NEW YORK INSTITUTE OF TECHNOLOGY

Human Research Protections Program

PROCEDURES AND GUIDELINES MANUAL
Volume 1

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

I. IRB Mandate - Human Studies Protection at NYIT

Evolution of modern concepts of human subjects 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 subjects, including the essentiality of voluntary consent and comprehension of the risks and benefits involved in experimentation involving human subjects. 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 subjects; 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 subjects 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 patient 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* designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships.) Research is usually 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 when research is designed to evaluate the safety and efficacy of a therapy. The Belmont Report suggests that the safety and effectiveness of such “experimental” procedures should be investigated early and that institutional oversight mechanisms, e.g. IRBs, ensure that the need is met by requiring that “major innovation[s] be incorporated into a formal research project”. The general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects.

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 ,1991, 2005 and 2018. 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 and often referred to as the “Common Rule”.

Since the Common Rule was promulgated, the volume and landscape of research involving human subjects have changed considerably. Research with human subjects has grown in scale and become more diverse. Examples of developments include: an expansion in the number and types of clinical trials, as well as observational studies and cohort studies; a diversification of the types of social and behavioral research being used in human subjects research; increased use of sophisticated analytic techniques to study human biospecimens; and the growing use of electronic health data and other digital records to enable very large datasets to be rapidly analyzed and combined in novel ways. Yet these developments have not been accompanied by major change in the human subjects research oversight system, which has remained largely unaltered over the past two decades. Those regulations were last amended in 2005, and have remained unchanged until the issuance of this final rule, effective January 21, 2019.The final rule is designed to more thoroughly address the broader types of research conducted or otherwise supported by all of the Common Rule departments and agencies such as behavioral and social science research. It also benefits from continuing efforts to harmonize human subjects’ policies across federal departments and agencies. The revisions are intended to better protect human subjects involved in research, facilitate research, remove ambiguity and reduce regulatory burden. It also benefits from continuing efforts to harmonize human subjects’ policies across federal departments and agencies.

New Regulations have been issued called the 2018 Requirements. The *2018 Requirements* means the Federal Policy for the Protection of Human Subjects requirements contained in Title 45-Subtitle A-Subchapter A-Part 46 Subpart A, B, C, D and E. The general compliance date for the 2018 Requirements is January 21, 2019. The compliance date for §46.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

Subsequently, the New York Institute of Technology has made the cited federal policy applicable to all research involving human subjects 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 subjects participating in research conducted under the auspices of NYIT and any of its components.

IRB review is required for all research involving human subjects, 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 subjects or prospective subjects.

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

- whether the activity involves research; and
- whether it involves human subjects

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 subjects are adequately protected, possible benefits exceed the risk involved, and that subjects are selected fairly.

III. Definitions

- *Clinical Trial* is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
- *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.
- *Human subject* is defined as "a living individual(s) about whom an investigator (whether professional or student) conducting research obtains
    - (1) information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
    - (2) obtains, stores, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
- *Human subjects 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 subjects research.
- *Identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
- *Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.,
- *Interaction* includes communication or interpersonal contact between investigator and subject.
- *Intervention* includes both physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

- *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.
- *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, *legally authorized representative* means an individual recognized by institutional policy as acceptable for providing consent in the nonresearched context on behalf of the prospective subject to the subject's participation in the procedure(s)involved in the research.
- *IRB* means an institutional review board established in accord with and for the purposes expressed in this policy.
- *Minimal Risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- *Public Health Authority* means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contact with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.
- *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).
- *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. For purposes of this part, the following activities are deemed not to be research:
    - (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
    - (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
    - 3)Collection and analysis of information…. for criminal justice purposes

- (4) Authorized operational activities in support of intelligence, homeland security, defense…

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 New York Institute of Technology 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 and who is not part of the immediate family of a person who is affiliated with the institution.
- A member whose primary concerns are in non-scientific areas and who is not engaged in research.
- No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB
- An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

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 https://www.nyit.edu/ospar/institutional_review_board

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 an 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 subjects, including children, students, prisoners, individuals with impaired decision-making capacity or economically or educationally disadvantaged 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 subjects, the IRB will include at least one person primarily specifically concerned with the welfare of these subjects.

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. Please refer to https://www.nyit.edu/policies/conflicts_of_interest_in_research for information regarding conflicts of interest for researchers in sponsored projects.

VI. Administration of the IRB

The Office of Sponsored Programs and Research (OSPAR) administers the IRB. The Senior Director of OSPAR has been designated the Human Protections Administrator (HPA). OSPAR works with the IRB 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, subjects 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 at citiprogram.org. FAQs about the program and instructions can be accessed via the OSPAR web site at https://nyit.edu/ospar/institutional_review_board.

IRB members receive a “Member Handbook” and are encouraged to attend national meetings sponsored by OHRP or professional organizations related to human subject’s 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 subjects 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 subjects. 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 consider 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, individuals with impaired decision-making capacity, 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, individuals with impaired decision-making capacity, 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 superseded by the possibility of benefit to the subject.
- Informed consent has been based on adequate information given to and understood by the subject without pressure or fear of penalty.
- The medical, legal and personal rights of each subject 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 subject regarding experimental procedures and the anticipated results;
- The conditions set for subject selection must be unbiased, equitable and cannot significantly medically compromise the subject;
- 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;
- Subject 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 IRB 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 further action is required unless the project is modified significantly. If you plan substantial changes to the project, please be sure to contact the IRB before implementing the changes, as they may change the project's status.

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 or by one or more experienced reviewers designated by the Chair from among members of the IRB. 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.
- Each IRB that uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals that have been approved under the procedure
- An IRB may use the expedited review procedure to review either or both of the following:

  some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk;
  minor changes in previously approved research during the period (of one year or less) for which approval is authorized
  research for which limited IRB review is a condition of exemption under §_.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7) and (8)

Protocols that require review by the full IRB will be reviewed at a regularly-scheduled IRB meeting. One member will be designated the preliminary reviewer to help ensure the protocol is as close to complete at the full board meeting. 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 new protocols.

c) New Protocols

Generally, if more than minimal risk is involved or there are substantive 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

d) Continuing protocols

An IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as described in 46.109(f).

(f)(1) Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:

(i) Research eligible for expedited review in accordance with 46.110;
(ii) Research reviewed by the IRB in accordance with a limited IRB review described in 46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8);

(iii) Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:

(A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
(B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.
(C) An IRB shall have authority to observe or have a third party observe the consent process and the research.

New York Institute of Technology's IRB has determined it will review all Expedited Protocols annually until the protocol is closed.

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.

e) 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 to grants@nyit.edu 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 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 one 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 VII., and on the Review Checklist listed below.

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?
(f) Does the study involve prisoners, pregnant women, fetuses or neonates? If yes, refer to the appropriate vulnerable subject population form
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 or the subject's legally authorized representative, in accordance with, and to the extant required by 45 CFR 46.116. and will be appropriately documented or appropriately waived in accordance with 45 CFR 46.117.

(a) Does the informed consent document include key information essential to decision making and receive priority by appearing at the beginning of the consent form and being represented first in the consent discussion?
(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 assent/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/biospecimens 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 an "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 subjects 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 take 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 below.

(f)(1) Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:

(i) Research eligible for expedited review in accordance with 46.110;

(ii) Research reviewed by the IRB in accordance with a limited IRB review described in 46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8);

(iii) Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:

This applies only to new studies approved after January 2019. However, NYIT has adapted the policy for continuing review on all Expedited protocols.

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 Department Chair
Notice of closure of protocol file	HPA	Email	IRB Chair 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 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 preliminary 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 files 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

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 subject's 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 will be created and sent to the Office of General Counsel which encompasses Compliance at NYIT

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

The IRB has the authority to consider, and act upon, requests for a partial or complete waiver or alteration of the Privacy Rule's Authorization requirement for uses and disclosures of PHI for research. Any such actions shall be contemporaneously forwarded to NYIT's HIPAA Compliance Officer.

IX. General Limitations for Research with Human Subjects

Special Considerations are enforced when research involves:

1. Pregnant women Newborns.
2. individuals with impaired decision-making capacity
3. Any other vulnerable population.
4. Any investigational drug or device study.
5. Any transfer of genetic material to a human subject is involved.
6. Exposure of the subject to radiation.
7. Recruitment of subjects in emergency situations.
8. The research involves multiple clinical sites AND federal funding.
9. 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 subjects is a collaborative or cooperative endeavor between NYIT and another institution and the principal investigator is a member of that institution, in the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.

(b)(1) Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.
(2) the following research is not subject to this provision:

(i) Cooperative research for which more than singe IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe; or

(ii) Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

(c) For research not subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort.

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 subjects 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;

XII. Suspected scientific misconduct in any form.

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 subject 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 patient 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 subjects, including the following:

- Changes to the protocol to minimize risks to subjects;
- Changes to the consent form to accurately reflect the nature, frequency or severity of the event;
- Re-consenting of subjects enrolled in 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 subjects;
- 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 subjects 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 Subjects Regulations or IRB Requirements

The IRB reviews all allegations of non-compliance with human subjects' 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 subjects 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 subjects, 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.

1. <u>Initial Inquiry</u>

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 subjects 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.

2. 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.

3. 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 subjects 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.

4. 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 subjects or to suspend approval of research project(s) to ensure the protection of human subjects. Except in cases of imminent harm to research subjects 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 subjects 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 decides 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.