# New York Institute of Technology

## Human Research Protections Program

# PROCEDURES AND GUIDELINES MANUAL

## Volume 1

## IRB Operations

Updated 7/2004 and 9/2013

`TABLE OF CONTENTS

## NYIT Institutional Review Board for the Protection of Human Participants (IRB)

### I. IRB Mandate - Human Studies Protection at NYIT.

Evolution of modern concepts of human participants protection began with the Nuremberg Code developed for the Nuremberg Military Tribunal following World War II. The Code defined basic principles governing the ethical conduct of research involving human participants, including the essentiality of voluntary consent and comprehension of the risks and benefits involved in experimentation involving human participants. Since then, regulations have been set forth by the World Medical Association in its Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Participants, adopted in 1964.

In 1974, the US Congress passed the National Research Act, establishing the National Commission for the Protection of Human Participants in Biomedical and Behavioral Research. In 1978 the Commission published the Belmont Report, setting forth the basic ethical principles that should underlie the conduct of both biomedical and behavioral research involving human participants; these three principles are:

- *Respect for persons* – involves a recognition of the personal dignity and autonomy of individuals, and special protection for those persons with diminished autonomy and underlies the need to obtain informed consent
- *Beneficence* – entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm and underlies the need to engage in risk/benefit analysis.
- *Justice* – requires that the benefits and burdens of research be distributed fairly and that participants be fairly selected.

The report distinguished between "research" and "practice":

- *Practice* constitutes "interventions that are designed solely to enhance the well-being of an individual participant or client and that have a reasonable expectation of success." The purpose of medical or behavioral (including educational and marketing) practice is to provide diagnosis, preventive treatment, therapy, or education to particular individuals, that is, practice is designed to benefit specific individuals.
- *Research* is described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective, and is inherently intended to generate new knowledge. Experimental procedures do not necessarily constitute research and research and practice may occur simultaneously. The Belmont Report suggests that the safety and effectiveness of such "experimental" procedures should be investigated early and that institutional oversight mechanisms, e.g. IRB's, ensure that the need is met by requiring that "major innovation[s] be incorporated into a formal research project."

The Department of Health and Human Service (DHHS) regulations for protection of human participants are codified at Title 45 Part 46 of the Code of Federal Regulations of January 16, 1981, revised 1983 and 1991. The 1991 revision involved adoption of the Federal Policy for the Protection of Human Participants by the sixteen federal agencies that conduct, support, or otherwise regulate human participants research. The Food and Drug Administration (FDA) also adopted certain of its provisions. FDA regulations are codified at Title 21 Parts 50 and 56 of the Code of Federal Regulations. Additional FDA regulations relevant to IRB review of research are Parts 312 (Investigational New Drug Application), 812 (Investigational Device Exemptions) and 860 (Medical Device Classification Procedures). These regulations are mirrored for the Department of Education under Title 34 Part 97 - Protection of Human Participants.

Subsequently, the New York Institute of Technology has made the cited federal policy applicable to all research involving human participants without consideration of funding sources in all of its divisions.

## II. Jurisdiction of the NYIT Institutional Review Board

A New York Institute of Technology (NYIT) IRB was established to protect the rights and welfare of human research participants participating in research conducted under the auspices of NYIT and any of its components.

IRB review is required for all research involving human participants, if:

- The research is sponsored by NYIT; or
- The research is conducted by or under the direction of any employee or agent of NYIT in connection with his or her institutional responsibilities; or
- The research is conducted by or under the direction of any employee or agent of NYIT using any property or facility of NYIT; or
- The research involves the use of NYIT's non-public information to identify or contact human research participants or prospective participants.

The IRB starts the review process by considering two fundamental questions;

- whether the activity involves research and
- whether it involves human participants.

Proposals that include both of these elements *in any measure* fall under the jurisdiction of the IRB.

Research that has been reviewed and approved by the IRB may be subject to further review and disapproval by other officials of NYIT. However, institutional officials may not approve research if it has been disapproved by the IRB. Furthermore, approved research is subject to continuing IRB review.

An IRB has authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and institutional policy. The IRB makes an independent determination whether to approve or disapprove the protocol based upon whether or not human participants are adequately protected, possible benefits exceed the risk involved, and that participants are selected fairly.

## III. Definitions

- Research is defined as "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities". This applies to all investigations including physical and psychological studies, review of medical records, and questionnaires and surveys. Case studies or single treatment studies may constitute research.
- Human participants are defined as "living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information".
- Human participants research includes, but is not limited to, studies with tissues, fluids, or other material removed from a living human, as well as a wide range of medical, behavioral, biological and epidemiology studies. Investigators are encouraged to contact the IRB for guidance in determining whether a particular study is considered human participants research.
- Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes.
- Interaction includes communication or interpersonal contact between investigator and participant.
- Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public or shared with others (for example, test results, questionnaire responses, medical records). Private information is individually identifiable (i.e., The identity of the participant is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human participants.
- Experimental Therapies are interventions intended to benefit an individual patient or client whose safety or efficacy have not been established to the point where they may be considered standard practice.

The IRB will consider whether a proposed new therapy or treatment activity requires IRB review, pursuant to both federal regulations and institutional policy. Research itself is not therapeutic, and research interventions may or may not be beneficial. Since the NYIT IRB reviews all research, it may sometimes be required to determine whether a particular activity performed with therapeutic intent is research and should be reviewed. It may also be required to determine whether a formal research protocol should be developed (and reviewed by the IRB) for a new or non-validated procedure that is being used for therapeutic purposes within the institution.

## IV. Authorized Institutional Official

The President of the New York Institute of Technology, Dr. Edward Guiliano, has the legal authority to act and speak for the institution and to ensure that it can effectively fulfill its

research oversight function. This authority may be delegated by the president so long as the designated official has full legal authority to speak for the school and the appropriate credentials and training. The president has designated the Provost to appoint IRB members and oversee the IRB functions.

## V. Composition of an NYIT Institutional Review Board

NYIT has established two Institutional Review Boards: the Educational, Social Science & Behavioral Research (ESB) IRB, and the Biomedical and Health Sciences Research (BHS) IRB. NYIT's Institutional Review Boards have been established and registered with the Office of Human Research Protections (OHRP) to assure compliance with federal regulations.

### A. Chair

The Chair should be an experienced member of the IRB who is familiar with the regulatory requirements, the design and conduct of human research, and ethical considerations.

The Chair's duties shall include presiding at meetings of the IRB and any other duties identified in this Manual. The Chair may, from time to time, delegate certain duties to other members of the IRB. Duties of the Chair identified in this Manual may therefore also be performed by other members as designated by the Chair.

### B. Deputy Chair

A deputy chair may be appointed by the Institutional Official or designee. The deputy chair will serve as an additional resource to the Chair and other members and have the same authorities as the Chair when chair is not available.

### C. Membership

In accordance with Federal Policy, each NYIT IRB is comprised of at least five members with varying backgrounds.

OHRP mandates that "The IRB must be and must be perceived to be fair and impartial, immune from pressure either by the institution's administration, the investigators whose protocols are brought before it, or other professional and nonprofessional sources." Membership must be consistent with this policy.

Members are appointed by the Institutional Official or designee for a period of three years. Memberships may be renewed.

Membership includes at least one of the following:

- A professional scientist and member of the NYIT research community,
- A member not affiliated with the institution,
- A member whose primary concerns are in non-scientific areas and who is not engaged in research.

The NYIT IRBs include members of both genders, with diverse experiences and expertise.

A member is expected to attend at least two-thirds of the regularly scheduled meetings of the IRB. Participation by telephone conference call constitutes attendance.

Members are expected to review carefully all materials provided in connection with IRB activities and to participate actively in convened meetings. All members must complete a training course in the purpose and functions of the IRB prior to beginning their duties, and certify that they have completed such course.

OSPAR will maintain a list of IRB members and make it available on the IRB website (http://iris.nyit.edu/sponsoredprograms).

### D. Designated Alternates and Ad Hoc members

Designated alternate IRB members may be used. To ensure maintaining an appropriate quorum, the alternate's qualifications should be comparable to the member to be replaced. When alternate substitutes for a member, the alternate must have received and reviewed the same material that the member received or would have received. IRB members are responsible for contacting their alternates if they cannot attend a meeting. Alternate members may conduct expedited reviews if designated by the Chair. The IRB minutes should document when an alternate replaces a member at a meeting.

The IRB also has the option, when reviewing research that involves a vulnerable category of participants, including children, students, prisoners, pregnant women, handicapped or mentally disabled persons, to include one or more individuals knowledgeable about and experienced in working with these participants on an ad hoc basis.

In accord with the Department of Education (ED) regulations, when the IRB reviews research for one of its programs that purposefully requires inclusion of disabled persons as research participants, the IRB will include at least one person primarily specifically concerned with the welfare of these participants.

### E. Conflicts of Interest

No IRB member will participate in the review of any project in which the member has *present or potential conflict of interest*, except to provide information requested by the IRB. Any such member will be absent from the room during deliberation and voting phases of the review and approval process. IRB minutes will reflect that these requirements have been met in such circumstances.

Members of the faculty or administration who, by virtue of the intrinsic interests of their position or responsibilities, may be perceived as having a real or potential conflict of interest with a broad range of projects shall not be members of an IRB.

## VI. Administration of the IRB

The Office of Sponsored Programs and Research (OSPAR) administers the IRBs. The Director of the OSPAR has been designated the Human Protections Administrator (HPA). OSPAR shall work with the IRBs to ensure consistency within the institution and compliance with Federal regulations.

### A. Staff, Space, Supplies and Communication

The IRB shall be supported by adequate administrative staff, who shall educate and communicate with investigators and oversee and manage the records of the IRB. The staff shall be supervised by the HPA who shall have professional credentials, skills and IRB experience appropriate to the duties of the position. The HPA cannot, by federal regulations and terms of the FWA, serve as chair of an IRB.

Open communication will be maintained at all levels. The IRB encourages staff, participants and other interested parties to communicate information about the conduct of a research project to IRB members, department heads, Deans and other institutional officials. These individuals with responsibility for oversight of research have open access to the highest levels of authority within the institution, including the office of the President.

### B. Training

All key personnel on research projects are required to complete a training program before beginning work on a project. No project will be approved without documentation of the completion of the training by the Principal Investigator.

The training module can be completed online and accessed via the OSPAR web site at http://iris.nyit.edu/sponsoredprograms.

IRB members receive a "Member Handbook" and are encouraged to attend national meetings sponsored by OHRP or professional organizations related to human subjects research. New members will receive an orientation by the HPA and IRB Chair(s).

### C. Internal and External Audits

NYIT has adopted self-assessment procedures and practices to assure proper protocol and consent document preparation, protocol submission, review and approval by the IRB and timely monitoring of protocol implementation. These practices are:

- Consent documents are stamped with an expiration date to ensure that the form is not used beyond the expiration date.
- Standardized language for consent documents that meet minimal regulatory requirements is provided. Each investigator should use the consent form template to create an appropriate informed consent document.
- IRB minutes and records are available for routine site visits and audits conducted by federal officials, sponsors of research, and other organizations that assure regulatory compliance, but are generally held to be confidential for the protection of the participants and the integrity of the research.
- An annual report on IRB activities is submitted to the Provost and the Institutional Official.
- Biennial audits are conducted by the Office of Internal Audit and Process Re-Engineering
- OHRP quality improvement tools are used for self-assessment of the IRB.

## VII. IRB Responsibilities

### A. Ethical Standards of the IRB

The IRB's foremost consideration is to safeguard the rights and well-being of human participants. Therefore, the ethical implications of the proposed procedures must conform to the DHHS regulations, The Belmont Report, and the Helsinki Declaration adopted by the World Medical Assembly (1964 rev. 1975).

### B. IRB Review

In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

- Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

- Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

- Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

- Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Primary among the responsibilities of the IRB when reviewing research protocol are to assure that:

- Risks to the participant are minimized and superceded by the possibility of benefit to the participant.
- Informed consent has been based on adequate information given to and understood by the participant without pressure or fear of penalty.
- The medical, legal and personal rights of each participant will be adequately protected and confidentiality assured.

Intrinsic to these specific considerations is an evaluation of the credentials of the investigator(s) and the quality of the research project. While an IRB may in part rely on evaluation by outside agencies, approval by outside agencies is insufficient on its own. For example, approval for funding by a Federal or private source does not relieve the IRB of this obligation. The criteria to be met in the research design consideration by the IRB must address the following issues:

- The appropriateness of the background and knowledge of the primary investigator to the project;

- Manner of educating the participant regarding experimental procedures and the anticipated results;
- The conditions set for participant selection must be unbiased, equitable and cannot significantly medically compromise the participant;
- The degree of medical or psychological invasiveness;
- The participation of other medical professional other than the primary investigator;
- The appropriateness of the facilities to the research project;
- Contingency plans in case of adverse reaction to the experiment (when applicable);
- Clearly defined research objectives with an adequately controlled study;
- Evaluation of experimental progress; recording and retention of data;
- Monitoring of experimental progress;
- Application or use of experimental results;
- Timetable for experimental design;
- Participant financial remuneration (when applicable);
- The issue of confidentiality, access to the resultant data and experimental replication.

## 1. Procedures

Protocols should be submitted to the Office of Sponsored Programs and Research according to the instructions that accompany the forms. The HPA and Chairs will determine which IRB is appropriate to conduct the review.

### a. Exempt Protocols

Protocols that appear to qualify for exempt status will be reviewed by the Chair or designee. If the Chair or designee finds the protocol to be exempt, the HPA will send a letter notifying the PI of the exemption and exemption category. No other action is required.

### b. Non-Exempt Protocols

New and continuing protocols that do not qualify for exempt status will be reviewed by the full committee using a primary reviewer system or, if they fall within the expedited review categories, by the Chair and/or one or two other IRB members. The materials submitted to reviewers under the expedited procedures will be the same as those described for protocols reviewed at a convened meeting (below).

Reviewers of expedited protocols are expected to:

- Review the protocol in detail according to the standards outlined in 45 CFR 46 using the Review Checklist
- Review the Informed Consent documents and procedures for compliance with 45 CFR 46
- Contacting the Principal Investigator about questions or concerns about the protocol
- Make a recommendation in writing to the Chair for conditional approval or approval. The reviewer may also refer the protocol to the full committee for review. In this case the protocol will be reviewed at the next scheduled IRB meeting. A copy of the recommendation(s) should also be sent to the HPA.

Protocols that require review by the full IRB will be reviewed at a regularly-scheduled IRB meeting. One member will be designated the primary reviewer. Primary reviewers will be selected by the Chair(s) based on appropriate research expertise.

Primary reviewers are responsible for:

- Reviewing the protocol in detail according to the standards outlined in 45 CFR 46 using the Review Checklist
- Reviewing the Informed Consent documents and procedures for compliance with 45 CFR 46
- Contacting the Principal Investigator about questions or concerns about the protocol
- Presenting the protocol at the IRB meeting

Primary reviewers will be assigned for both new and continuing protocols.

### i. New Protocols

Generally, if more than minimal risk is involved or there are sustantative concerns by IRB members, the chair may invite the principal investigator for a scheduled time within the IRB meeting where the proposal can be presented in order to answer questions and address the critiques.

Protocols that require review by the full IRB will be reviewed at a regularly-scheduled IRB meeting. A majority of members must be present including at least one nonscientific member. At least one week before the meeting the HPA will send the following items to the IRB members for review:

- IRB Application form
- Full protocol description
- Informed consent form
- Recruitment material (e.g., advertisements, recruitment letters, scripts for telephone conversation or focus groups etc.)
- Investigator qualifications [e.g., CV, medical licenses(s), etc.]
- Questionnaires/surveys/tests
- Other elements that may apply.

Primary reviewers will also receive:

- A copy of all related grant proposals
- A Review Checklist

### ii. Continuing protocols

Continuing protocols that do not qualify for expedited review will be reviewed at IRB meetings. At least one week before the meeting, IRB members will receive:

- The Protocol Renewal Form and attachments
- The current approved informed consent document(s)

Primary reviewers will also receive:

- A copy of all related grant proposals
- A copy of the current approved protocol including all previously approved modifications
- A Review Checklist

All members will have access to the complete file before or during the meeting.

### iii. Protocol Modifications

Modifications to approved protocols must be reviewed and approved by the IRB before they are implemented. Requests for modifications to protocols may be submitted by email or on paper to the OSPAR using the Protocol Modification form or following its outline. Minor modifications will be reviewed using expedited procedures.

The IRB defines a "minor change" as one that:

- does not change the risk/benefit ratio for individual subjects;
- does not substantially alter the IRB's original conditions for approval; and
- would probably not impact on a subject's decision to remain in the research.

Significant changes will be reviewed by the IRB at a convened meeting at which a quorum is present.

Minor and significant modification requests will be assigned to a primary reviewer designated by the Chair(s) and who will receive:

- The request for modification and attached materials, if applicable
- A copy of the approved protocol and/or informed consent document(s)

Documents regarding the modification and IRB review and approval of it will be kept in the file with the original protocol. Researchers should incorporate all modifications into the protocol when submitting the protocol for renewal.

## 2. Meetings

### a. Agenda and Materials

At least one week before the meeting, IRB members will receive:

- An agenda for the meeting
- Draft minutes from the previous meeting
- Informational materials (if applicable)
- A report of protocols found to be exempt and protocols that were approved through expedited procedures since the last meeting
- Copies of protocols under review as described above

### b. Quorum

A majority of members, including a nonscientific member, must be present at the meeting.

### c. Review

The primary reviewers will be responsible for presenting the protocols and their reviews of them according to the Review Checklist. Principal Investigators may be present to describe the project and respond to questions but may not be present for deliberations and voting. The IRB may invite other guests with knowledge of the research area or population to contribute to the discussion. These guests will not be present during the vote. IRB members will discuss the project according to the standards described in section VIII.B and on the Review Checklist.

Review Checklist

1. Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.

(a) Is the hypothesis clear? Is it clearly stated?
(b) Will the research contribute to generalizable knowledge and is it worth exposing subjects to risk?
(c) Does the research design minimize risks to subjects?
(d) Would use of a data & safety monitoring board or other research oversight process enhance subject safety?
(e) Is the information for study design and statistical methods adequate?
(f) Is the proposed number of subjects adequate to answer the study questions?
(g) Will personally-identifiable research data be protected to the extent possible from access or use?
(h) Are any special privacy & confidentiality issues properly addressed?

Comment: _____

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

(a) Are reasonably foreseeable risks described?
(b) Are risks reasonable in relation to benefits?
(c) Are psychological and social risks addressed?
(d) Does the level of risk meet federal regulations for protecting children in research:

- Minimal risk **or**
- Greater than minimal risk with prospect of direct benefit **or**
- Greater than minimal risk, with no direct benefit, but generalizable knowledge?

(e) If risks are greater than minimal risks, are they minimized?

Comment: _____

3. Selection of subjects is equitable

(a) Are inclusion/exclusion criteria adequate to protect subjects?
(b) Are inclusion/exclusion criteria for each subject group described?
(c) Is there equitable gender and minority representation? If not, explain.
(d) Is the source of subjects described?
(e) Are letters of cooperation from recruitment sites provided?
(f) Does the study involve subjects from vulnerable populations?
(g) Have additional safeguards for vulnerable subjects been included?

Comment: _____

4. Informed consent will be sought from each prospective subject and will be appropriately documented.

(a) Does the informed consent document include the eight required elements?

(b) Is the consent document understandable to subjects?

(c) Is the process for obtaining informed consent appropriate?

(d) Parental consent

- Will it be obtained?
- If a waiver is requested, is it justified?

(e) Assent

- Will it be obtained?
- If a waiver is requested, is it justified?

(f) Is the timing of accent/consent appropriate to the situation?

(g) Are personnel obtaining assent/consent appropriate?

(h) Is the person obtaining consent named on the consent form?

(i) Is this person knowledgeable about the research and able to answer questions?

(j) Is assent/consent obtained verbally?

(k) Is assent/consent obtained in written form?

(l) Are plans for storage of consent documents appropriate?

Comment: _____

5. Subject privacy & confidentiality are maximized.

(a) Are study data anonymous (no way to link to the individual)?

(b) Are study data confidential (linked by code to names or medical record numbers)?

(c) Provisions to protect confidentiality:

- Are data/specimens stored without identifiers?
- Is the key to the code kept separate from data?
- Is access to research data limited to researchers?

(d) Does the project involve collection of private health information (PHI)?

(e) Is there adequate provision for monitoring the data collection to insure safety of subjects?

(f) Are provisions for protecting privacy adequate?

(g) Are the provisions for maintaining confidentiality adequate?

Comment: _____

6. Is "annual" continuing review sufficient?

Comment: _____

7. Do the research staff/investigators have appropriate expertise to perform their responsibilities in the study?

Comment: _____

### d. Approval Period

The IRB will determine the appropriate approval period (not more than 12 months) for each non-exempt protocol. The length of the approval period may be based on 1) level of risk to participants or 2) PI experience conducting research with human subjects. Other factors may also contribute to the determination of approval period.

The IRB will also determine whether the project warrants specific measures to verify ongoing compliance. This determination, and the measures, must be approved by a majority vote. Criteria for determining that verification is needed include:

- Level or type of risk to subjects
- History of non-compliance by the PI or other investigator(s)
- Indications of non-compliance on the request for renewal or other sources
- Adverse events

Measures for verification may include unannounced review of protocol files and consent documents and interviews of research personnel. (See Project Oversight.)

### e. Votes

The IRB will vote to take one of the following actions for each protocol:

- Approved
- Conditionally Approved
- Deferred
- Disapproved

A simple majority vote of those present is required.

### f. Conditional Approvals

The IRB may determine that a protocol may be approved pending fulfillment of specified conditions. These conditions may be minor or substantive. Minor conditions that require simple concurrence by the investigator(s) (such as minor wording changes in the consent documents, receipt of certificates of completion, approval letters from other institutions) may be reviewed by the HPA or an IRB member outside of the meeting. If the conditional approval is based on fulfillment of substantive conditions, the protocol should be resubmitted for review at the next meeting.

When deciding on conditional approval, the IRB will document whether the conditions are minor or substantive.

### g. Minutes

The Deputy Chair, HPA, or other member, as appropriate, will record the minutes of each meeting. The minutes will record separate deliberations, actions and votes for each protocol. Individual IRB members' votes will not be recorded. Minutes will also include:

- the attendance, including guests;
- start and end times;
- date of the meeting;
- announcements and informational items;

- review of minutes from the previous meeting and votes for approval/disapproval of those minutes; and
- review of report of protocols found to be exempt or approved under expedited procedures since the last meeting;

Minutes should include record of any change in quorum during the meeting (e.g., if a member leaves the room or meeting).

## 3. Project Oversight

The IRB will oversee non-exempt research according to 45 CFR 46. Investigators must request continuing review 45 days before the end of the approval period specified on the approval letter. Requests for continuing review will be conducted as described above.

If the need for additional verification of compliance has been determined by the IRB (see above), the IRB will conduct announced or unannounced reviews of research records or interviews with research personnel or other actions to verify compliance. In addition, the IRB may conduct random audits of research records.

## 4. Communication with Investigators, Record Keeping and Reporting

### a. Correspondence

Investigators will receive the following correspondence from the Chair(s) or HPA as appropriate:

| Correspondence to PI(s) | Signed by | Method | Copy to |
|---|---|---|---|
| Determination of exempt status | Chair | Letter | Department Chair |
| Notice of conditional approval and conditions | Chair/HPA | Letter or email | Department Chair |
| Notice of approval and approval period (with stamped copy of the approved consent form(s)) | Chair | Letter | Department Chair |
| Notice of deferral of protocol(s) to the next meeting/Request for additional information | Chair/HPA | Letter or email | IRB Chair<br>Department Chair |
| Notice of closure of protocol file | HPA | Email | IRB Chair<br>Department Chair |
| Notice of approval/disapproval of modifications | Chair | Letter | Department Chair |
| Notice of reports due, as appropriate | Chair/HPA | Email | IRB Chair |
| Notice of impending expiration (at 2 months prior to the expiration date) | Chair/HPA | Email | Department Chair |
| Notice of approval expiration | Chair/HPA | Letter | Department Chair<br>IRB Chair |

Approval letters will include the approval period, review type (expedited or full), protocol number and title, PI and co-investigators' names, a description of the process for renewal and PI responsibilities, the reporting requirements, a description of the process for modifying a protocol, and instructions for using the approved consent document.

All approval letters will also include a statement for the PI to sign indicating receipt of the letter and understanding of his/her responsibilities as PI. The signed statement should be returned to OSPAR and will be placed in the protocol file.

### b. Records

#### i Protocol Files

Each protocol file will contain:

- The initial protocol and related materials
- Associated grant proposals
- Copies of certificates of completion of the required training
- Copies of all correspondence, email or letter, pertaining to the protocol
- The review checklist completed by the primary reviewer
- Reports as required
- Modification requests
- Requests for continuing review
- Adverse event reports
- Findings of audits
- Termination reports

These records will be kept in the OSPAR for a period of 3 years beyond the termination date of the approval. Records will be accessible for review by appropriate officials.

If the IRB requests additional information or clarification from an investigator, the file will remain open for three (3) months. If there is no response within 3 months, the PI will be notified by email that the file will be closed.

#### ii IRB Records

The OSPAR will maintain files for the Federal-wide Assurance, IRB meeting minutes, IRB member appointments and training, IRB education and outreach activities, statements by the Institutional Official pertaining to human subjects research, and other IRB-related materials. These records will be maintained for at least 3 years.

### c. Reporting

The following reports of IRB activities and actions will be submitted to the Provost and the Institutional Official:

- Annual report of approved protocols and IRB education and outreach activities
- Biennial quality assurance reports by the Office of Internal Audit and Process Re-engineering

In addition, the VPAA and President will receive notification of any reports of adverse events and serious or continuing noncompliance as described in section XIII.

## VIII. HIPAA

An IRB is not necessarily authorized to function as a privacy board under HIPAA (Health Insurance Portability and Accountability Act) for research involving protected health information ("PHI"). NYIT has a separate HIPAA compliance officer, and the IRB's only current role is to certify that the investigator has taken the necessary steps to ensure compliance with this separate legislation. A copy of the certification will go to the HIPAA compliance officer.

## IX. General Limitations for Research with Human Participants

Special Considerations are enforced when research involves:

1. Pregnant women.
2. Newborns.
3. Mentally, emotionally, psychologically, physically or sociologically compromised individuals not capable or reasoned judgment in their own behalf are the participants of research.
4. Any other vulnerable population.
5. Any investigational drug or device study.
6. Any transfer of genetic material to a human participant is involved.
7. Exposure of the participant to radiation.
8. Recruitment of participants in emergency situations.
9. The research involves multiple clinical sites AND federal funding.
10. Research conducted outside of the United States.

**NO RESEARCH WILL BE UNDERTAKEN WHEREIN:**

1. In vitro fertilization is the subject of research,
2. A drug study when an Investigated New Drug number (IND #) is not on file in the IRB office.
3. Stem cells not derived from a pre-existing recognized cell line.
4. There is suspicion or accusation of scientific misconduct in any form.

## X. Collaborative and Cooperative Research

Wherein a research project involving human participants is a collaborative or cooperative endeavor between NYIT and another institution and the principal investigator is a member of that institution, it becomes the other institution's obligation to meet OHRP requirements for safeguarding the rights of human participants. Their qualified Institutional Review Board criteria, procedure and findings will be made known to NYIT for joint review in an effort to avoid procedure duplication. Even after review of another institution, an NYIT IRB may still disapprove participation of an NYIT employee in the research, but such restriction will be undertaken with utmost concern.

As previously stated, if the principal investigator is an employee of NYIT or the research is being conducted on the premises or using the facilities of NYIT, an NYIT IRB has principal responsibility for human protections.

## XI. Termination of Approval

A research project can be terminated at any time by the IRB due to:

1. An OHRP directive stopping all experimentation using human participants in specific research areas;
2. The investigator(s) failure to obtain consent and/or approval by the IRB;
3. New knowledge of risks unknown at the time of approval;
4. New or serious side effects;

5. The project not being funded if funding is required;
6. Significant deviation from the approved protocol;
7. Suspected scientific misconduct in any form.

## XII. IRB Enforcement Functions

### A. Review of Serious and/or Unexpected Adverse Events

Principal Investigators are required to report serious or unexpected adverse events to the IRB as well as the sponsor or FDA (if applicable) within five (5) working days. Principal Investigators must provide comprehensive information in their written notice.

A **serious adverse event** is defined as any event that suggests a significant hazard, contraindication, side effect, or precaution. A serious adverse event includes any event that:

- is fatal;
- is life threatening, meaning that the participant was, in the view of the Principal Investigator, at immediate risk of death from the reaction as it occurred; this definition does not include a reaction that, had it occurred in a more serious form, might have caused death;
- is a persistent or significant disability/incapacity, i.e., The event: (i) causes a substantial disruption of a person's ability to conduct normal life functions; (ii) requires or prolongs subject hospitalization; or (iii) is a congenital anomaly/birth defect; or
- is an important medical event, based upon appropriate medical judgment, that may jeopardize the participant or may require medical or surgical intervention to prevent one of the other outcomes defining a serious adverse event.

An **unexpected adverse event** is any adverse event that is not identified in severity or specificity in the consent form or proposal.

Adverse event reports are first reviewed by the Chair or the Chair's designee. Upon receipt of a report of an adverse event, the Chair or designee will decide if urgent action is necessary, and will unilaterally direct that such action be taken, to eliminate apparent immediate hazards to the human participants, including the following:

- Changes to the protocol to minimize risks to participants;
- Changes to the consent form to accurately reflect the nature, frequency or severity of the event;
- Re-consenting of participants waiting the study
- And/or halting the study.

Adverse event reports (and actions taken by the Chair or his or her designee upon receipt of the adverse event report) will be discussed at the next convened IRB meeting. The IRB shall determine appropriate action in response to the report, including one or more of the following:

- No further action is necessary (i.e., The research may continue);
- Further investigation by a member or outside expert designated by the Chair prior to the next meeting of the IRB;
- Request additional information regarding risks be given to participants;

- Suspend approval; and/or
- Terminate approval.

The Principal Investigator shall receive written notice of any action taken by the IRB and the reasons for that action within five (5) working days.

The IRB is required to report to the appropriate federal department or agency any unanticipated problems involving risks to participants or others. If the research protocol is suspended or terminated, additional notice shall be provided as discussed below (XII.D., Suspension and Termination).

## B. Serious or Continuing Noncompliance with Human Participants Regulations or IRB Requirements

The IRB reviews all allegations of non-compliance with human participants regulations. Any individual or organization may submit a complaint or allegation of non-compliance to the IRB. The IRB also may initiate a complaint based on information available to the IRB (e.g., Deficiencies noted in IRB files, media or scholarly reports of research activity subject to IRB jurisdiction).

Non-compliance means conducting research involving human participants in a manner that disregards or violates federal regulations and/or NYIT policies governing such research. This can include, but is not limited to, failure to obtain IRB approval for research involving human participants, inadequate procedures for obtaining informed consent, inadequate supervision in research involving experimental drugs, devices or procedures, failure to follow recommendations made by the IRB to ensure the safety of participants, failure to report adverse events or proposed protocol changes to the IRB, and failure to provide ongoing progress reports.

Whenever an allegation of non-compliance is made, the Chair will forward the allegation to a member of the IRB with appropriate expertise and the HPA. The Chair also will send written notice of the allegations to the researcher and request a response.

The designated member will review the allegation of non-compliance, the response from the researcher and any other information necessary to determine whether a full investigation is warranted. At the conclusion of his or her inquiry, the member will make a recommendation to the IRB concerning appropriate action. Possible recommendations may include:

- Dismissal of the allegation or complaint as unjustified;
- Referral of the matter to another more appropriate process or authority within NYIT for resolution;
- Resolution through corrective or educational measures where the violation of human participants or privacy regulations is minor or inadvertent; and/or
- A formal IRB investigation where the allegation or complaint appears founded and is of a serious nature.

The IRB will promptly act upon the recommendations of the member and notify the investigator in writing of the outcome of the inquiry. This notice will include a statement of the reasons for the IRB's decision. Depending on the nature of the allegations and the extent of the review required, the inquiry phase is generally expected to be completed within thirty (30) days. The IRB may grant an extension of this time frame if warranted.

### 1. Further Investigation

The IRB may decide to institute a formal investigation if the IRB determines that an allegation appears founded and is of a serious nature. The investigation will be conducted

by an ad hoc panel of three (3) IRB members (other than the Chair) known as the "Investigation Committee." The members of the Investigation Committee will be IRB members whose areas of expertise are suited to reviewing the complaint and area of study and will include the member who conducted the initial inquiry.

The Investigation Committee may use any and all materials and reports gathered during the initial inquiry phase. The Investigation Committee may obtain documents and other records relevant to the investigation and may interview any persons who may have information relevant to the complaint. The investigator under investigation will be given an opportunity to submit written comments and to appear before the Investigation Committee on at least one occasion prior to the Investigation Committee issuing its report.

Based on its investigation, the Investigation Committee will prepare a report summarizing the information it considered and outlining its conclusions and recommended actions. The Investigation Committee will send the report to the IRB and to the OSPAR. Depending on the case, the investigation phase is generally expected to be completed within sixty (60) working days.

**2. Decision**

The IRB will consider the report of the Investigation Committee and any comments submitted by the researcher in reaching its decision. Actions the IRB may take with respect to the investigation include, but are not limited to:

- Dismissal of the complaint as unjustified;
- Remediation or educational measures;
- Monitoring of research activities;
- Increased reporting by the investigator of his/her human participants research activities;
- Restrictions on research practice, such as limiting the privilege to minimal risk or supervised projects; suspension of approval for one or more of the investigator's studies; termination of approval for one or more of the investigator's studies; and/or
- Referral to other NYIT officials or IRBs for possible further review and action by those bodies.

The IRB will send a copy of its decision to the investigator and the OSPAR. If the IRB's approval is suspended or terminated, additional notice will be provided as discussed below.

### 3. Action Prior to Decision

At any time during the inquiry or investigation process, the IRB may determine that it is necessary to suspend accrual of research participants or to suspend approval of research project(s) to ensure the protection of human participants. Except in cases of imminent harm to research participants or others, the IRB will not suspend approval of research studies until the researcher has had an opportunity to respond to the initial allegation of non-compliance. Notice of suspension or termination shall be provided as discussed below in Section XII.D., Suspension and Termination.

## C. Reporting of Serious or Continuing Non-Compliance to NYIT officials and Federal Agencies

The IRB is required to report to the appropriate Federal Department or Agency any serious or continuing noncompliance with the regulations governing the protection of human participants or the requirements or determinations of the IRB. Serious or continuing non-compliance will also be reported to the Department Chair and Dean of the appropriate department and school, the Provost, and the President (Institutional Official).

## D. Suspension and Termination

When the IRB makes a decision to suspend or terminate approval of research for any reason, the following individuals, in addition to the investigators listed on the protocol and institutions involved in the research, will be notified, where applicable:

- Department Chair
- Dean
- Provost
- President

Notice will be given within five (5) working days of such suspensions or terminations.

# New York Institute of Technology

## Human Research Protections Program

# PROCEDURES AND GUIDELINES MANUAL

### Volume 2

### Investigator Responsibilities and Instructions for Applying for IRB Approval

(This page intentionally left blank.)

# Volume II. Investigator Responsibilities
# And Instructions for Applying for Approval of Research with Human Participants

## *Preface:*

The regulations set forth in this manual are intended to safeguard the human participants involved in research at the New York Institute of Technology and assure the quality and integrity of clinical research as well as *in vitro and in vivo* basic science research projects involving human tissue.

This Manual sets forth the basic ethical principles underlying the acceptable conduct of research involving human participants as set forth in the ***Belmont Report: Ethical Principles and Guidelines for the Protection of Human Participants of Research.*** Those principles are now accepted as the three quintessential requirements for the ethical conduct of research involving human participants.

- Respect for persons involves a recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy.
- Beneficence entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm.
- Justice requires that the benefits and burdens of research be distributed fairly.

The Belmont Report also describes how these principles apply to the conduct of research. Specifically, the principle of respect for persons underlies the need to obtain informed consent; the principle of beneficence underlies the need to engage in a risk/benefit analysis and to minimize risks; and the principle of justice requires that participants be fairly, not just conveniently, selected.

**This Manual in its entirety is composed of seven (7) short volumes in order to facilitate referencing of specifically applicable material. There is some redundancy among volumes to insure that important information is not overlooked. Investigators and IRB members are expected to be familiar with the entire manual.**

Volume I - IRB Operations

Volume II - Investigator Responsibilities and Approval Application Procedures

Volume III - Participant Recruitment and Special Populations (Children, prisoners, pregnant women, etc.)

Volume IV - Special protocols (FDA, Radioactivity, Genetic transfer, Genetic heritability, etc.)

Volume V Federal Regulations and Guidance

Volume VI NYIT IRB forms

Volume VII References and Appendices

(This page intentionally left blank.)

# Volume II.
# Investigator Responsibilities and Approval Application Procedures for Research of Human Participants (IRB)

## A. Human Research Protection at NYIT - General principles.

In 1974, the US Congress passed the National Research Act, establishing the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In 1978 the Commission published the Belmont Report, setting forth the basic ethical principles that should underlie the conduct of both biomedical and behavioral research involving human participants; these three quintessential requirements are:

- ***Respect for persons*** – involves a recognition of the personal dignity and autonomy of individuals, and special protection for those persons with diminished autonomy. This provision is the basis for the need to obtain for informed consent. The principle involved recognizes that no research can be conducted on people without their willing and free choice to involve themselves, regardless of the intended benevolence of the outcome of the research.
- ***Beneficence*** – entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm. This principle underlies the need to engage in risk/benefit analysis.
- ***Justice*** – requires that the benefits and burdens of research be distributed fairly (that participants be fairly selected).

The report distinguished between “research” and “practice”:

> *Practice* constitutes “interventions that are designed solely to enhance the well-being of an individual participant or client and that have a reasonable expectation of success.” The purpose of medical or behavioral (including educational and marketing) practice is to provide diagnosis, preventive treatment, therapy, or education to particular individuals, that is, practice is designed to benefit specific individuals.
>
> *Research* is described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective, and is inherently intended to generate new knowledge. Experimental procedures do not necessarily constitute research, and research and practice may occur simultaneously. The report suggests that the safety and effectiveness of such “experimental” procedures should be investigated early and that institutional oversight mechanisms, e.g. IRB's, ensure that the need is met by requiring that “major innovation[s] be incorporated into a formal research project.”

The Department of Health and Human Service (DHHS) regulations for protection of human subjects are codified at Title 45 Part 46 of the Code of Federal Regulations of January 16, 1981, revised 1983 and 1991 (CFR45). The 1991 revision involved adoption of the Federal Policy for the Protection of Human Subjects by the sixteen federal agencies that conduct, support, or otherwise regulate human subjects research.

The Food and Drug Administration (FDA) also adopted certain of its provisions. FDA regulations are codified at Title 21 Parts 50 and 56 of the Code of Federal Regulations. Additional FDA regulations relevant to IRB review of research are Parts 312 (Investigational New Drug Application), 812 (Investigational Device Exemptions) and 860 (Medical Device Classification Procedures). These regulations are mirrored for the Department of Education under Title 34 Part 97 - Protection of Human Subjects.

Additional information the Human Subjects Protection System and suggestions for further reading can be found in the IRB Guidebook found at http:www.nih.gov/grants/opr/IRB/IRB_introduction.htm

The New York Institute of Technology has made the cited federal policy applicable and adaptable to all research involving human participants without consideration of funding sources in all of its divisions. The identical guidelines and philosophy apply to all clinical, basic in vivo and in vitro, and social science research.

## B. Investigator's basic obligations when conducting research involving Human Participants

All employees or agents of NYIT are required by NYIT policy to follow Federal law established in CFR 45 part 46, known as the "Common Rule", when undertaking any research involving human participants. In addition, in so far as the policies of NYIT go beyond the requirements of this legislation, all employees, agents, or associates of NYIT engaging in research at or in conjunction with NYIT must comply with the policies of NYIT.

IRB review is required for all research involving human participants, and all other activities that even in part involve such research, regardless of sponsorship, if one or more of the following apply:

1. The research is sponsored by NYIT; or
2. The research is conducted by or under the direction of any employee or agent of NYIT in connection with his or her institutional responsibilities; or
3. The research is conducted by or under the direction of any employee or agent of NYIT using any property or facility of NYIT; or
4. The research involves the use of NYIT's non-public information to identify or contact human research participants or prospective participants.

An IRB has authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and local institutional policy. The IRB makes its determination whether to approve or disapprove the protocol based upon whether or not human participants are adequately protected, possible benefits exceed the risk involved, and that participants are selected fairly.

The investigator must consider two fundamental questions;

1. whether the activity involves research and
2. whether it involves human participants.

Proposals that include both of these elements ***in any measur****e* fall under the jurisdiction of the IRB, and every investigator is obligated to seek approval from an IRB. In cases where these two questions cannot be absolutely answered in the negative, it is the function of the IRB to make the determination, not the investigator. If any doubt exists, the investigator MUST contact an IRB before undertaking any activity that might be considered human

participants research. You may contact an IRB through its chair or through the Office of Research and Sponsored Programs.

As part of its assurance with the Office of Human Research Protections (OHRP) in Washington, D.C., NYIT agrees to protect the welfare of all human participants involved in research, whether or not the research is conducted or supported by a federal department or agency.

It is understood that research that has been reviewed and approved by an IRB may be subject to further review and disapproval by other officials of NYIT. However, Institutional officials may not approve research if a NYIT IRB has disapproved it. Furthermore, approved research is subject to continuing IRB review and must be reevaluated at least annually.

## C. Definitions

Additional definitions may be found in a Glossary at the end of this manual, but the definitions below are critical to understanding the Human Protections Program at NYIT.

**Research** is herein defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge", in accordance with DHHS definitions. This applies to all investigations including physical and psychological studies, review of medical records, and questionnaires and surveys. Note: Case studies or single individual treatment studies may constitute research.

**Human participants** are defined by the regulations as "living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information".

Human participants research includes, but is not limited to, studies with tissues, fluids, or other material removed from a living human, as well as a wide range of medical, behavioral, biological and epidemiological studies. Investigators are encouraged to contact the IRB for guidance in determining whether a particular study is considered human participants research. Generally, stored tissue of deceased persons from a tissue bank is not subject to continuing IRB review, however all such tissue or samples must be accounted for by an IRB and therefore documentation as to the source and use must be provided to the appropriate IRB.

**Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and participant.

**Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public or shared with others (for example, test results, questionnaire responses, medical records). Private information is individually identifiable (i.e., the identity of the participant is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human participants.

**Exclusions:**

Some research that involves human participants may be exempt from the regulations requiring IRB review.

## D. Institutional Procedures and Guidelines.

In accordance with Federal Regulations, the NYIT IRB Procedures and Guidelines Manual contains written procedures and guidelines to be followed by the IRB when conducting its initial and continuing review or research and for reporting its findings and actions to the investigator and the administration of the institution. (Volume I) The procedures provide guidance for determining which projects require review more often than annually and which projects require verification from sources other than the investigator that no material changes have occurred since the last IRB review.

The guidelines also provide procedures for the investigator for requesting IRB approval (Volume II). The guidelines also delineate procedures for ensuring prompt reporting to the IRB, by the investigator, of proposed changes in a research activity. They also provide procedures for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the participant.

Any investigator representing NYIT and intending to conduct activities involving human participant must, *without exception*, have any protocol for such activities, approved and monitored by the IRB. This applies to non-invasive as well as invasive physical and/or psychological modalities.

**Note to Investigators:** the NYIT IRB monitors ongoing research protocols to detect lapses in investigator compliance such as unreported changes in protocols, misuse or nonuse of the informed consent document or failure to submit protocols to the IRB in a timely fashion. Should unapproved research be discovered, the IRB and the institution will act promptly to halt the research, assure remedial action regarding any breach of regulatory or institutional human participant protection requirements, and address the question of the investigator's fitness to conduct human participant research.

## E. Authorized Institutional Official

The President of the New York Institute of Technology is recognized as the legal authority to act and speak for the institution and to ensure that it can effectively fulfill its research oversight function. This authority can be delegated by the president so long as the designated official has full legal authority to speak for the school and the appropriate credentials and training.

## F. Basic Components of the IRB Review Process

*1. Exempted and Expedited Protocols Review (See additional information in Volume V)*

a. Exempted Protocols

Certain types of research may be exempt from IRB review. This determination is made by the Chair of the IRB or an individual designated by an IRB chair. The investigator does NOT determine whether research is exempt but may request consideration of exempt status. To request exemption, review the categories below carefully and submit the "Request for Exemption form.

To qualify for exempt status, the proposed research must pose minimal risk (see **Definitions**) and fall precisely into one of the following categories:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
   i. research on regular and special education instructional strategies, or
   ii. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

**Research with participants under 18 years of age may be included in this category.**

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   i. information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; **and**
   ii. any disclosure of the human participants' responses outside the research could reasonably place the participant at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

**Research with participants under 18 years of age may NOT be included in this category UNLESS it involves observations of public behavior where the researcher does not participate in the behaviors being observed.**

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
   i. the human participants are elected or appointed public officials or candidates for public office; or
   ii. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

(5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
   i. public benefit or service programs;
   ii. procedures for obtaining benefits or services under those programs;
   iii. possible changes in or alternatives to those programs or procedures; or
   iv. possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies,
   i. if wholesome foods without additives are consumed or
   ii. if a food is consumed that contains a food ingredient at or below the level

and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture

b. Expedited Review

The Chair of the IRB is empowered to determine if a protocol is eligible for expedited review in cases where proposals present minimal risk. Expedited review should not necessarily be seen as a more rapid form of approval - expedited review often takes as long as a full review.

Research activities that present no more than minimal risk to human participants, and involve only procedures listed in one or more of the categories listed below may be considered for expedited review.

The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review.

If the protocol meets the criteria for expedited review, the Chair will submit the protocol for review to an IRB member knowledgeable in the research area. The reviewer's recommendation of approval will be considered by the Chair. If the reviewer cannot recommend approval, the protocol will be considered for full review in compliance with the aforementioned regulations and criteria.

The Chair will advise all IRB members of research proposals approved through expedited procedures. The expedited categories are outlined below:

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children[2], considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participants privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) where

(i) the research is permanently closed to the enrollment of new participants;

(ii) all participants have completed all research-related interventions; and

(iii) the research remains active only for long-term follow-up of participants; or

(b) where no participants have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

2. *New Expedited or Full Review Protocols*

The proposal must be typed, with pages numbered. A table of contents is suggested. The proposal must contain all of the following components:

a. Application Checklist

b. Application form

c. Abstract

In no more than 400 words, describe the research objective(s), proposed methodology, and anticipated results or goals. .

d. Protocol Description

*i. Purpose*

State the purpose of the research. Include major hypotheses and research design. If the study is part of a larger study, briefly describe that larger study. Please keep in mind that the IRB is composed of individuals from many disciplines and thus the description of your research should be written in terms readily comprehensible by non-experts.

*ii. Source(s) of participants and the selection criteria*

Describe the source(s) of participants, the selection criteria and the recruitment methods. Selection of participants must be equitable and, in the case of protected populations such as children, prisoners, pregnant women, the mentally disabled, etc. should address their special needs. Provide a detailed description of the participant population including criteria for inclusion/exclusion, number of participants involved in the study, age, sex and health status. The text of any advertisement, letter, flier, oral script or brochure used to solicit potential participants must be attached.

*iii. Description of the procedures to be followed*

Provide a description of the procedures to be followed and a detailed description of all drugs to be used including dosages, dosage changes varying from manufacturers' recommendations, frequency of use, FDA status of a formerly approved drug being used for new therapies, IND# of all new drugs and all other drug information necessary. Include copies of questionnaires and/or interview protocols, or a sufficiently detailed description of the measures to allow the IRB

to understand the nature of participants' involvement. Include a time line for the study.

iv. *Assessment of risks and benefits*

Describe any potential harms or benefits to be derived by participants, with a discussion of the risk/benefit ratio. For approval of any study with more than minimal risk, the benefits must clearly be shown to outweigh the risk. Describe how the study may expose participants to stress, physical, psychological or interpersonal hazard, including the possibility of pain, injury, disease, discomfort, embarrassment, worry or anxiety.

v. *Protection of data/privacy*

Describe the specific methods by which confidentiality and anonymity will be protected, including the use of data coding systems, how and where data will be stored and who will have access to it, and what will happen to data after the study has been completed.

vi. *Debriefing procedures (if applicable)*

If applicable, provide the following: 1) a description of the debriefing procedures to be used in cases where deception has occurred; 2) a statement describing what actions you will take should the research reveal the possibility of a medical or other potentially troubling condition.

vii. *Description of alternative treatments (if applicable)*

viii. *Consent procedures*

Before submitting this application, all investigators should familiarize themselves with the discussion of informed consent (see section 3 below). Describe the oral and written consent processes and attach all consent documents, including scripts for oral consent and assent forms. When the consent form to be used will be in a language other than English, an English translation must be provided. Use the Informed Consent Checklist (ATTACHMENT D) as a guide in drafting your consent form. The draft consent form(s) must be attached.

ix. *Investigator background and other relevant information*

Please provide information about your background. Attach a copy of the Curriculum Vitae for the Principal Investigator and co-investigators.

e. Attachments

The following items must be attached.

i. Surveys, questionnaires, test, interview questions and other instruments

ii. Recruitment flyers and letters

iii. Copy of the Certificate of Completion of training in human participants protections

iv. Letters of agreement from study sites

v. Curriculum vitae for the Principal Investigator and co-investigators (unless the PI is the instructor)

*3. Informed Consent*

Informed consent is contingent upon the participant or his/her legal representative, being knowledgeable of:

the question, condition, or disease involved;

the usual course of treatment or practice,

and the experimental protocol.

This information must be presented absent of any kind of intimidation, duress, deceit, paternalism or a sense that their health, rights, or welfare will be compromised if they do not participate. This must be presented to the participant in layman terms to be clearly understood and subsequent dialogue must also be presented to the participant in manner he/she or legal representative can easily understand.

**Informed consent is a process,** not just a form, by which the individual is given all the information that a participant may want or need to make a full and free decision to participate in research. This information minimally includes the following elements:

- A statement that the study involves research
- An explanation of the purposes of the research
- The expected duration of the participant's participation
- A description of the procedures to be followed
- Identification of any procedures which are experimental
- A description of any reasonably foreseeable risks or discomforts to the participant
- A description of any benefits to the participant or to others which may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained
- For research involving more than minimal risk, an explanation as to whether any compensation will be offered, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
- An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits, to which the participant is otherwise entitled

  Additional elements (if appropriate) are

  - A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant), which are currently unforeseeable

- Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent
- Any additional costs to the participant that may result from participation in the research
- The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant
- A statement that significant new findings developed during the course of the research, which may relate to the participant's willingness to continue participation, will be provided to the participant
- If minors are involved, an **assent** form

No informed consent form, whether oral or written, may include any exculpatory language through which the participant or representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, the sponsor, NYIT or its agents from liability for negligence.

The Risk: Benefit ratio must be fully evaluated by the investigator and the steps taken to lessen the risk factors fully described. When making this evaluation, the investigator should define risk in terms of psychological harm as well as physical pain or discomfort. By this definition, it also includes harassment, loss of dignity, loss of confidentiality and loss of privacy. Being at risk also includes the possibility of physical, psychological or sociological harm resulting from any practice or action that goes beyond the norms of accepted medical practice.

In research involving videotapes or written tests, the IRB must see a sample when the protocol is submitted for review/approval. The IRB must know, and the Consent Form must indicate how confidentiality and privacy will be assured under these research conditions.

Informed Consent Forms must be obtained from every person who agrees to participate in a research project unless specifically waived by the IRB.

The original Consent Form must be retained upon completion of the study for 3 years after publication and made available for audit by the IRB or Federal Authorities upon request. Failure to produce valid consent forms for every participant will compel the Institution to take severe disciplinary action against the investigator.

Generally, unless it is counter to the purpose of the research, the NYIT logo, address, and phone numbers must appear on consent forms to ensure that the participant understands the association of the research with NYIT and to provide another avenue of contact if desired.

Frequently, the elements of informed consent can be included in the header of a survey so that no separate consent form is needed. However, the header information is essential and must constitute sufficient information on which to base consent.

<u>Each Consent Form must be signed by</u>:

- The investigator who certifies that the information was given to the participant and that the investigator was available for questioning; Students CANNOT sign as investigator.
- The participant, or representative/guardian (in some cases both the minor participant and the parent or guardian); and

- The person who witnesses the process of informed consent if there is any component of informed consent that is not contained within the form, even if redundant with the form. For example, if there is a recruitment speech involved, or a verbal explanation is provided, a witness to the process is required. Students may sign as witness, if appropriate, and they are above the age of 18.

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants, if it finds either:

1. That the only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; or
2. That the research presents no more than minimal risk of harm to participants, and involves no procedures, for which written consent is normally required outside of the research context.

Use informed consent checklist as a guide in preparing informed consent forms. Sample consent forms are available on the OSPAR website at http://iris.nyit.edu/sponsoredprograms.

*4. Approval Duration and Continuing Review.*

A protocol may be approved for a maximum period of one (1) calendar year. The approval period is determined by the IRB. The IRB will conduct a continuing review of all approved studies.

If any modification to approved protocols is contemplated, application for approval of changes must be made in writing to the IRB via the appropriate form (Volume VI).

Research approved by the IRB may be subject to review and approval or disapproval by College officials. However, these administrative officials cannot approve the research if it has not been approved by the IRB.

*5. Protocol Renewal Applications*

If a principal investigator intends the research of an approved protocol to go beyond the initial approval date, a renewal application must be submitted. Renewals are subject to the same scrutiny as new proposals.

The Renewal/Termination form must be submitted no less than **60 days** prior to the termination of the approved protocol. Renewal of a protocol should not be assumed to be automatic.

Note: Approval of a renewal **MUST be completed before expiration of the current protocol**. It is the Investigator's responsibility to ensure that a renewal request is submitted to allow sufficient time for IRB review.

**Failure to renew a protocol before the expiration date will result in the immediate termination of the project on the expiration date. No research may be conducted after the expiration date.**

## G. Protections for Vulnerable Populations

Special considerations are enforced when research involves:

- Pregnant women, (See Volume III)
- Newborns, (See Volume III)
- Mentally, emotionally, psychologically, physically or sociologically compromised individuals not capable or reasoned judgement in their own behalf are the subjects of research. (See Volume III).
- Any other vulnerable population (See Volume III)
- Any investigational drug or device study. (See Volume IV)
- Any transfer of genetic material to a human participant. (Volume IV)
- Exposure of the participant to radiation (Volume IV)
- Recruitment of participants in emergency situations (Volume IV).
- The research involves multiple clinical sites AND federal funding (Volume IV)
- Research conducted outside of the United States. (Volume IV)

Any research falling into these classifications are subject to the rules and regulations found in Volumes III and/or IV.

**NO RESEARCH WILL BE UNDERTAKEN WHEREIN:**

- In vitro fertilization is the subject of research,
- A drug study when an Investigated New Drug number (INC #) is not on file in the IRB office. (See Volume IV)
- Stem cells not derived from a pre-existing recognized cell line.
- There is suspicion or accusation of scientific misconduct in any form.

## H. Student Involvement in Research

**NO STUDENT MAY BE A PRINCIPAL INVESTIGATOR**. A student cannot legally represent NYIT independently of the course director or supervisor. It is recognized that the student may have earned recognition for almost the entire design, implementation, and analysis of a research project, and is thus afforded the professional recognition for the responsibility of the project. However, student projects require oversight by a member of the faculty or staff who is qualified and agrees to take responsibility for human protections in the project.

If registered students of NYIT will be part of the research project, investigators must clearly describe their participation and complete Attachment C of the Application Form.

If the research is being conducted between an NYIT student and another institution, letters of agreement from a legal representative of the other institution fully acknowledging the status of the student must be provided.

It is incumbent upon the INSTRUCTOR of the course to ensure that all students in research courses understand the procedures contained herein. **The instructor will be held responsible** for compliance with these procedures.

*Student Research Instruction*

Some activities involving experimental design, data collection, and analysis but not fitting the definition of research are not subject to IRB review. These excluded activities are designed primarily for instruction in the procedures and processes of research within the context of a structured class and are not designed for the generation of new knowledge. Therefore, such exercises would fall outside of the federal definition of research, and would be considered ***excluded activities, and not exempt research*.** These exercises must still be designed keeping in mind the principles and practices of the Human Protection programs, but will not be required to obtain IRB review and approval. It is important to note that some activities performed within a classroom setting *may* still be considered research and thus need IRB oversight.

No project that is specifically designed with the intention or likelihood to disseminate the acquired information outside of the immediate educational setting can be considered excluded. By definition, activities *designed* to acquire generalizable knowledge are considered research.

While a full proposal and approval application are not required for academic exercises, determination of whether they are excluded from consideration must be made by the chair of an IRB or *other person authorized by the chair* to make such a determination. No course director or instructor should make that determination unless specifically authorized to do so by the chair of an IRB.

If a chair (or his/her designee) makes such a decision and excludes certain activities based on information provided, the instructor is held responsible for conducting the exercise consistent with the information given to the IRB chair and/or his /her designee. Substantive changes must be reported to the IRB Chair (or his/her designee). Any case where a project was purported to be excludable under false pretenses will be treated as scientific misconduct.

The IRB chair may authorize persons to make the determination of whether a class-associated activity constitutes research only upon evidence of sufficient training and expertise to make the distinction between research and educational exercise.

## I. Collaborative and Cooperative Research

Wherein a research project involving human participants is a collaborative or cooperative endeavor between NYIT and another institution and the principal investigator is a member of that institution, it becomes the other institutions obligation to meet OHRP requirements for safeguarding the rights of human participants. Their qualified Institutional Review Board criteria, procedure and findings will be made known to NYIT for joint review in an effort to avoid procedure duplication. Even after review of another institution, an NYIT IRB may still disapprove participation of an NYIT employee in the research, but such restriction will be undertaken with utmost care.

Correspondence verifying the collaboration is required prior to review, and any approval by an NYIT IRB will be absolutely contingent upon documentation that the collaborating institution has also approved the project.

As previously stated, if the principal investigator is an employee of NYIT or the research is being conducted on the premises or using the facilities of NYIT, an NYIT IRB has principal responsibility for Human Protections.

## J. Records

Research records should be maintained for a minimum of three (3) years after *publication*.

## K. Termination of Approval

A research project can be terminated or suspended at any time by the IRB if:

- The OHRP issues a directive stopping all experimentation using human participants in specific research areas;
- The investigator(s) failure to obtain approval by the IRB;
- New knowledge of potential risks unknown at the time of approval becomes available;
- New or serious side effects necessitate a halt;
- The project is not being funded (if funding is required);
- Completion of the project;
- Significant deviation from the approved protocol;
- Suspected scientific misconduct in any form.

A suspended protocol can only be continued with written permission of an IRB chair after corrective measures have been taken. A terminated protocol cannot be continued.

## L. IRB Enforcement Functions

*1. Review of Serious and/or Unexpected Adverse Events*

Principal Investigators are required to report serious or unexpected adverse events to the IRB as well as the sponsor or FDA (if applicable) within five (5) working days. Principal Investigators must provide comprehensive information in their written notice.

A **serious adverse event** is defined as any event that suggests a significant hazard, contraindication, side effect, or precaution. A serious adverse event includes any event that:

- is fatal;
- is life threatening, meaning that the participant was, in the view of the Principal Investigator, at immediate risk of death from the reaction as it occurred; this definition does not include a reaction that, had it occurred in a more serious form, might have caused death;
- is a persistent or significant disability/incapacity, i.e., The event: (i) causes a substantial disruption of a person's ability to conduct normal life functions; (ii) requires or prolongs insubject hospitalization; or (iii) is a congenital anomaly/birth defect; or
- is an important medical event, based upon appropriate medical judgment, that may jeopardize the participant or subject or may require medical or surgical intervention to prevent one of the other outcomes defining a serious adverse event.

An **unexpected adverse event** is any adverse event that is not identified in severity or specificity in the consent form or proposal.

Adverse event reports are reviewed by the IRB Chair or the Chair's designee. Upon receipt of a report of an adverse event, the Chair or designee will decide if urgent action is necessary, and will unilaterally direct that such action be taken, to eliminate apparent immediate hazards to the human participants, including the following:

- Changes to the protocol are needed to minimize risks to participants;
- Changes to the consent form are needed to accurately reflect the nature, frequency or severity of the event;
- Participants should be asked to re-consent to study participation; and/or
- The study should be placed on temporary hold to new enrollment and/or the study procedures should be discontinued, because based on the information available, the risk/benefit ratio appears to be unfavorable to the participants.

Adverse event reports (and actions taken by the Chair or his or her designee upon receipt of the adverse event report) will be discussed at the next convened IRB meeting. The IRB shall determine appropriate action in response to the report, including one or more of the following:

- Deciding that no further action is necessary (i.e., The research may continue);
- Requiring further investigation by a member or outside expert designated by the Chair prior to the next meeting of the IRB;
- Requiring that additional information regarding risks be given to participants;
- Suspending approval; and/or
- Terminating approval.

The Principal Investigator and the ORSP shall receive written notice of any action taken by the IRB and the reasons for that action within five (5) working days.

The IRB is required to report to the ORSP and the appropriate federal department or agency any unanticipated problems involving risks to participants or others. If the research protocol is suspended or terminated, additional notice shall be provided as discussed below (Suspension and Termination.)

2. *Serious or Continuing Noncompliance with Human Subjects Regulations or IRB Requirements*

   The IRB reviews all allegations of non-compliance with human subjects regulations. Any individual or organization may submit a written complaint or allegation of non-compliance to the IRB. The IRB may also initiate a complaint based on information available to the IRB (e.g., Deficiencies noted in IRB files, media or scholarly reports of research activity subject to IRB jurisdiction).

   Non-compliance means conducting research involving human participants in a manner that disregards or violates federal regulations governing such research. This can include, but is not limited to, failure to obtain IRB approval for research involving human participants, inadequate or non-existent procedures for obtaining informed consent, inadequate supervision in research involving experimental drugs, devices or procedures, failure to follow recommendations made by the IRB to ensure the safety of participants, failure to report adverse events or proposed protocol changes to the IRB, and failure to provide ongoing progress reports.

   a. <u>Initial Inquiry</u>

      Whenever an allegation or complaint of non-compliance is made, the Chair will forward the allegation to a member of the IRB (other than the Chair) with appropriate expertise. The Chair also will send written notice of the allegations to and request a response from the principal investigator.

The designated member will review the allegation of non-compliance, the response from the researcher and any other information necessary to determine whether a full investigation is warranted. At the conclusion of his or her inquiry, the member will make a recommendation to the IRB concerning appropriate action. Possible recommendations may include:

Dismissal of the allegation or complaint as unjustified;

Referral of the matter to another more appropriate process or authority within NYIT for resolution;

Resolution through corrective or educational measures where the violation of human participants or privacy regulations is minor or inadvertent; and/or

A formal IRB investigation where the allegation or complaint appears founded and is of a serious nature.

The IRB will promptly act upon the recommendations of the member and notify the investigator in writing of the outcome of the inquiry. This notice will include a statement of the reasons for the IRB's decision. Depending on the nature of the allegations and the extent of the review required, the inquiry phase is generally expected to be completed within thirty (30) days. The IRB may grant an extension of this time frame if warranted.

b. Further Investigation

The IRB may decide to institute a formal investigation if the IRB determines that an allegation appears founded and is of a serious nature. An ad hoc panel of three (3) IRB members (other than the Chair) known as the "Investigation Committee" will conduct the investigation. The members of the Investigation Committee will be IRB members whose areas of expertise are suited to reviewing the complaint and area of study and will include the member who conducted the initial inquiry.

The Investigation Committee may use any and all materials and reports gathered during the initial inquiry phase. The Investigation Committee may obtain documents and other records relevant to the investigation and may interview any persons who may have information relevant to the complaint. The investigator under investigation will be given an opportunity to submit written comments and to appear before the Investigation Committee on at least one occasion prior to the Investigation Committee issuing its report.

Based on its investigation, the Investigation Committee will prepare a report summarizing the information it considered and outlining its conclusions and recommended actions. The Investigation Committee will send the report to the IRB and to the ORSP. Depending on the case, the investigation phase is generally expected to be completed within sixty (60) working days.

c. Decision

The IRB will consider the report of the Investigation Committee and any comments submitted by the researcher in reaching its decision. Actions the IRB may take with respect to the investigation include, but are not limited to:

Dismissal of the complaint as unjustified;

Remediation or educational measures;

Monitoring of research activities;

Increased reporting by the investigator of his/her human participants research activities;

Restrictions on research practice, such as limiting the privilege to minimal risk or supervised projects; suspension of approval for one or more of the investigator's studies; termination of approval for one or more of the investigator's studies; and/or

Referral to other NYIT officials or another NYIT IRB for possible further review and action by those bodies.

The IRB will send a copy of its decision to the investigator and the OSPR. If the IRB's approval is suspended or terminated, additional notice will be provided as discussed below.

Note: A decision by an IRB to halt or modify the condition of research cannot be changed by any authority at NYIT. Since there is no appellate authority, the investigator should be assured that IRB will take such actions most seriously and with all due considerations.

d. Action Prior to Decision

At any time during the inquiry or investigation process, the IRB may determine that it is necessary to suspend accrual of research participants or to suspend approval of research project(s) to ensure the protection of human participants. Except in cases of imminent harm to research participants or others, the IRB will not suspend approval of research studies until the researcher has had an opportunity to respond to the initial allegation of non-compliance. Notice of suspension or termination shall be provided in writing to the investigator.

*3. Reporting of Serious or Continuing Non-Compliance to ORSP, OHRP, and Federal Agencies*

The IRB is required to report to the ORSP, OHRP, and the appropriate Federal Department or Agency any serious or continuing noncompliance with the regulations governing the protection of human participants or the requirements or determinations of the IRB.

*4. Suspension and Termination*

When the IRB makes a decision to suspend or terminate approval of research for any reason, the following individuals, in addition to the investigators listed on the protocol and the departments or institutions involved in the research, will be notified, where applicable:

Notice will be given within five (5) working days of such suspensions or terminations.

*5. Misconduct*

In the event that the quality and/or integrity of any human participant research project, or publication(s) resulting therefrom, is/are found to be unethical, fraudulent, fabricated, falsified, plagiarized, deceptive or otherwise deviating from intellectual honesty, the IRB will deal with those issues as scientific misconduct.

The IRB will cooperate in the review of allegations of conflicts of interest, scientific misconduct, financial mismanagement, FDA inspections, etc. In cases that appear to involve scientific misconduct, the IRB will report allegations of such misconduct to appropriate NYIT officials. Where scientific misconduct and IRB investigations are pending against the same investigator, the IRB will participate in a close coordination of processes to avoid duplication of effort and to minimize competing use of resources.

Some cases require review by other NYIT or external authorities. The IRB will cooperate in the review of allegations of conflicts of interest, scientific misconduct, financial mismanagement, FDA inspections, etc. In cases that appear to involve scientific misconduct, the IRB may report allegations of such misconduct to appropriate NYIT officials. If NYIT and IRB investigations are pending against the same investigator, the IRB will participate in a close coordination of processes to avoid duplication of effort and to minimize competing use of resources.

*Scientific misconduct, impropriety and unethical behavior will be deemed as having occurred in any instance in which an employee, consultant or a member of a governing body uses his/her position to influence decision making by bribery, coercion or for reasons of private financial gain his/herself or close ties.*

These guidelines also include conflict of interests, gifts, gratuities, nepotism and favors. NYIT has separately published policies on conflict of interest for the institution at large and the IRB will assume that investigators are familiar with these policies. Should a charge of misconduct be made against an individual involved with a Human Participant Project, the NYIT official overseeing the investigation or inquiry will immediately inform the Chair of the IRB overseeing the project.

In cases of real or alleged incidences of scientific misconduct in research associated with human studies, the IRB's primary concern is that the standards, ethics, and research procedures, as described in this manual, have not been violated.

Should a charge of scientific misconduct occur involving human research, the IRB will:

Cooperate in protecting the confidentiality and identity of the person(s) making the allegations and others that may become part of the investigative procedures;

Request from the "accused", the immediate release of all experimental data and records for study by the IRB if relevant to the specific charge of misconduct.

Cooperate with an NYIT investigation of the matter assisting the study of preliminary raw experimental data, final experimental data, publications, and interviews with others involved with the research project, as requested;

Determine whether immediate suspension of the research is appropriate prior to investigation taking into account only the risk to the participants.

The IRB, on the basis of an NYIT investigation or its own investigation, can:

Take no further action if the allegations are found to be unsubstantiated;

Censure and require instruction of the investigator if the accusation is substantiated but found not to be overt or deliberate on the part of the accused;

End the research project and notify the funding agency, if applicable, that approval has been withdrawn.

In cases where funds have been misused or human life placed in unnecessary peril, the funding agency, if applicable, whether public, private, or other entity will be notified immediately upon the IRB's having made its decision.