NEW YORK INSTITUTE OF TECHNOLOGY

Human Research Protections Program

PROCEDURES AND GUIDELINES MANUAL

Volume 2

Investigator Responsibilities and Instructions for Applying for IRB Approval

Contents

Preface

The regulations set forth in this manual are intended to safeguard the human subjects 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 subjects 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 subjects.

- 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 subjects be fairly, not just conveniently, selected.

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

A. Human Research Protection at NYIT - General principles.

In 1974, the US Congress passed the National Research Act, establishing the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In 1978 the Commission published the Belmont Report, setting forth the basic ethical principles that should underlie the conduct of both biomedical and behavioral research involving human subjects; 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 subjects be fairly selected).

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

Practice refers to “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 or therapy, 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 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 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 and 1991 2005 and 2018. (CFR45). The 1991 revision involved adoption of the Federal Policy for the Protection of Human Subjects by the sixteen federal agencies that conduct, support, or otherwise regulate human subjects research.

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

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.

Additional information on the Human Subjects Protection System and suggestions for further reading can be found in OHRP's IRB Written Procedures: Guidance for Institutions and IRB's at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html and at NIH's Research using Human Subjects found at https://www.niaid.nih.gov/grants-contracts/human-subjects

The New York Institute of Technology has made the cited federal policy applicable and adaptable to all research involving human subjects 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 Subjects

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 subjects. 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 subjects, 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 subjects or prospective subjects

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

The investigator must consider two fundamental questions;

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

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

Clinical Trial means 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.

Human subject means 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, 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 epidemiological studies. Investigators are encouraged to contact the IRB for guidance in determining whether a particular study is considered human subjects 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.

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.

An **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

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.

Interaction includes communication or interpersonal contact between investigator and subject.

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 non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

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.

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 means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. 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, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
(4) Authorized operational activities (as determined by each agency), in support of intelligence, homeland security, defense, or other national security missions.

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.

Some research that involves human subjects 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 of 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 subject.

Any investigator representing NYIT and intending to conduct research activities involving a human subject 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.

Some studies such as data collection for internal departmental, school or other internal University administrative purposes; information gathering interviews where questions focus on things products or policies rather than people do not require IRB review. However, the investigator should check with the IRB office to make the determination.

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 subject protection requirements, and address the question of the investigator's fitness to conduct human subject 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. Categories of Research that Qualify for Exemption

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.

Unless otherwise required by law or by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the 8 categories below are Exempt. To qualify for Exempt status, the proposed research must pose minimal risk (see **Definitions**) and fall precisely into one of the following categories:

Subpart D.(Extra Protection for Minors) The exemptions at paragraphs (d)(1), (4), (5), (6), (7), and (8) of this section may be applied to research subject to subpart D if the conditions of the exemption are met. Paragraphs (d)(2)(i) and (ii) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research subject to subpart D.

(1) Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research

on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Research with subjects may include minors under 18 years of age, when the investigator(s) do not participate in the activities being observed, but not for (d)(2) (iii) of this section

(2) Research that only includes interactions involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

- **i.** The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- **ii.** any disclosure of the human subjects" responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects" financial standing, employability, educational advancement or reputation, **or**
- **iii.** The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by S46.111(a)(7).

(3) (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria are met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
(C)The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 46.111(a)(7).

(ii) for the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else (note: this is only for behavioral research- not biomedical research).

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Research with subjects under 18 years of age may be included in this category:

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) the research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C.3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C.552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency or otherwise subject to the approval of Department or Agency heads (or the approval of the heads of bureaus of other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections

1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this prior to commencing the research involving human subjects.

(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

(7) Storage or maintenance for secondary research for which broad consent is required. Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

i. Broad consent for storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

ii. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

iii. An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

2. Categories of Research that Qualify for Expedited Review

The Chair of the IRB can 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, but can be conducted by the Chair and or other members designated by the Chair and does not need a full board review.

A. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

B. The categories in this list apply regardless of the age of subjects, except as noted.

C. The expedited review procedure may not be used were identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects=financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

D. The expedited review procedure may not be used for classified research involving human subjects.

E. IRBS are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review-expedited or convened-utilized by the IRB

F. Categories one (1) through seven (7) pertain to both initial and continuing IRB 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 subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
>
> (b) from other adults and children[2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

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

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

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

> Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's 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 subjects;

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

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

(b) where no subjects 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.

3. Eliminating Continuing Review for Certain Expedited Studies

According to the Common Rule, the IRB is required to conduct continuing review for a study under its purview at least annually until the study is terminated with the IRB, unless an exception applies where continuing review is not required [45 CFR 46.109(f)(1)]

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

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

(3). 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

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

4. ***How to Submit a New Exempt, Expedited or Full Board Application***

Submit either a Request for Exemption, or the Application for Expedited/Full Board Review which can be found on our website at https://www.nyit.edu/ospar/institutional_review_board

Follow the instructions on the application. The proposal should be typed, with pages numbered. A table of contents is suggested. Depending on which application is submitted, some or all of the following components are required:

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 subjects and the inclusion and exclusion criteria

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

iv. Assessment of risks and benefits

Describe any potential harms or benefits to be derived by subjects, 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 subjects 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. For survey requests, use REDCAP or Qualtrics, and

use the appropriate disclaimer found on the application.

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 template on the website 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. <u>Attachments</u>

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 subjects protections See Completing the Required IRB Training on OSPAR's website at https://www.nyit.edu/ospar/institutional_review_board
iv. Letters of agreement from study sites (if applicable)
v. Curriculum vitae for the Principal Investigator and co-investigators (unless the PI is the instructor)
vi. Name and Email of Each Investigator, including students, so OSPAR can initiate the Conflict of Interest Form (see our policy at https://www.nyit.edu/policies/conflicts_of_interest_in_research)

5. Informed Consent

Informed consent is contingent upon the subject 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 is to facilitate a prospective subject's or legally authorized representative's understanding of the reasons why an individual might or might not want to participate in the research. Key information essential to decision making should appear at the beginning of the consent form and in the consent discussion. 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 subject in layman terms to be clearly understood and subsequent dialogue must also be presented to the subject in manner he/she or legal representative can easily understand.

Informed consent is a process, not just a form. The prospective subject or legally authorized representative must be provided with the information that a reasonable person would want in order to make an informed decision about whether to participate, and an opportunity to discuss that information. This information minimally includes the following elements:

- A statement that consent is being sought for research and that participation is voluntary;
- An explanation of the purposes of the research,
- The expected duration of the subjects' 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 subject
- A description of any benefits to the subject 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 subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject 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 subjects' rights, and whom to contact in the event of a research-related injury to the subject
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled; and
- One of the following statements about research that involves the collection of identifiable private information or identifiable biospecimens:
    - (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

- (ii)a statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
- 46.116(c)(7) (if applicable) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.
- 46.116(c)(9) For research involving biospecimens, whether the research will (if know) or might include whole genome sequencing (i.e. sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Additional elements (if appropriate) are

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
- Anticipated circumstances under which the subjects participation may be terminated by the investigator without regard to the subjects consent
- Any additional costs to the subject that may result from participation in the research
- The consequences of a subjects decision to withdraw from the research and procedures for orderly termination of participation by the subject
- A statement that significant new findings developed during the course of the research, which may relate to the subjects willingness to continue participation, will be provided to the subject
- The approximate number of subjects involved in the study
- If minors are involved, an **assent** form
- 46.116(c)(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions

Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens. Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted as an alternative to the informed consent requirements in paragraphs (b) and (c) of section 46.116. If the subject or the legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative:

(1) The information required in paragraphs 46.116 (b)(2), (b)(3), (b)(5), and (b)(8) and, when appropriate, (c)(7) and (9)

(2) A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient

information such that a reasonable person would expect that the broad consent would permit the types of research conducted;

(3) A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;

(4) A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);

(5) Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;

(6) Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and

(7) An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

No informed consent form, whether oral or written, may include any exculpatory language through which the subject or representative is made to waive or appear to waive any of the subjects' 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 subject 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 subject 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 subject and that the investigator was available for questioning; Students CANNOT sign as investigator.
- The subject, or representative/guardian (in some cases both the minor subject and the parent or guardian); and

The informed consent may be either of the following:

(1) A written informed consent form that meets the requirements of §46.116. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.

(2) A short form written informed consent form stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative, and that the key information required by §46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form.

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

1. The research involves no more than minimal risk to the subjects;
2. The research could not practicably be carried out without the requested waiver or alteration;
3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
4. (The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Use informed consent templates as a guide in preparing informed consent forms. Sample consent forms are available on the OSPAR website at https://www.nyit.edu/ospar/institutional_review_board

6. 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 modification form found on the OSPAR website at https://www.nyit.edu/ospar/institutional_review_board

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.

7. 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 form must be submitted no less than **60 days** prior to the expiration 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 means that all research activities need to cease as of the expiration date. No research may be conducted after the expiration date. **Please contact OSPAR if your renewal has lapsed to determine how to restart your research.**

G. Protections for Vulnerable Populations

Special considerations are enforced when research involves:

- Pregnant women
- Minors
- Newborns
- Individuals with impaired decision making capacity, or economically or educationally disadvantaged persons.
- Any other vulnerable population
- Any investigational drug or device study.
- Any transfer of genetic material to a human subject
- Exposure of the subject to radiation
- Recruitment of subjects in emergency situations
- The research involves multiple clinical sites AND federal funding
- Research conducted outside of the United States.

Any research falling into these classifications are subject to additional rules and regulations.

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.
- 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 in the Expedited/Full Board 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 Activities Not Considered Human Subjects Research

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.

Some Examples of Studies that do not require IRB Review

1. Data collection for internal departmental, school, or other University administrative purposes. Examples: teaching evaluations, customer service surveys.

2. Information-gathering interviews where questions focus on things, products, or policies rather than people or their thoughts regarding themselves. Examples: canvassing librarians about their libraries' inter-library loan policies or periodical purchases or interviews with company engineers or managers about how a product is made.

3. Course-related activities designed specifically for educational or teaching purposes, where data are collected as part of a class exercise or course requirement, but are not intended for use outside of the classroom.

4. Publicly available data do not require IRB review. Examples: census data, labor statistics. Note: Investigators should contact the IRB if they are uncertain as to whether the data qualifies as "publicly available."

   Note: these are only some examples and not an all inclusive listing.

I. 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, it becomes the other institutions obligation to meet OHRP requirements for safeguarding the rights of human subjects. Their qualified Institutional Review Board criteria, procedure and findings will be made known to NYIT for joint review or a Reliance Agreement may be signed in an effort to avoid procedure duplication. Even after review of another institution, an NYIT IRB may still disapprove participation of an NYIT employee in the research, but such restriction will be undertaken with utmost care.

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

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

Updates to the Common Rule include a requirement for institutions located in the U.S. that are engaged in federal cooperative research (projects involving more than one institution) to rely upon approval by a sIRB for the portion of the research that is

conducted in the U.S. The reviewing sIRB will be specified by the federal department or agency supporting or conducting the research; the "lead institution" may propose the reviewing IRB, but final federal approval will be required. Documents specifying the responsibilities of each entity (institution, reviewing IRB, ceding [also known as relying] IRB) when research takes place at an institution in which IRB oversight is outsourced.

J. Records

Research records should be maintained for a minimum of three (3) years after the completion of the research. (46.115(b))

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 subjects 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 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 inpatient hospitalization; or (iii) is a congenital anomaly/birth defect; or
- is an important medical event, based upon appropriate medical judgment, that may jeopardize the 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 subjects, including the following:

- Changes to the protocol are needed to minimize risks to subjects;
- Changes to the consent form are needed to accurately reflect the nature, frequency or severity of the event;
- Subjects 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 subjects.

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 subjects;
- Suspending approval; and/or
- Terminating approval.

The Principal Investigator and OSPAR 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 OSPAR and 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 (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 subjects 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 subjects, 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 subjects, failure to report adverse events or proposed protocol changes to the IRB, and failure to provide ongoing progress reports.

A. <u>Initial Inquiry</u>

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

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

Dismissal of the allegation or complaint as unjustified;
Referral of the matter to another more appropriate process or authority within NYIT for resolution;

Resolution through corrective or educational measures where the violation of human 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.

B. <u>Further Investigation</u>

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 OSPAR. 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 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 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 OSPAR 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 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 in writing to the investigator.

3. Reporting of Serious or Continuing Non-Compliance

The IRB is required to report to OSPAR, OHRP, and 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.

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 subject 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 Subject 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.