECTIVE DATE: March 19, 2003

Introduction

The Code of Federal Regulations (Title 45, Code of Federal Regulations, Part 46). published by the Office for Protection from Research Risks (OPRR) was adopted by National-Louis University as institutional policy in 1990. The policy is administered by the Office of the Provost. These regulations mandate the formation of an Institutional Research Review Board and provide specific guidelines for the types of research activities that are subject to review.

Definition of Research

NLU's Institutional Research Review Board (IRRB) ensures compliance with NLU's policies and procedures for conducting ethical research involving human participants. Any activity that gathers or will use information which involves human participants (directly or indirectly) may fall within the definition of research and be under the purview of IRRB review. This includes any research conducted by NLU faculty and NLU students that is considered part of one's academic work at NLU, funded research, and research involving NLU students by outside institutions.

Definition of "Human Subjects (Participants)" and "Persons"

A researcher must receive approval by the IRRB before conducting research depending on how human participants are used.

Definition of "Human Subject" from the Federal Regulations -- Section 102 (f) of 45 CFR 46

"Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

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

Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human participants."

(<http://ohrp.osophs.dhhs.gov/humanparticipants/guidance/45cfr46.htm#46.102>)

According to federal regulations, research that involves "persons" does not necessarily involve human participants (as defined by federal regulations). By definition, research on persons, such as historical research, does not involve intervention, interaction or identifiable private information. Therefore, no protocol is required.

Requirement

Every research investigator involved in any aspect of human subject research at NLU must submit a protocol, regardless of exempt/expedited/full review designation, that includes appropriate forms and documents, such as informed consent. This is true for all NLU faculty and doctoral students, and may be true for other graduate students according to departmental needs.

All protocols and appropriate documentation must be classified in accordance with the policies and procedures of IRRB. See IRRB forms A and B.

Changes or Amendments

Any change to a previously submitted protocol, including the addition of investigators, a change of study method, or a change of location, requires the submission of a change of status form along with appropriate documentation. If a new protocol is required, the primary research investigator will be notified.