

UNIVERSITY SENATE  
STATE UNIVERSITY OF NEW YORK AT ALBANY

University Policies for  
Research Involving Human Subjects

INTRODUCED BY: Council on Research  
October 5, 1981

IT IS HEREBY PROPOSED THAT THE FOLLOWING BE ADOPTED:

- I. That the attached policies for research involving human subjects be implemented for a period of six months.
- II. During this period, the Research Council will summarize changes in activities of the Campus Institutional Review Board and will solicit reactions from interested faculty about their satisfaction with campus policies regulating human subject research.
- III. Prior to the end of this academic year, the Council will report on their findings to the Senate and make recommendations for future policy.
- IV. That this resolution be referred to the President for his approval.

APPROVED November 5, 1981

Policies:

- I. In accordance with state and federal regulations and the highest standard of ethical conduct, it is the responsibility of the University reasonably to insure that the rights and welfare of human subjects, in research conducted under its auspices, are adequately protected. The primary responsibility for protecting human subjects rests with each individual who initiates, directs or engages in research.
  
- II. In order for the University to fulfill its responsibility, ALL research involving human subjects conducted under the auspices of the University must receive prior review and approval by the Institutional Review Board (IRB), regardless of the source of funding. This includes student research involving subjects from outside the class.
  - A. "Human Subjects Research" is defined as a systematic investigation designed to develop or contribute to generalizable knowledge, which involves the collection of data from or about living human beings. It does not include research utilizing published or publicly available documents or research on elected or appointed public officials or candidates for public office.
  
  - B. The members of the IRB are appointed by the Vice President for Research. In addition to other requirements of state and federal regulations, the membership of the IRB is composed of individuals of varying backgrounds who are qualified through maturity, experience, and expertise, and the diversity of the members' racial and cultural backgrounds to assure complete and adequate review of activities commonly conducted by the institution, and to insure respect for its advice and counsel for safeguarding the rights and welfare of human subjects. The IRB possesses the professional competence necessary to ascertain the acceptability of proposals in terms of institutional commitment and regulations, applicable law, standards of professional conduct and practice, and community attitudes.
  
  - C. The determination regarding whether a given activity should be considered human subjects research must be made by the Institutional Review Board or its designee.
  
  - D. Certain categories of research involving little or no risk to subjects need not be reviewed and approved by the full IRB, but, rather, by a duly authorized designee. The IRB shall develop and promulgate appropriate categories of research eligible for this procedure.
  
- III. The IRB shall adopt appropriate procedures to implement these policies. The IRB shall develop all procedures with the advice and counsel of the Council on Research and shall keep the Council informed of any changes in procedures.

Approved by the Council on Research, September 16, 1981.

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Rationale:

Research involving human subjects is governed by federal and state regulations, as well as professional standards of ethical conduct. Since 1977, the University has been complying with these regulations by requiring that all human subjects research receive prior review and approval by the University's Institutional Review Board. In January 1981 the federal government published a new set of regulations governing human subjects research. Under the new federal regulations, the government has placed more of the responsibility for insuring the protection of human subjects on the individual institutions. This was done by significantly reducing the scope and requirement of the regulations. New York State law, however, has not been revised and its requirements still remain broad. While the new regulations provide the University with the opportunity to greatly reduce the burden on researchers and on the IRB, the University must take care not to violate the NY State law or to fail to fulfill its responsibility for the protection of subjects.

After carefully reviewing the new regulations, in light of the University's responsibilities and the necessity to remain in compliance with NY State law, the IRB recommended that the University adopt policies that go somewhat beyond the federal regulations in two basic ways. First, although the federal regulations state that they only apply to DHHS-funded research, we should continue to apply the same procedures to all human subjects research, regardless of funding. Second, although the federal regulation exempt broad categories of research, we should not make exemptions, but continue to review all human subjects research. Not all research, however, would need to be reviewed by the full IRB. By reviewing all human subjects research under the same standard, the University can best insure that it is in compliance with all regulations and is fulfilling its responsibility to subjects.

Under the new policies, the IRB will not be reviewing any more research than it did in the past. The new regulations, however, give us the opportunity to reduce the burden of compliance on the researchers. Much of the research which the IRB formerly reviewed (about 80%) will now be eligible for "expedited review." Under this procedure one person, designated by the IRB, would be able to approve these projects without them being reviewed by the full IRB. This will mean much less paperwork and much less delay for the researchers.

These policies are being presented to the University Senate because the university's procedures for reviewing human subjects can no longer be based simply on compliance with regulations, but must now be based on University policy. We therefore request that the University Senate approve these policies and refer them to the President for his approval.