
**PROTECTION OF HUMAN SUBJECTS IN RESEARCH
THE UNIVERSITY OF NORTH CAROLINA AT GREENSBORO**

**(Approved by the Chancellor, August, 1978)
(Revised March 1982 and August 1989)**

BACKGROUND

In July 1974 the United States Congress passed the National Research Act, which is intended to guarantee the protection of the rights of human subjects involved in biomedical and behavioral research. The Department of Health and Human Services maintains implementing regulations for the use of human subjects in research that is funded by the Federal Government. These guidelines specify the ethical principles that must be followed to insure that research subjects are treated humanely, that their dignity is maintained, and that their rights are preserved. The Federal guidelines and their revisions are published in the Code of Federal Regulations.

The University adopted policies for the protection of human subjects in research in August 1978. Since that time revised Federal regulations have allowed for certain exemptions and expedited review procedures. Consequently, the University's Policy on Protection of Human Subjects in Research has now been modified. The following statement supersedes all earlier communications about the use of human subjects in research at The University of North Carolina at Greensboro.

POLICY

Research done under the jurisdiction of The University of North Carolina at Greensboro shall not expose persons who participate as subjects or respondents to unreasonable risks to their health, general well being, or privacy. Specifically, the University is concerned that in all research, development, and related activities involving the use of human subjects,

- (1) the rights and welfare of the individuals involved be adequately protected;
- (2) the participation of subjects be based on freely given, informed consent; and
- (3) the risks to the subject be so outweighed by the sum of the benefit to the subject or by the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks.

Therefore, all projects involving human subjects and conducted under the auspices of the University are subject to review to ensure the protection of the rights and welfare of the individuals who participate as subjects.

This policy applies to all research involving human subjects whether or not requests for outside funding are involved.

The Chancellor has responsibility for overseeing the implementation of this policy. The Chancellor authorizes signature of compliance documents and special reports required by Federal regulations. To assist in carrying out this policy, the Chancellor has established the Institutional Review Board (IRB) and has delegated to that body specific responsibilities. Composition of the IRB and procedures for its activities conform to Federal regulations. Appeals of approving decisions of the IRB are heard by the Chancellor. No appeal may be taken of a disapproving decision.

The Chancellor has designated the Director of the Office of Research Compliance as the Institutional Official responsible for submitting reports to Federal agencies on protection of human subjects in research.

This policy does not constrain the continuation or adoption of more restrictive review policies or additional review procedures at the departmental or college/school level.

I. Institutional Review Board

The Institutional Review Board reviews all plans for the use of human subjects in research prior to the beginning of the research, unless the project has been specifically exempted under Federal guidelines. Members are appointed by the Chancellor to staggered three-year terms. Composition of the IRB will continuously conform to Federal regulations, but at minimum will include five members demonstrating the following characteristics:

- (1) diverse professional backgrounds
- (2) racial and cultural diversity
- (3) representation from both sexes
- (4) one member whose primary concerns are in nonscientific areas
- (5) one member who is not affiliated with the institution or related to someone affiliated with the institution

Recommendations for appointment to the IRB will be made to the Chancellor by the Office of Research Compliance.

II. Office of Research Compliance

The Office of Research Compliance establishes procedures to implement the University's policy regarding human subjects in research and provides administrative support to the IRB. The Director of the Office of Research Compliance, or his/her delegate, serves as ex-officio voting member of the IRB and, in consultation with other administrators, prepares assurance documents as necessary. The Director has ongoing responsibility to communicate concerns regarding the protection of human subjects in research to responsible University officials and faculty.

IMPLEMENTATION

The Office of Research Compliance and the Institutional Review Board will establish and publish procedures for the implementation of this policy. These procedures will be consistent continuously with the regulations published by the Department of Health and Human Services.

Primary responsibility for assuring that the rights and welfare of the individuals involved are protected continues to rest with principal investigators conducting research involving the use of human subjects. Researchers who plan activities involving the use of human subjects or respondents are responsible for knowledge of the University's procedures. Faculty who assign or supervise research conducted by students have an obligation to consider carefully whether those students are qualified to safeguard adequately the rights and welfare of subjects and to make sure that such students are adequately informed about the procedures for review of research activities.