

## GOVERNORS STATE UNIVERSITY

### Policy for Protection of Human Research Subjects

#### I. Rationale

The purpose of the Institutional Review Board (IRB) is to ensure the protection of human research subjects. Federal regulation, *Title 45, Code of Federal Regulations, Part 46*, requires that all institutions receiving federal funds and conducting research using living humans as subjects establish and operate an IRB. Projects which originate at Governors State University involving human subjects are subject to review and approval by the IRB. IRB review shall determine:

- A. that the rights and welfare of the subjects involved are adequately protected;
- B. that the risks to an individual, whether physical, psychological or social, as a consequence of any activity which goes beyond the application of accepted routines necessary to meet his/her needs, are outweighed by potential benefits to the individual and/or to the society; and
- C. that legal, informed consent is obtained by methods that are appropriate and adequate.

IRB approval or a determination that the project is exempt from IRB review must be obtained before any research involving human subjects is initiated. All faculty, students, and staff must adhere to the procedures established by the IRB. These procedures are available from the Office of the Provost.

#### II. Ethical Principles

Governors State University is guided by ethical principles regarding all research involving human subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, entitled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (also known as the Belmont Report).

The three primary principles for protection of human subjects established in the Belmont Report are:

##### A. Respect for Persons:

Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished

autonomy.

#### B. Beneficence:

Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do no harm, and (2) maximize possible benefits and minimize possible harms.

#### C. Justice:

An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are: (1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, and (5) to each person according to merit.

Other principles that may guide Governors State University in protecting the rights and welfare of human subjects are found in the existing codes of federal, state, and local agencies, and in the codes of conduct of professional organizations including, but not limited to:

1. Vol. 45 *Code of Federal Regulations* Part 46 Dept. of Health and Human Services Regulations for the Protection of Human Subjects, Final Regulations, Subparts A-D, as well as those of other applicable federal, state, and local agencies;
2. 21 CFR Parts 16, 20, 50, 312, 809, and including 812 Medical Devices;
3. 34 CFR Part 97 (Basic ED Policy for Protection of Human Research Subjects).

### **III. Institutional Policy**

A. The University will establish and maintain an Institutional Review Board (IRB).

B. The IRB will review all research involving human subjects, and will approve only those research protocols that comply with its requirements for approval.

C. All of the following research activities involving human subjects are subject to the

review and approval of the IRB. This includes research that is

1. Sponsored by the University, or
2. Conducted by or under the direction of any employee or agent, including students, of the University in connection with his or her University responsibilities, or
3. Conducted by or under the direction of any individual or agent using the property or facilities of the University. Projects being conducted on Governors State University premises but not directed by a Governors State University employee must be approved by the Governors State University IRB.

D. The IRB will establish and implement procedures for the review of research involving human subjects. These procedures will detail the processes to be used for:

1. The initial review of a newly proposed research protocol, including the classification of that protocol (i.e., exempt from, expedited, or full) and the manner for its review by the IRB;
2. The review of proposed modifications to approved research protocols;
3. The consideration of requests for the continuation and/or extension to approved protocols nearing the end of their approval periods;
4. The investigation reports of possible harm to human subjects and/or possible non-compliance by any person covered by this policy, including the suspension or termination of approved protocols and reporting to necessary offices/agencies; and
5. Procedures and forms for Human Subjects Research constructed in compliance with federal regulations.

E. The IRB will approve research protocols involving human subjects that meet the following criteria:

1. Risks to the subjects are minimized;
2. Risks to the subjects are reasonable in relation to the anticipated benefits;
3. Selection of the subjects is equitable;
4. Informed consent is sought from each prospective subject or the subject's legally authorized representative;

5. Informed consent is documented;
6. When appropriate, the research plan includes adequate provision for monitoring the data collected to ensure the safety of the subjects;
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data; and
8. Additional safeguards are included in the study to protect the rights and welfare of subjects likely to be vulnerable to coercion or undue influence, such as: children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

F. The IRB may stipulate conditions for the approval of human subjects research, including specific requirements for the monitoring of human subject rights and/or welfare and limited periods of approval prior to re-authorization. The IRB may temporarily suspend its approval for research pending an investigation of potential harm to human subjects. The IRB may terminate its approval for any research following an investigation of potential harm to human subjects.

G. The IRB will comply with federal, state, and local laws as they might relate to the activities covered by this policy.

#### **IV. Review**

A. Any IRB review may conclude in one of four ways:

1. “Approved” means that neither minor nor major errors or difficulties were detected in the application; the Principal Investigator may proceed with the research study;
2. “Conditional Approval/Resubmit to IRB Chair” means that there were minor errors or difficulties that must be clarified, corrected and resubmitted to the IRB Chair before the research study may proceed. The IRB Chair or designee will review the corrected application and report back to the full IRB committee and the Principal Investigator with the second determination. If the second determination results in another “Conditional Approval/Resubmit to IRB Chair”, the Principal Investigator may be required to meet with either the IRB Chair or designee or the full IRB committee.
3. “Conditional Approval/Resubmit to Provost” means that there were major errors or difficulties or several minor errors/difficulties that must be clarified and corrected. The Principal Investigator must resubmit seven (7) copies of the corrected application to the Provost. The Provost will review the corrected application, and, if it meets criteria for program relevance and public responsibility and

contains no real or apparent conflict of interest the Provost will forward the application copies to all IRB members. The Principal Investigator will be required to attend a full IRB review of the corrected application. Corrected applications will either receive (1) an “Approved” status – in which case the Principal Investigator may proceed with the research study, or (2) a “Disapproved” status – see #4 below.

4. “Disapproved” means that there were catastrophic errors in either the research design and/or the protection of the rights and welfare of human subjects. Any research application that receives a “Disapproved” status – regardless of the review “type” of the first submission – must be clarified, corrected, and resubmitted for full IRB review. The Principal Investigator must resubmit an entire, new and revised application (original and six copies) to the Office of the Provost and must attend the full IRB review. Corrected applications will either receive (1) an “Approved” status – in which case the Principal Investigator may proceed with the research study, or (2) a “Disapproved” status – in which case the Principal Investigator must resubmit a complete application for another Provost and full IRB review.

This review may end with the IRB asking for specific changes, further clarification, giving approval after certain changes, or simple approval. Project approval is based on majority vote. The principal investigator may be asked to be present for clarification. University General Counsel is available to clarify reading of applicable law.

## **V. Investigation and Reporting Responsibilities**

- A. The IRB will have the authority to and will, at its discretion and for any reason whatsoever, investigate any activity, persons, or records covered by this policy. The IRB will investigate all unanticipated problems involving risk and/or injury to human subjects.

The IRB Chairperson, or his or her designee, may:

1. Interview a principal investigator, co- investigator(s), subject or any other person connected with research involving human subjects;
  2. Examine the research records involving human subjects, including informed consent documents and collected data; and
  3. Inspect any facilities, laboratories, equipment, or supplies used in human subjects research.
- B. The IRB will prepare and maintain adequate records of its activities.

C. The IRB will report promptly to the Governors State University Provost and, if appropriate, the federal Office of Human Research Protections (OHRP) or other state or federal office(s), knowledge of:

1. Any serious or continuing noncompliance with the requirements of the IRB;
2. Any suspension or termination of IRB approval of a research protocol;
3. Injuries to human research subjects; and
4. Any changes in the membership of the IRB to agencies with which the University has filed an assurance.

D. The IRB will require investigators to:

1. Promptly report all unanticipated problems involving risks or injury to human research subjects or others;
2. Initiate no changes to a research protocol previously reviewed and approved by the IRB without requesting and receiving an IRB review and approval for those specific modifications; and
3. Maintain complete records of all research activities involving human subjects research.
4. File a final report with the IRB.

## **VI. Institutional Review Board (IRB) Membership**

The Institutional Review Board (IRB) is delegated by the Provost/Vice President for Academic Affairs and convened by that office as defined by statute.

- A. The IRB shall consist of at least seven members, who are individuals with various experiences and skills, which are defined by statute, in evaluating human research and its institutional, legal, scientific and social implications.
- B. There shall be at least five faculty members appointed by the Faculty Senate, one shall be from each of the four colleges and one shall be from Library/Student Affairs and Services/CELCS.
- C. The members of the IRB shall serve two-year terms. The Chair of the (IRB) will be elected by IRB members every two years. Consecutive terms are allowable.

- D. The IRB shall include at least one member whose primary concerns are in a scientific discipline, and at least one member whose primary concerns are in nonscientific areas. (These shall be among the five recommended by Faculty Senate.)
- E. Each IRB shall include at least one member who is not affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. The Office of the Provost shall appoint this person upon recommendation from the IRB..
- F. The IRB shall include at least one member who is a practicing physician. The Office of the Provost shall appoint this person upon recommendation from the IRB.
- G. IRB membership shall be diversified with regard to race, gender, and cultural backgrounds. To ensure this diversity the Office of the Provost shall provide additional members. The Office of the Provost shall appoint additional persons with expertise to review specific proposals as recommended by the IRB.
- H. All persons acting as IRB members or researchers must be properly qualified (through education and experiences) and trained to conduct their duties. GSU requires that each member of the IRB have on file a current resume or curriculum vitae attesting to their personal education and experiences. In addition, each member of the IRB is required to participate in annual training.

## **VII. Meetings**

- A. Regular scheduled meetings of the IRB will be held monthly or as needed to conduct the timely review of proposed human subjects research. A special meeting of the IRB may be called by the Chairperson (or his or her designee in his or her absence) to consider any matter related to the protection of the rights and welfare of human research subjects.
- B. A quorum shall be 50% of the members of the committee plus one. A quorum must be present at a meeting for any action to be taken by the IRB. A majority of those present at any meeting at which a quorum is present is necessary for the IRB to approve any action.

## **VIII. University Responsibilities**

- A. The university will provide adequate administrative support and oversight for the activities of the IRB, including the preparation and maintenance of adequate documentation of IRB activities. This includes, but is not limited to:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects;
  2. Minutes of IRB meetings which will be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the notes on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution;
  3. Records of continuing review activities;
  4. Copies of all correspondence between the IRB and the investigators;
  5. A list of IRB members containing the detail required by federal regulations;
  6. Written procedures for the IRB.
  7. With the assistance of the IRB, education and training regarding human research policies and procedures.
- B. The records required by this policy will be retained for at least three (3) years, and records relating to research that is conducted, will be retained for at least three (3) years after the completion of the research. All records will be accessible for inspection and copying by authorized representatives of the federal Office of Human Research Protections (OHRP) or other state or federal office(s) at reasonable times and in a reasonable manner.
- C. The University will provide adequate meeting space for the IRB.

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