

***Policies and Procedures for Human Subject Research***

**June 1997**

## **Procedures for the Review of Human Subjects Research**

### **I. General Description of the System of Review of Research Involving Human Subjects**

In accordance with Federal Regulators, (45 CFR 46 as amended) all research, development and related activities involving human subjects must be reviewed prior to conducting any research.

Research studies which involve human subjects may include the following categories:

1. School Surveys and the evaluation of teaching methods.
2. Video tape studies in which the individual will be identifiable.
3. Studies in which the subject will be technically “at risk” whether in a real or technical sense.

In order to carry out these responsibilities, an Institutional Review Board known as the Committee for Protection of Human Subjects, exists. The Committee is required to perform in the following manner:

#### **A. Review of New and Ongoing Projects**

The committee will meet for review of new applications on a timely basis, and review continuing projects annually to make certain that the research is following acceptable guidelines.

#### **B. Composition of the Committee**

The Committee will consist of at least seven members appointed by the President. The chairman will be appointed by the President. A quorum consists of four members of the Committee. The Committee may include appropriate faculty members, lawyers, a behavioral scientist, a

social scientist, a physician (if proposals involve medical research), a member of the community, Director of Sponsored Programs.

C. Review Procedure

In reviewing a proposal for a research project involving human subjects, the Committee members will consider the information provided by the principal investigator to determine the following:

1. Assess any potential risk; physical, psychological, social, legal, economic and evaluate the likelihood and seriousness of the risks.
2. Ascertain that the rights and welfare of the individuals will be protected.
3. Ascertain that legally effective informed consent will be obtained by adequate and appropriate methods.
4. The risks to the individuals are outweighed by the potential benefits to him/her and by the importance of the knowledge gained.
5. Acceptability of the research project in terms of institutional commitments and regulations.

D Options

1. The Committee may approve the proposal.
2. The Committee may require minor to major changes.
3. A request for outside consultant review. Ordinarily the consultant will not be a member of the same department as the principal investigator and not be a participant on the proposed project.

4. Disapproved – When a project is rejected, the principal investigator must revise the proposal in accordance with the committee’s recommendations, or withdraw the project.

E. Voting

Action on any of the options requires a majority vote for the members present. IRB members cannot vote on projects with which they are associated.

F. Hearings

The IRB will request the appearance of a proposed principal investigator at its review of the projects.

G. Expedited IRB Review.

The IRB may perform expedited review for certain studies involving no more than minimal risk\* and for minor changes in approved research. Under expedited review, the chairperson, or one or more experienced IRB reviewers designated by the chairperson, may exercise all the authorities of the IRB except disapproving research.

Action taken under expedited review shall be reported at the next full IRB meeting, and writing to the appropriated investigator.

\*Minimal risk, as defined by the Federal Regulations would permit the following research activities to be reviewed by the expedited review procedure.

1. Collection of hair, nail clippings, teeth.
2. Collection of excreta, external secretions, placenta at delivery, amniotic fluid at time of rupture.

3. Recording of data from subjects 18 years of age and older but does not include invasion of the subject's privacy, exposure to radiation (i.e. x-rays, microwaves).
4. Collection of blood samples by venipuncture from subjects 18 years of age and older, who are in good health and not pregnant.
5. Collection of dental plaque and calculus provided the procedure is not more invasive than routine prophylactic scaling of the teeth.
6. Voice recording.
7. Moderate exercise by healthy volunteers.
8. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.
9. The study of existing data, documents, records, specimens.

The list has established by the FDA and subject to amendments published in the Federal Register.

## II. General Responsibilities of the Investigator

The following general responsibilities of the principal investigator involved in human subjects is intended for general guidance.

- A. The principal investigator will need to complete appropriate project questionnaire involving human subjects.
- B. He/She will refrain from starting the research project involving human subjects until review is complete and approval is received.
- C. He/She will design and implement research in such a manner as to exclude or minimize risk to human subjects.

- D. Appropriate professional competence and adequate facilities must be employed in all research involving human subjects.
- E. Any modification of the research project must be submitted to the IRB for review prior to implementation.
- F. He/She will obtain from each human subject informed consent to participate in the project's goals and procedures.
- G. It is the principal investigator's responsibility to establish and maintain a complete record of the history and procedures of his/her research project. Under federal regulations (45 CFR 46 as amended) the original signed copy of the consent form must be kept on file.

All documentation from the review committee are to be part of the official institute file for that activity.

Lauren Rethwisch, Director of the Office of Sponsored Programs will be responsible for implementing the policy concerning the use of human subjects.

Procedures for Protection of Human Subjects Committee

March 4, 1981

## Procedures for Protection of Human Subjects Committee

1. The Committee for the Protection of Human Subjects will send copies of the minutes of its meetings to the Vice President for Academic Affairs, the Academic Deans, to Members of Committee on Bio-Hazards, and to Members of Committee on Bio-Hazards, and to Members of Committee on Campus Services Committee.
2. If the Committee for the Protection of Human Subjects rejects a proposal for violating Institute's procedures for dealing with human subjects a written report recommending changes in the proposal or in extreme cases reasons for withdrawal of the proposal will be sent to the Associate Vice President for Research and Graduate Studies, appropriate Dean, Department Chairman, and Principal Investigator.
3. The Committee for the Protection of Human Subjects may recommend that certain major or minor changes be made on the proposal. A written report on the proposed changes will be sent to the Associate Vice President for Research and Graduate Studies. The Associate Vice President for Research and Graduate Studies will send the copy of the report to appropriate Dean, Department Chairman, and to the Principal Investigator.
4. If there is a request for an "outside specialized consultant" to review the proposal. The consultant shall not be a member of the same department as the principal investigator and shall not be a participant on the proposed project. The Consultant's report on the proposal will be sent to the Committee for the Protection of Human Subjects. The Committee will send copies of the report to the Associate Vice President for Research and Graduate Studies, appropriate Dean, Department Chairman, and Principal Investigator.
5. The appropriate Dean and the Associate Vice President for Research & Graduate Studies will discuss with the Department Chairman and the Principal Investigator the recommended changes made by the Committee for the Protection of Human Subjects.
6. Any modification of the research project must be submitted to the Committee for the Protection of Human Subjects for review prior to implementation.

7. The Committee will file written report with the Associate Vice President for Research and Graduate Studies concerning corrective action taken.
8. The Director of Sponsored Programs will be a member of the Committee for the Protection of Human Subjects. The Director will be responsible for keeping the members informed of the activities of the Bio-Hazards and Radiation Committee, and the Institute Services Committee.
9. The Office of Sponsored Programs will be responsible for maintaining the files of the committee i.e. reports, procedures and all changes in federal regulations with regard to Committee and all changes in federal regulations with regard to Committee for the Protection of Human Subjects.
10. Each faculty member will receive a copy of the Policies and Procedures manual for the Protection of Human Subjects. He/she will be responsible for making sure that he/she is following the required Institute procedures and is in compliance with the federal government regulations.

Policies for Human Subject Research

Prepared by  
Judith W. Ennis  
Director of Sponsored Programs

November 19, 1980

## Procedures for the Review of Human Subjects

### I. General Description of the System of Review of Research Involving Human Subjects

In accordance with NJIT policy under HEW regulations OPHR Reports (45 CFR 46 as amended) all research, development and related activities involving human subjects must be reviewed prior to conducting any research.

Research studies which involve human subjects may include the following three categories:

1. School surveys and many types of studies involving the evaluation of teaching methods.
2. Video tape studies in which the individual will be identifiable, and questionnaire studies would be another example.
3. This category includes studies in which the subject will be technically “at risk” whether in a real or technical sense.

In order to carry out these responsibilities, an Institutional Review Board known as the Committee for Protection of Human Subjects will be established. The Committee is required to assure the following:

#### A. Receipt or Review Projects

The committee will meet for review of new applications on a timely basis, and review continuing projects annually to make certain that the research is following acceptable guidelines.

#### B. Composition of the Committee

The Committee will consist of at least seven members appointed by the President. The chairman will be appointed by the President. A quorum consists of five members of the Committee. Committee members include appropriate faculty members, lawyers, a behavioral scientist, a social scientist, a physician (if proposals involve medical research), a member of the community, Director of Sponsored Programs.

C. In reviewing a proposal for a research project involving human subjects, the Committee members will consider the information provided by the principal investigator on Form A to determine the following:

1. Assess any potential risk, physical, psychological social, legal, economic and evaluate the likelihood and seriousness of the risks.
2. The rights and welfare of the individuals will be protected.
3. Legally effective informed consent will be obtained by adequate and appropriate methods.
4. The risks to the individuals are outweighed by the potential benefits to him and by the importance of the knowledge gained.
5. Acceptability of the research project in terms of institutional commitments and regulations.

D. Options

1. The Committee may approve the proposal.
2. The Committee may require minor or major changes.
3. A request for “outside specialized consultant” review. Ordinarily the consultant will not be a member of the same department as principal investigator and not be a participant on the proposed project.
4. Disapproved – When a project is rejected, the principal investigator must revise the proposal and in accordance with the committee’s recommendations, discuss project with committee, or withdraw the project.

E. Voting

Action on any of the above options requires a majority vote of the members present. IRB members cannot vote on projects with which they are associated.

F. Hearings

The IRB may request the appearance of a proposed principal investigator at its review of the project.

II. General Responsibilities of the Investigator

The following general responsibilities of the principal Investigator involved in human subjects are intended for general guidance.

- A. The principal investigator will need to complete Form A if he will be engaging in behavioral or biomedical research involving human subjects.

- B. He will refrain from starting the research project involving human subjects until review is complete and approval is received.
- C. He will design and implement research in such a manner as to exclude or minimize risk to human subjects.
- D. Appropriate professional competence and adequate facilities must be employed in all research involving human subjects.
- E. Any modification of the research project must be submitted to the IRB for review prior to implementation.
- F. He will obtain from each human subject informed consent to participate in the project after providing a full explanation of the project's goals and procedures.
- G. It is the principal investigators responsibility to establish and maintain a complete record of the history and procedures of his research project. Under federal regulations (HEW-45 CFR 46 as amended) the original signed copy of the consent form must be kept in the grant/contract file.

All documentation concerning instruction, guidelines, from the review committee are to be part of the official institute file for that activity.

Ms. Judith Ennis, Director of the Office of Sponsored Programs will be responsible for implementing the policy concerning the use of human subjects.