2. GRANT ADMINISTRATION

2.1 Policy

The Albert Einstein College of Medicine of Yeshiva University (“Einstein”) encourages its faculty to engage in a broad range of scientific research projects. Research may involve human subjects, animals, the use of radioactive and other potentially hazardous materials including infectious agents, patients and records at affiliated and non-affiliated institutions, and access to national and international databases.

These activities, whether funded by outside agencies and organizations (governmental and private, commercial and not-for-profit) or internal sources, are closely regulated by rules that have been imposed by federal and local governments—and Einstein itself. All applications must conform with the policies of the agency from which funding is being requested. Equally important are those regulations concerned with ethical performance, protection of human subjects, proper use of experimental animals, and conflict of interest in research.

GENERAL POLICY

A Principal Investigator (“PI “) on a grant application must be a member of the faculty at Einstein holding the rank of Instructor, Assistant Professor, Associate Professor, or Professor. All applications must be approved by the Dean’s office before submission to a granting agency or private entity. To obtain such approval, the application will have to have been reviewed and approved by the Department Chairperson and the various departments or committees concerned with chemical and biological hazards, human subjects, animal use, College facilities, and relations with industry and finance. Such review and approval will indicate to the Dean that appropriate space and facilities are available to perform the proposed research and that the application conforms to governmental and College regulations. A printed form, the Internal Face Sheet (GA Form 6741) will be provided by Grant Accounting (room 1108, Belfer, ext. 3711) or from your Department Administrator (“Administrator”). This Face Sheet will guide you in the approval process and must accompany the submitted application. It lists the Einstein departments, such as the Animal Institute, Institutional Review Board, Environmental Health and Safety, and Facilities Management that must approve the application if their services or approvals are required to carry out the proposed research and a time schedule that should be followed. It also provides specific instructions for inter-institutional applications, including research to be performed at affiliated hospitals.

Administrators who are familiar with this process can assist the PI with the preparation of a grant application. Assistance can also be found at the Office of Grant Support (OGS), room 917, Belfer, ext. 3642.

BUDGETS

All applications for funding from outside sources must be approved by the Office of Grant Accounting, room 1108, Belfer, ext. 3711. The budgets should be prepared carefully and provide for sufficient funds to cover the costs that will be incurred for salaries and fringe benefits, and the purchase and care of the animals to be used in the project, engineering services that may be required for renovations, and other institutional expenses (OTPS). Special care should be taken to make certain that the percentage of an investigator’s time and salary that is to be charged to the project is consistent with the percentage of effort allotted to that project.
HUMAN SUBJECTS

All research involving human subjects conducted at an Einstein facility or funded through Einstein resources must be approved by the Institutional Review Board (IRB). All research involving human subjects conducted at any one of Einstein’s other affiliated institutions must be approved by the IRB having jurisdiction over the particular patient population, i.e., Montefiore Medical Center, Bronx Lebanon Hospital, Long Island Jewish Hospital, Bronx Psychiatric Center, etc. The Einstein IRB reviews research conducted at the Jacobi Medical Center. The Weiler Hospital, as a Division of Montefiore Medical Center, is under the jurisdiction of the Montefiore Medical Center Institutional Review Board; however, in the case of research conducted at Weiler under an Einstein grant by faculty on the Einstein payroll, the protocol may be submitted to the Einstein IRB. This also applies to tissue obtained at Weiler and analyzed at Einstein. Blood or tissue obtained for research at Einstein from individuals at other institutions requires approval by the IRB at that institution and the Einstein IRB.

Use of an investigational drug or device for patient care must also be approved by the IRB, as well as emergency/compassionate use of such drug or device.

Indemnification language and/or terms of contracts for clinical trials funded by pharmaceutical companies must also be approved by the University’s counsel. This process is coordinated by the IRB office.

Review by the IRB is very thorough, and applications coming before the full Board must be submitted at least 12 working days prior to the meeting. Detailed information and applications for IRB approval with complete instructions are available from the IRB office at room 1002, Belfer, ext. 2237.

ANIMALS IN RESEARCH

The care and use of animals is governed by the NIH Policy on Humane Care and Use of Laboratory Animals, as well as other Federal, State, and City regulations. To ensure that research at Einstein conforms to these regulations, the Institute for Animal Studies and the Institutional Animal Care and Use Committee (IACUC) provides investigators with a detailed Guide for Review and Approval of Animal Use. By following the instructions in this Guide, the PI will be able to meet these requirements and obtain approval from the IACUC for research that uses animals. The Guide and detailed information can be obtained from the Institute for Animal Studies, room 1005, Ullmann, ext. 3571.

Review by the IACUC is very thorough and covers every aspect of newly-designed protocols related to animals, including experimental design and appropriate number of animals. Consequently, such protocols must be submitted for review at least 30 days prior to submission of an application.

CONFLICT OF INTEREST

To ensure that research at Einstein will not be influenced by a relationship between the College or the investigator and a commercial enterprise, Einstein has adopted a Conflict of Interest Policy that requires disclosure to the Dean by the faculty of all such relationships.
CHEMICAL, RADIOACTIVE, BIOLOGICAL, AND OTHER HAZARDS IN RESEARCH

The Environmental Health and Safety Department (EH&S), is responsible for maintaining a safe work environment at the College. EH&S must approve all research applications that utilize hazardous materials (e.g., chemicals, biohazards, and radionuclides). The activities of EH&S are carefully supervised by four faculty committees. These are the Institutional Biohazards Committee, Chemical Hazards Committee, Non-Human Use Radiation Safety Committee, and the Human Use Radiation Safety Committee. The EH&S department and the faculty safety committees ensure that activities involving hazardous materials are conducted safely and conform with Federal, State, and City regulations. For further information, including specific regulations and dates of workshops concerned with safety, contact EH&S in room 800, Forchheimer, ext. 4150.

RENOVATIONS AND STRUCTURAL CHANGES

All research projects that will require laboratory and office renovations or structural changes must be approved by the Department Chairman and by Facilities Management, room C03 Golding, ext. 2805, prior to submission. Alterations cannot be made on short notice; therefore, advance planning and budgeting are essential.

INDUSTRY SPONSORED RESEARCH

All industry sponsored research agreements are negotiated by the Office of Biotechnology. Faculty are encouraged to consult the Office of Biotechnology (room 908, Belfer, ext. 3357) as early as possible when contemplating collaborating with industry regarding research projects. As research sponsored by industry incurs the same overhead costs as research funded by the National Institutes of Health (NIH), privately funded research budgets must bear the same overhead rates as specified in the Department of Health and Human Services agreement with Einstein. Exceptions may be made for small projects with limited budgets. The College’s regulations in this regard (Administrative Policy No. 4.4) may be obtained from Grant Accounting or the Administrator. Clinical trials funded by pharmaceutical companies must be approved by the Institutional Review Board (IRB) and university counsel according to the principles described in the section on “Human Subjects.”

PATENTS AND COPYRIGHTS

All faculty members, trainees, students, and staff are subject to the College’s Policy on Patents and Licensing Agreements. All faculty members and trainees and are required to sign an agreement accepting its provisions. The Policy, which was written to conform to federal law and NIH regulations, mandates that all inventions that are related to work at the College must be disclosed to the Patent Committee and assigned to Einstein. If the Dean decides to patent and/or license the invention, two-thirds of the net income from such inventions are returned to the inventor in the form of both direct remuneration and research support. For additional information, consult the Patent Committee, room 908, Belfer, ext. 3357.