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

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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
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 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 measure 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 children², 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) uncanunculated 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.

Each Consent Form must be signed by:
- 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 a 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. Initial Inquiry

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.