

**ALBANY STATE UNIVERSITY
ALBANY, GEORGIA
INSTITUTIONAL POLICY AND PROTOCOL FOR REVIEWING RESEARCH
PROPOSALS INVOLVING HUMAN SUBJECTS
INSTITUTIONAL PROFILE AND INTRODUCTION**

A historically black institution, Albany State was established in 1903 as the Albany Bible and Manual Training Institute, supported by private and religious organizations to train black youths in southwest Georgia. In 1917, it became the state-supported, two year Georgia Normal and Agricultural College. In 1943 it became a four-year institution and was named Albany State College. The current name, Albany State University, was approved by the Board of Regents in June 1996.

Albany State University is a growing regional institution in southwest Georgia that offers undergraduate and graduate liberal arts and professional degree programs, and a wide range of outreach programs to the community. The university is located in Albany, a progressive city with a population of about 80,000.

Albany State offers several undergraduate degree programs of which the most popular majors are biology, psychology, criminal justice, computer science, education, business management, and nursing. The University offers six advanced degrees: a master of science in criminal justice, a master of public administration, a master of business administration, a master of science in nursing, a master of education in eleven (11) majors, and an education specialist degree. The University offers a Board of Regents engineering transfer program and a dual degree program in engineering with Georgia Tech.

Albany State serves its community through a range of outreach initiatives, particularly through service-learning programs. It is, therefore, the intent of the institution to put in place policies/protocol that will ensure that its research activities are in compliance with standards set by federal mandates with appropriate modifications applicable to Albany State University's research.

LEGAL FOUNDATION FOR ESTABLISHING AN IRB

On July 12, 1974, the National Research Act (public Law 93-384) was signed into law, thereby creating the National Commission for the protection of Human Subjects of Biomedical and Behavioral Research. The commission was charged with the responsibility of identifying, among others, ethical principles that should guide the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. Specifically, the commission was asked to consider the following: (i) the boundaries between biomedical and behavioral research and the accepted routine practice of medicine, (ii) the role of

assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects, (iii) appropriate guidelines for the selection of human subjects for participation in such research and (iv) the nature and definition of informed consent in various research settings. During a four-day intensive deliberation, the BELMONT REPORT was produced in February 1976 and published in the Federal Register. The two-volume Appendix, containing the lengthy reports and the list of experts and specialists who assisted the commission in accomplishing its responsibility is available as DHEW Publication No. (OS) 78-0013 and No. (OS) 78-0014, for sale by the Superintendent of Documents, U. S. Government Printing Office, Washington, D.C. 20402. The commission recommended that the document be adopted by the Secretary of Health, Education and Welfare in its entirety.

There are three Basic Ethical Principles which were derived from the commission's report that must guide the conduct of research involving human subjects, they are:

1. RESPECT FOR PERSONS: This consists of two ethical convictions: first, that all individuals should be treated as autonomous agents and second, that persons with diminished autonomy are entitled to protection. Some persons are in need of protection even to the point of excluding them from activities that may harm them, including research. Respect for persons demands that subjects enter into the research voluntarily and with adequate information about risk and harm.

2. BENEFICENCE: Two general rules have been formulated as complementary expressions of beneficent actions in this regards: (1) do not harm and (2) maximize possible benefits and minimize possible harms.

3. JUSTICE: Who ought to receive the benefits of research and bear its burden? This is the question of justice in the sense of "fairness in distribution" or "what is deserved." The formulations are: to each person an equal share; to each person according to individual need; to each person according to individual effort; to each person according to societal contribution and to each person according to merit. In essence, no one or no group should be systematically selected as a study group and no one or no group should be denied the benefits of a research outcome.

The Policy and Protocol for conducting research involving human subjects at Albany State University shall be in compliance with the provisions of the Belmont Report and other federal guidelines related to this matter.

Albany State University operates an Institutional Review Board (IRB) under an assurance approved by the Department of Health and Human Services Office for Human Research Protections and within U.S. regulations found at 45 CFR 46. The Albany State University Institutional Review Board (IRB) consists of at least 10 members appointed by the President and representing a wide variety of academic disciplines and backgrounds. Its major function is to ensure protection of the rights of human subjects who participate in research endeavors conducted by ASU faculty, professional staff, and students through research proposal review and approval. Students shall also include ASU faculty who conduct research as part of a requirement for a degree. The board meets monthly and/or when the

board chair calls a meeting due to urgency. Faculty or staff who wish to engage in a research project involving human subjects "under, the auspices of the University" should consult with their immediate supervisor to obtain, appropriate guidance and direction for accessing the IRB. "Under the auspices of the University" is to include but not limited to: 1) research activities by Albany State University employees within the scope of employment; 2) research activities which require use of University facilities; 3) research activities which require use of confidential records within the University; and 4) research activities utilizing the University's name. Researchers, investigators, and project directors must obtain appropriate forms from the chair of the IRB and submit them along with the required copies of their proposal at any time. All reviews will be completed within three weeks from the date on which the proposal was received by the IRB chairperson. When a project is under appeal, a different time frame applies (please see the appeals section of this document).

Review Policies

The following three kinds of review may be requested:

1. Exempt Research - there is clearly No Risk to human subjects.

Example 1: All students' research papers submitted to the faculty in order to complete the requirements for a class and which are not classified as thesis, dissertation, or publishable will be granted automatic exemption status. All such papers must follow departmental procedure for approval and are not required to be submitted to the IRB. The IRB, however, assumes that departmental procedures are consistent with United States government guidelines on confidentiality and protection of human subjects.

Example 2: Research which will involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is to be recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

- **NO EXEMPTION will be granted if the research involves children as subjects.** Research outcomes or proposals that meet the requirements for exclusionary status may be submitted to the researcher's immediate supervisor for approval. Two copies of the proposal signed by the researcher's immediate supervisor must be sent to the IRB chairperson. Two Board members will review the proposal and make recommendation to the chairperson. If exemption status is approved, the IRB chairperson shall grant that status and notify in writing the researcher, his/her immediate supervisor, the ASU Office of Research and Sponsored Programs, the Dean of the Graduate School, and, in the case of undergraduates, the dean of his/her college. One copy of the proposal will be placed on file for future reference.

2. Expedited- research which involves minimal risk for human subjects.

Example 1: Voice recordings made for research purposes such as investigations of speech defects.

Example 2: Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game memory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

Research projects that meet the requirements for expedited review must be submitted in triplicate at any time. Three members of the Board will Review the proposal and be prepared to summarize it at an IRB meeting for appropriate action. All Board members will have the opportunity to deliberate on matters relating to the research and vote accordingly. A majority vote of members present shall constitute this approval and/or denial. If expedited review status is granted, the chairperson shall notify the researcher, his/her immediate supervisor, the ASU Office of Research and Sponsored Programs and the Dean of the Graduate School in writing and place one copy of the proposal on file for future reference.

3. Full Review -research involving human subjects who may be at risk.

Example 1: Research involving humans in which the investigator participates in the activities and influences participant behavior.

Example 2: Research in which subjects can be identified, directly or through identifiers linked to the subjects. Projects that require full review requires 10 copies (or as many as there are board members) of the proposal to be submitted to the IRB chairperson three months before the planned execution of the research for review. These copies of the proposal shall be distributed to each of the Board members. Members shall be prepared to summarize and discuss the proposal at an IRB meeting and to take appropriate action. A majority vote of all members present shall constitute the approval or denial. The chairperson shall notify the researcher, his/her immediate supervisor, the ASU Office of Research and Sponsored Programs, and the Dean of the Graduate School in writing and place one copy of the proposal on file for future reference.

For each of the three types of review, the reviewers shall provide an explanation at the Board meeting as follows:

- 1) risk to human subjects, or
- 2) reasons for expediting or excluding the study (whichever applies).

Before action is taken on any proposal at a meeting, a quorum consisting of at least 51% Board members and the chairperson must be present.

APPEALS

Where an investigator, researcher or project director is denied permission to conduct research because the IRB finds that the risk and or harm to humans would be extraordinary, the investigator, researcher or project director may appeal by:

(a) Sending a letter of intent to the IRB chair, his/her immediate supervisor, Office of Research and Sponsored Programs and the Dean of the Graduate School.

(b) Sending a revised and/or original copy of the research proposal and completed full review forms to the principals named in (a) above and to all members of the IRB, not more than 30 days after the date of the letter of intent sent to the IRB chair.

ACTION ON APPEAL

Ten days after the receipt of the original and/or revised copy of the proposal by the IRB chair, the chair shall inform all IRB members of the researcher's, investigator's or project director's intent to appeal and summon a board meeting within 30 days from the date of his letter to the IRB members. The director of Research and Sponsored Programs, Dean of the Graduate School, the investigator's immediate supervisor or their representatives shall be present at that meeting; they will have voting powers at the meeting. 50 percent of the IRB members plus the IRB chair, along with the aforementioned persons shall constitute a quorum at this meeting. Action taken at this meeting by a majority vote for or against approval shall be deemed final.

- A researcher or investigator may be called to make oral presentation to the appeals committee prior to the committee taking final action on the matter.

Board actions will be recorded in minutes. Actions taken by the Board will be transmitted by memorandum to the immediate supervisor, researcher or project director, the ASU Office of Research and Sponsored Programs, and the Graduate Dean.

THE PROCESS THAT THE IRB FOLLOWS IS CONSISTENT WITH REQUIREMENTS OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES DOCUMENTATION OF INFORMED CONSENT

When approval is granted for conducting research, a letter from the chairperson of the Institutional Review Board will be issued to the researcher indicating that consent for such research has been granted. Such a letter must be placed in the appendix of the research by the researcher. This action must be taken in compliance with federal regulations on this matter.