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STANDARD OPERATING PROCEDURES

1 HUMAN RESEARCH PROTECTIONS PROGRAM

1.1 MISSION

The New York University IRB's mission is to cultivate a research environment that promotes respect for the rights and welfare of individuals recruited for or participating in research conducted by or under the auspices of the University. In human research review, the principles outlined in the Belmont Report will guide the actions of the University. These actions will comply with all applicable federal, state, and local laws and regulations.

To fulfill its mission, the University's Human Research Compliance Office has established a Human Research Protections Program (HRPP). The purpose of the HRPP is to:

- safeguard and promote the health and welfare of human research participants by ensuring that their rights, safety, and well-being are protected.
- Provide timely and high-quality education, research review, and monitoring of human research projects; and
- facilitate quality in human research.

The HRPP includes procedures to:

- institute formal processes to monitor, evaluate and improve human research participant protections,
- dedicate sufficient resources to do so,
- educate investigators and research staff about their ethical responsibility to protect research participants, and when appropriate,
- intervene in research and respond directly to the concerns of research participants.

1.2 INSTITUTIONAL AUTHORITY

The standard operating procedures (SOPs) in these pages serve as the governing procedures for the review and conduct of all human research under the auspices of the New York University Washington Square Campus. These SOPs will be made available.
on the New York University IRB website to all New York University investigators and research staff.

1.3 DEFINITIONS GOVERNING HUMAN SUBJECTS RESEARCH

**Human subject:**

a living individual *about whom* an investigator (whether professional or student) conducting research:

(1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

(2) Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

(3) Interaction includes communication or interpersonal contact between investigator and subject.

(4) 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

(5) 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.

(6) 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.

**Research:**

A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research, whether 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.

(see NYUIRB FAQs)

(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.

Clinical trial:

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 those interventions on health-related biomedical or behavioral outcomes.

Institutional Review Board (IRB):

An IRB is a board established in accordance with, and for the purposes expressed in, the Common Rule [45 CFR 46.102(g)]

Institutional Official (IO):

The IO is responsible for ensuring that NYU's HRPP has the resources and support necessary to comply with all federal regulations and guidelines that govern human research. The IO is legally authorized to represent the institution and assumes the obligations of the institution's Assurance.

IRB Approval:
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.

**Research under the auspices of the University:**

Research under the auspices of the University is research conducted by or under the direction of any employee or agent of New York University (including students) in connection with his or her institutional responsibilities.

For the NYU IRB, research under the auspices of the University covers only research reviewed under its HRPP.

**IRB Protocol:**

The research procedures submitted to the HRPP/IRB for review, including a description of the research design and methodology as well as a complete description of the procedures for the protection of human participants in the research. The components of an IRB protocol may vary depending on the complexity of the research design and its methodology.

**A legally authorized representative (LAR):**

A LAR is 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, a 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. If there is no applicable law addressing this issue, a 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:**

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.

1.4 ETHICAL PRINCIPLES
The New York University HRPP is committed to promoting research with the highest regard for the welfare of human participants. It upholds and adheres to the principles of The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research by the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research (1979). These principles are:

1. **Respect for Persons**: ensured by obtaining informed consent, consideration of privacy, confidentiality, and providing additional protections for vulnerable populations.

2. **Beneficence**, which is assured by ensuring that potential benefits are maximized, and possible risks are minimized to all participants.

3. **Justice**, as a principle of research ethics, embodies the practice of equitable selection of participants.

The New York University HRPP, in partnership with the NYU research community, is responsible for ensuring the ethical and equitable treatment of all human participants in research conducted under its auspices.

### 1.5 REGULATORY COMPLIANCE

The HRPP is responsible for ensuring compliance with federal regulations, state law, and institutional policies. New York University shall abide by the policies and regulations found in 45 CFR 46 for research sponsored by local, state, and common rule agencies that adhere to the regulations and for unfunded research programs that meet the definition of human subjects research. The HRPP will also comply with all applicable laws and regulations where the research is carried out.

### 1.6 FEDERALWIDE ASSURANCE, IRB, AND ORGANIZATION NUMBERS

The HRPP operates under the authority of a Federalwide Assurance with the Department of Health and Human Services (DHHS) and provides support to an independent Institutional Review Board, which reviews all human research protocols under its jurisdiction that meet the federal definitions of human subject and research.

The pertinent DHHS registration information for NYU is:

Federalwide Assurance (FWA): 00006386

Institutional Review Board (IRB): 00000310

IRB Organization (IORG): 0000190
1.7 INSTITUTIONAL OFFICIAL

New York University has designated the Vice Provost for Research as the Institutional Official overseeing the University's human research protections program.

1.8 WRITTEN POLICIES AND PROCEDURES

The written policies and procedures in these pages apply only to those research programs that have been reviewed by the NYU IRB (formerly the University Committee on Activities Involving Human Subjects). The policies, once approved by senior leadership, shall remain in effect for a maximum of three years. Standardized policies and procedures which require revision or amending outside of the three-year term will require the approval of the IO or the IO designee.

1.9 HUMAN RESEARCH COMPLIANCE OFFICE ORGANIZATION

The Human Research Compliance Office supports the day-to-day operations of the IRB and HRPP.

1.9.1 THE INSTITUTIONAL OFFICIAL

The IO is authorized to establish IRBs, assure compliance with applicable laws, regulations, and University policy in the review, approval, and monitoring of human subject research. The IO maintains NYU's Federal-wide Assurance (FWA) with the Office of Human Research Protections of the United States Department of Health and Human Services.

The IO is responsible for ensuring the New York University HRPP has the resources and support necessary to comply with all institutional policies and with federal regulations and guidelines that govern human research.

The IO is legally authorized to represent New York University. The IO is the signatory of the FWA and assumes the obligations of the FWA. The IO, along with the Human Research Compliance Director, is the point of contact for correspondence addressing human research with the DHHS Office for Human Research Protections (OHRP) and any other federal regulatory agencies.

The IO also holds ultimate responsibility for oversight of the Institutional Review Board (IRB) and its administrative office and all New York University investigators; for assuring the IRB members are appropriately knowledgeable and apply ethical standards and applicable regulations accurately; for ensuring the investigators are adequately knowledgeable to conduct research under ethical standards and
applicable regulations; and for the development and implementation of an educational plan for IRB members, staff, and investigators.

1.10 THE HUMAN RESEARCH COMPLIANCE DIRECTOR

The Human Research Compliance Director reports to the Vice Provost for Research and is responsible for:

1. Developing, managing, and evaluating policies and procedures that ensure compliance with all state and federal regulations governing research. This responsibility includes monitoring changes in regulations and policies that relate to human research protection and overseeing all aspects of the HRPP.
2. Advising the VPR on essential matters regarding research under the auspices of the NYU IRB.
3. Implementing the institution's HRPP.
4. Maintaining an approved FWA through the VPR and the Department of Health and Human Services Office for Human Research Protection (OHRP).
5. Managing the finances of the NYU HRPP.
6. Assisting investigators in their efforts to carry out the University's research mission.
7. Developing and implementing needed improvements and ensuring follow-up of actions, as appropriate, to manage risk in the research program.
8. Developing training requirements as required and as appropriate for investigators, committee members, and research staff, and ensuring that training completion on a timely basis.
9. Carrying out responsibilities delegated by the VPR:
   • Reviewing and signing memoranda of understanding and cooperative agreements between the institution and other organizations, including those that establish reliance on IRBs of record (e.g., IRB Authorization Agreements, Individual Investigator Agreements).
   • Drafting appointment letters for IRB members. Suspending or terminating the IRB membership of any individual determined not to be fulfilling membership responsibilities and or obligations.
10. Maintaining adequate documentation of IRB activities as required by the federal regulations at 45 CFR 46.115.
11. Sharing responsibility with the Senior IRB Manager for overseeing the day-to-day operation of the IRB office, including the supervision of IRB staff.

1.11 INSTITUTIONAL REVIEW BOARD (IRB)
The IRB is the administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of NYU. The IRB functions in coordination with other review committees but maintains its independence to review, approve, and monitor research with human subjects appropriately.

1.12 THE PRINCIPAL INVESTIGATOR

Eligibility – PI Qualifications

To ensure that research is conducted by those who have the requisite training and skill, as well as the appropriate relationship to NYU, the IRB will usually review protocol applications only when the principal investigator is employed full-time by the University and holds an appointment as an assistant professor, associate professor or professor.

The IRB recognizes one Principal Investigator (PI) for each study protocol. The Principal Investigator has ultimate responsibility for the research activities.

Exceptions and the exception requests process

Clinical professors, clinical associate professors, and clinical assistant professors are permitted to serve as Principal Investigators with the approval of the department chair and, where appropriate, the Dean of the relevant NYU school.

For research scientists/scholars or senior research scientists/scholars, requests for Principal Investigator status on human subject research must be approved by the department chair and, where appropriate, the Dean of the relevant NYU school.

PI status requests for Professional Research Personnel, Continuing Contract Faculty, as well as for those individuals whose appointments do not fall within the above-stated categories, may be requested if approved by the department chair and where appropriate, the Dean of the relevant NYU school.

PI requests for staff and administrators may be requested if approved by the appropriate unit supervisor. Only full-time staff and administrators may be granted PI status.

Consistent with University policy, exceptions are made only with the appropriate approvals in place.
See: Code 103 Professional Research Personnel and Continuing Contract Faculty as Principal Investigators of Sponsored Projects and Programs

Students and others "in-training" as Investigators

Any investigator whose status is "in training" (i.e., students and post-doctoral researchers) may not serve as a Principal Investigator but may serve as a co-investigator and must have a faculty sponsor.

Faculty Sponsor Qualifications

Faculty Sponsors must demonstrate sufficient qualifications to conduct and oversee the design, conduct, and reporting of student research involving human subjects. Human subjects research studies that require skills beyond those held by the Faculty Sponsor must be modified to meet the PI's qualifications or have one or more additional qualified faculty act as co-investigator(s).

1.13 RELATIONSHIP BETWEEN INSTITUTIONAL COMPONENTS

The IRB functions independently of, but in coordination with, other institutional regulatory committees and offices. The IRB makes independent determinations of whether to approve or disapprove a protocol based upon whether human participants are adequately protected. The IRB has review jurisdiction over all research involving human participants conducted, supported, or otherwise subject to regulation by any federal department or agency that has adopted the human research regulations.

Review by Institution [§46.112]: Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of the institution. However, those officials may not approve research if it has been disapproved by the IRB.

The Human Research Compliance Office, in supporting the IRB and administering the HRPP, interacts and coordinates with other units at NYU to ensure compliance, including:

- Division/Department Chairs: Oversee compliance in departmental human subject research activities and departmental response to allegations of non-compliance.
- School Deans: Aid in fostering and enabling compliant human subjects research by receiving and assessing reports of non-compliance and supporting the education and training of the NYU research community.
• **Office of the General Counsel**: The NYU HRPP relies on the Office of the General Counsel for interpretations and applications of New York State law and the laws of any other jurisdiction where research is conducted as they apply to human research.

• **Office of Sponsored Programs**: The Office of Sponsored Programs (OSP) and its Contract Office (CO) provides pre-award and non-financial post-award research administration service and support to all departments, schools, research centers, and institutes at the Washington Square campus as well as all of NYU’s global sites. The Human Research Compliance Office works with the OSP to ensure regulatory compliance with sponsored human research programs.

• **Environmental Health and Safety**: Environmental Health and Safety (EHS) provides occupational and environmental health and safety services to all faculty, students, and staff, including maintaining compliance with federal, state, and local laws and regulations related to occupational health and safety, environmental conservation and protection, and laboratory safety. Environmental Health and Safety department also provide emergency response, technical support, information and training programs, and environmental health and safety consulting and auditing services.

Programs under EHS’s charge related to human subject research are:

  o **Biosafety**: responsible for assisting the NYU community in implementing university workplace environment, health and safety policies while complying with applicable federal, state, and local regulations and guidelines, including the Institutional Biosafety Committee (IBC).

  o **Compliance Assessments**: Environmental Health and Safety conducts compliance assessments throughout the University to ensure compliance with federal, state, and local environmental, health, and safety regulations.

  o **Laboratory Safety**: NYU is responsible for the control of health hazards related to chemical and physical agents within the University’s laboratories. Programs designed to implement University policy and procedures have been established to protect the health and safety of students, faculty, and staff as well as to meet the regulatory requirements established by Occupational
Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), New York State and local authorities.

- **Occupational Health and Safety**: The site provides links to specific areas of occupational health and safety, including USDLOSHA requirements.

- **Office of Conflict of Interest**: The Office of Conflict of Interest (OCI) provides support to the Washington Square campus school Deans in their implementation of NYU's [Policy on Academic Conflict of Interest and Conflict of Commitment](#). The OCI supports the Deans in the review, identification, and management of conflicts of interest related to research. The OCI also provides administrative support to the Washington Square Conflicts Committee, which provides advice to the Deans for research-related conflict of interest issues, including recommendations on appropriate conflict management plans. The OCI also advises on issues of COI training, disclosure, policy, and conflict management and monitoring.

- **Office of Postdoctoral Affairs**

  The Office of Postdoctoral Affairs (OPA) supports, promotes, and enhances the research careers of NYU Postdocs, defined as individuals within five years of receiving their Ph.D. who are not yet on a tenure track. The OPA also provides [Responsible Conduct of Research](#) (RCR) training.

### 1.14 HUMAN RESEARCH COMPLIANCE OFFICE

The NYU Human Research Compliance Office (HRCO) is part of the NYU Office of Research Compliance (ORC). The HRCO, which is supervised by the Human Research Compliance Director, reports directly to the VPR.

The Human Research Compliance Director maintains Certification as an IRB Professional and has knowledge in and experience with regulatory issues regarding human research protections as well as experience in other university compliance areas. The HRCD is the primary contact at New York University for the Office for Human Research Protections (OHRP), Department of Health and Human Services (DHHS), and is responsible for the development of policy and procedures for the HRPP.

The Human Research Compliance Director and other staff share the day-to-day responsibilities for the operation of the HRPP. Duties include (but are not limited to) responding to faculty, student, and staff questions about human research, developing and disseminating educational programs, and organizing and documenting all the
activities of the HRPP. These senior staff members work closely with the IRB Chair and Committee and serve as voting members of the IRB.

To support the office functions and the HRPP, the office shares the services of a Systems Analyst who assists with the development of the IRB’s Electronic Research Administration System, Cayuse Human Ethics (IRB) website content management, and IRB review metrics and workflow analyses. Two experienced IRB Administrators and a Senior IRB Administrator who serves as a voting member and expedited reviewer for the IRB complete the IRB management team.

Duties and responsibilities for all staff are in their respective job descriptions, and their performance evaluation is done on an annual basis.

1.14.1 HRCO RESOURCES

The HRCO has the necessary office space, meeting space, storage space, and equipment to perform the functions required for the HRPP. The adequacy of personnel and non-personnel resources of the HRPP program is assessed annually by the Human Research Compliance Director. The IO provides resources, including adequate meeting and office space and staff for conducting IRB business.

1.15 COLLABORATIVE RESEARCH PROJECTS

In the conduct of collaborative research projects, New York University acknowledges that each institution is responsible for safeguarding the rights and welfare of research participants and for complying with applicable federal regulations and institutional policies. New York University may enter into a joint review arrangement or rely on the review of another IRB, ethics committee, or any institution with a Federalwide Assurance (FWA).

**Single IRB for Federal Common Rule Agencies**

The Common Rule requires that domestic institutions engaged in federally funded, non-exempt, cooperative human subjects research use a single Institutional Review Board. The following research is not subject to this provision:

(i) Cooperative research for which more than single 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.
The Common Rule definition of a cooperative research project is one that involves more than one institution. An institution is considered to be involved in human subjects research if it is "engaged" in the research. In general, an institution is engaged in research when:

1. It receives an award directly from a Common Rule agency for the human subjects research (i.e., grantee institutions), even where all activities involving human subjects are carried out by another institution.

2. Its employees or agents intervene for research purposes with any human subjects of the research by performing invasive or noninvasive procedures or manipulating their environment. (Examples include providing individual or group counseling or psychotherapy and orchestrating environmental events or social interactions)

3. Its employees or agents interact for research purposes with any human subject of the research. (Examples include administering surveys or conducting interviews)

4. Its employees or agents obtain the informed consent of human subjects for the research.

5. Its employees or agents obtain, use, study, analyze, or generate identifiable private information or identifiable biospecimens for research purposes.

NIH sIRB

If a multi-site study involving non-exempt human subjects research is funded by the National Institutes of Health (NIH) via a grant or contract submitted to the NIH on or after January 25, 2018, then the NIH single IRB (sIRB) policy requires the use of a single IRB to accomplish IRB review and approval for all domestic sites.

The NIH policy applies to all studies that are:

- Funded through grants, cooperative agreements, or contracts and
- Involve non-exempt human subjects research, and
- Involve multiple domestic sites, all of which are conducting the same protocol
- The policy does not apply to studies that are:
  - Funded to foreign awardees and/or conducted at foreign sites, or
  - Funded through career development, research training or fellowship awards, or
• Where review by the proposed sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy.

A formal relationship must be established between the University and the other institution(s) through either a Cooperative Agreement, a Memorandum of Understanding, or an IRB Authorization Agreement (IAA). This relationship must be formalized before the University will accept any human research proposals from the other institution or rely on the review of the other institution.

**Collaborative Research general requirements**

For all collaborative research in which NYU serves as an engaged institution, the PI must identify all institutions engaged in the research and the responsible IRB(s). The procedures for dissemination of protocol information (IRB initial and continuing approvals, relevant reports of unanticipated problems, protocol modifications, and interim reports) between all participating institutions will be determined in the following ways:

• When New York University relies on another IRB, the HRPP staff will ensure that the other organization has an active IRB registration and appropriate policies in place.

• When New York University reviews research on behalf of another institution, the particular characteristics of each institution's local research context must be considered, either (i) through knowledge of its local research context or (ii) through subsequent review and documentation by the appropriate designee of the relying institution.

The investigator is responsible for serving as the single liaison with outside regulatory agencies, with other participating facilities, and for all aspects of internal review and oversight procedures. The investigator is responsible for ensuring that all participating facilities obtain review and approval from their IRB of record and adopt all protocol modifications in a timely fashion. The investigator is responsible for ensuring that the research study is reviewed and approved by any other appropriate committees at the collaborating facility and the participating facilities before the enrollment of participants.

**2. THE INSTITUTIONAL REVIEW BOARD**

The following describes the authority, role, and procedures of the New York University Institutional Review Board (IRB).

**2.1 PURPOSE**
The IRB is established to ensure the protection of human participants in research under the auspices of New York University.

2.2 IRB AUTHORITY

The IRB is authorized to:

1. approve, require modifications to secure approval, or disapprove all research activities overseen and conducted under the auspices of New York University;
2. suspend or terminate approval of research not being conducted under the IRB’s requirements or that has been associated with unexpected serious harm to participants;
3. observe, or have a third party observe the consent process; and
4. observe, or have a third party observe, the conduct of the research.

Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of the institution. However, those officials may NOT approve of research if the IRB has disapproved of it. University officials may strengthen requirements and conditions, or add other modifications to secure University approval or approval by another University committee.

2.3 NUMBER OF IRBS

There is currently one Institutional Review Board. The IO, the HRC Director, and the Chair of the IRB shall review the activities of the IRB at least annually to determine the appropriate number of IRBs needed for the institution.

2.4 ROLES AND RESPONSIBILITIES

Chairperson of the IRB

The New York University IO (Vice Provost for Research), in consultation with the HRC Director, appoints a Chair and Vice-Chair of the IRB. Any change in appointment, including reappointment or removal, requires written notification. Appointments have a specified term of three years with the first year probationary. At the end of the probationary period, the new member is invited to continue on for two additional years, upon agreement of the new member and the IO, in consultation with the Chair and HRCO.

The IRB Chair shall be a highly respected individual with an active appointment at the University, fully capable of managing the IRB and the matters brought before it with fairness and impartiality. The task of making the IRB a respected part of the institutional community will fall primarily on the shoulders of the Chair. The IRB must
be perceived to be fair, impartial, and immune to pressure by the institution's administration, the investigators who bring protocols before it, and other professional and nonprofessional sources.

The IRB Chair is responsible for conducting the meetings and is a signatory for full-board correspondence generated by the IRB, as is the Vice Provost for Research, the Vice-Chair, or HRC Director.

The IRB Chair may designate other IRB members to perform duties, as appropriate, for review, signature authority, and other IRB functions (e.g., the Vice-Chair and HRC Director.)

The IRB Chair may advise the IO and HRC Director about IRB member performance and competence.

IRB Chair performance review is on an annual basis by the HRC Director in consultation with the IO. If the Chair is not acting in accordance with the IRB's mission, is not following these policies and procedures, has a disproportionate number of absences, or is not fulfilling the responsibilities of the Chair, the Chair will be removed.

Vice-Chair of the IRB

The Vice-Chair has comparable qualifications to the IRB Chair. In the Chair's absence, the Vice-Chair may exercise the authority and duties of the Chair.

Subcommittees of the IRB and Delegation of Expedited Review

The Chair, in consultation with the HRC Director, may designate one or more other IRB members, i.e., a subcommittee, to perform duties, as appropriate, for review, signature authority, and other IRB functions.

Duties of a subcommittee may include the following:

- Serve as designees by the IRB Chair for the expedited review of new or continuing protocols, and modifications. The subcommittee must be experienced in terms of seniority on the IRB.
- Review and approve the revisions requiring only simple concurrence submitted by investigators for a protocol given conditional approval by the convened IRB.
- Conduct an inquiry into allegations of non-compliance
- Conduct on-site review. The IRB determines on a protocol-by-protocol basis of the review interval and the need for additional supervision and participation. (For example, for an investigator who is performing particularly risky research,
or for an investigator who has recently had a protocol suspended by the IRB due to regulatory concerns, an on-site review by an IRB subcommittee might occur, or approval might be subject to an audit of study performance after a few months of enrollment or after enrollment of the first several participants).

2.5 IRB MEMBERSHIP

IRB members are selected based on appropriate diversity, including consideration of race, gender, cultural backgrounds, and specific community concerns, in addition to representation by multiple, diverse professions, knowledge, and experience with vulnerable participants and inclusion of both scientific and non-scientific members. The structure and composition of the IRB must be appropriate to the volume and nature of the research that is reviewed. Every effort is made to have member representation that understands the areas of specialty that encompass most of the research performed at New York University.

In addition, the IRB will include members who are knowledgeable about and experienced working with vulnerable populations that typically participate in New York University research or have ready access to consultants with appropriate knowledge and experience.

The IRB must promote respect for its advice and counsel in safeguarding the rights and welfare of research participants and possess the professional competence necessary to review specific research activities. A member of the IRB may fill multiple membership position requirements for the IRB.

2.6 COMPOSITION OF THE IRB

If the IRB regularly reviews research that involves a vulnerable category of participants, consideration will be given to the inclusion of one or more individuals on the IRB who are knowledgeable about and experienced in working with these participants. When protocols involve vulnerable populations, the review process will include one or more individuals who are knowledgeable about or experienced in working with these participants, either as members of the IRB or as consultants.

Every nondiscriminatory effort will be made to ensure that the IRB does not consist entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. The IRB shall not consist entirely of members of one profession.

The IRB includes at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas.
The IRB includes at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

One member may satisfy more than one membership category.

Senior staff of the Human Research Compliance Office may serve as voting members of the IRB.

2.7 APPOINTMENT OF MEMBERS TO THE IRB

Member appointment process and terms

The IO, IRB Chair, Vice-Chair, or the HRC Director may identify a need for a new or replacement member or alternate member. Individual IRB members may nominate candidates and send the names of the nominees to the HRC Director. Department Chairs and others may forward nominations to the IO, to the HRC Director, or to the IRB Chair or Vice-Chair. The IO, the IRB Chair, and the HRC Director have the final decision in selecting a new member. Appointments are made in writing by the IO or the HRC Director.

Faculty appointments to the IRB are usually for three-year renewable terms, with the first year probationary. Unaffiliated member and student member appointments are for terms of one year or less. Any change in appointment, including reappointment or removal, will be provided through written notification.

Members may resign by written notification to the Chair, HRC Director, or the IO.

All appointments are subject to annual review by the HRC Director and IRB Chair; recommendations for changes in membership shall be submitted to the IO for review. The IRB Chair and the HRC Director will review the membership and composition of the IRB to determine if it continues to meet both regulatory and institutional requirements. Recommendations for changes to Board composition will be submitted to the IO.

Alternate members

The appointment and function of alternate members are the same as that for primary IRB members, and the alternate’s expertise and perspective are comparable to those of the primary member. The role of the alternate member is to serve as a voting member of the IRB when the regular member is unavailable to attend a convened meeting. When an alternate member substitutes for a primary member, the alternate...
member will receive and review the same materials before the IRB meeting that the primary member received or would have received.

The IRB roster identifies the primary member(s) for whom each alternate member may substitute. The IRB minutes will document when an alternate member replaces a primary member. If both primary and alternate members are present at the meeting, it will be made clear at the outset which member is there in a voting capacity.

**Use of Nonvoting Consultants**

When necessary, the IRB Chair or HRC Director may solicit individuals from the University or the community with competence in select areas to assist in the review of issues or protocols which require appropriate expertise beyond or in addition to that available on the IRB. Requests for review by a non-voting consultant are made in advance of the meeting by IRB staff at the request of the Chair or HRCO. The Human Research Compliance Office (HRCO) staff shall provide all relevant materials to a non-voting consultant before the convened meeting.

Meeting minutes will document key information provided by consultants at meetings. The HRCO staff will ensure that consultants abide by the IRB Member and Consultant Conflict of Interest requirements and sign a COI statement.

The consultant’s findings will be presented to the full board for consideration, either in person or in writing. If in attendance, these individuals will provide consultation but may not participate in or observe the vote.

### 2.8 DUTIES OF IRB MEMBERS

All IRB members have access to the agenda, minutes from the previous meeting, and the protocols to be reviewed at the meeting. Members are provided these materials in a timely fashion, usually one to two weeks before the convened meeting.

All members will review their assigned work and add their review comments in the IRB’s Electronic Research Administration system at least two days before the meeting. Members must come prepared to answer questions about their assigned reviews and provide the board with possible resolutions to issues and concerns. Members should discuss minor issues with consent documents and missing information with the HRC Office staff before the convened meeting.

IRB members will treat the application materials as confidential. Members must hand-in to the HRC Office any physical copies of applications and supporting materials made for review purposes immediately following the meeting.
IRB members will not disclose IRB decisions and business outside of the convened meeting. All IRB determinations must be conveyed to investigators in writing.

2.9 ATTENDANCE REQUIREMENTS

Primary members are required to attend the majority of convened IRB meetings on an annual basis. To ensure continuity in the knowledge of IRB decisions, alternate members should attend meetings as much as possible, either in person or remotely. All IRB members are expected to attend convened meetings for which they have indicated a positive response to the meeting invitation. Occasional attendance via teleconference (e.g., Zoom conferencing) or telephone is permissible; however, the expectation is that members will attend in-person whenever possible.

If members are unable to attend a scheduled meeting, they must inform the HRC Office via email AND cc the IRB Chair. Members assigned to complete a review for a convened meeting must attend; if an emergency arises, an assigned reviewer is expected to inform the HRC Office immediately.

If an IRB member is to be absent for an extended period, such as for a sabbatical, the member will notify the HRC Office at least 30 days in advance so that an appropriate replacement can be secured, if necessary. The replacement can be temporary, for the period of absence, or permanent if the member is not returning to the University. If the member has a designated alternate, the alternate is expected to serve during the primary member's absence.

2.10 INITIAL AND ONGOING EDUCATION OF CHAIR AND IRB MEMBERS

A vital component of a comprehensive human research protection program is an education program for the IRB Chair and the IRB members. New York University is committed to providing training and ongoing education for all IRB members related to ethical concerns and regulatory and institutional requirements for the protection of research participants.

New IRB members are required to attend an orientation session. At a minimum, the session will cover:

- The Belmont Report;
- New York University policies and procedures; and
- Federal regulations governing human subjects research (AKA Federal Common Rule)
- How to review a protocol in the Cayuse Human Ethics (IRB) System
- New members must complete the orientation requirement before they may serve as a Primary Reviewer.
CITI training requirements

Upon appointment, IRB members will promptly complete the following training:

- NYU CITI training for Human subjects for researchers; and
- The IRB Member training in CITI

Continuing Education

To ensure that oversight of human research is ethically grounded and the decisions made by the IRB are consistent with current regulatory and policy requirements, the HRC Office will provide continuous training for IRB members throughout their service on the IRB. Educational activities may include, but are not limited to;

- in-service training at IRB meetings;
- training workshops and special issues meetings;
- copies of appropriate publications;
- new information that might affect the IRB, including laws, regulations, policies, procedures, and emerging ethical and scientific issues.
- links in the meeting agenda to relevant articles, videos, and podcasts as well as scheduled webinars sponsored by national organizations such as PRIM&R

2.11 REVIEW OF IRB MEMBER PERFORMANCE

The IRB members' performance will be reviewed annually by the HRC Director, who will report performance issues to the IRB Chair and IO. Members will be removed from service who are not acting in accordance with the IRB's mission or policies and procedures or complying with attendance requirements.

2.12 MEMBER COMPENSATION

IRB Participation by NYU faculty, staff, or students is considered a component of their University responsibilities as established by their respective departments and schools. Full voting members may be modestly compensated for the time spent on IRB activities. Full voting Members who are not affiliated with NYU may receive appropriate reimbursement as consultants and miscellaneous expenses (e.g., commuting expenses).

2.13 REPORTING AND INVESTIGATION OF ALLEGATIONS OF UNDUE INFLUENCE

If an IRB Chair, member, or HRC Office staff person feels that any party has unduly influenced the IRB, they shall make a confidential report to the HRC Director, or the
Institutional Official, depending on the circumstances. The official receiving the report, or his/her designee, will conduct a thorough investigation, and corrective action will be taken to prevent additional occurrences as warranted.

3. THE IRB REVIEW PROCESS

3.1 PURPOSE
The following describes the procedures required for the review of research by the IRB.

3.2 DEFINITIONS: IRB REVIEW

IRB Approval: 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.

Minimal Risk. 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.

Minimal Risk with Prisoners: Minimal Risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. (45 CFR 46.303(d)).

Minor change. A minor change is one which, in the judgment of the IRB reviewer, makes no substantial alteration in:

- the level of risks to participants
- the research design or methodology (adding procedures that are not eligible for expedited review would not be considered a minor change)
- the qualifications of the research team
- the facilities available to support safe conduct of the research
- any other factor which would warrant a review of the proposed changes by the convened IRB.

Quorum. A quorum of the IRB consists of a majority of the voting members, including at least one member whose primary concern is in a non-scientific area. Research involving prisoners requires that the quorum count contain a prisoner representative.
Suspension of IRB approval. A suspension is a directive of the convened IRB or another authorized individual to stop some or all previously approved research activities temporarily. Suspended protocols remain open and require continuing review.

Termination of IRB approval. A directive of the convened IRB to permanently stop all activities in previously approved research. Terminated protocols are considered closed and no longer require continuing review.

3.3 HUMAN SUBJECTS RESEARCH DETERMINATION

The responsibility for the initial determination of whether an activity constitutes human subjects research and therefore requires a submission to the IRB rests with the Investigator. The Investigator should make this determination based on the guidance provided by the NYU (Human Research Protections Program) HRPP on its website and the embedded assessments in the submission Applications.

3.4 EXEMPT STUDIES

Exempt research studies involve specific categories of research that do not require IRB review and approval. However, it is the policy of the NYU HRPP to have all such research submitted for review to the HRCO. The review ensures that the research truly meets the qualifications for exempt research as defined at 46.104 and ensures adherence to the ethical principles outlined in the Belmont Report. Experienced Human Research Office (HRCO) staff may conduct exempt research determinations that do not require a Limited IRB Review. Limited IRB review is a process that is required only for specific exempt subcategories and does not require an IRB to consider all of the IRB approval criteria in §46.111. In Limited IRB Review, the IRB must determine that certain conditions, which are specified in the regulations, are met. An experienced IRB member or the Chair may conduct a Limited IRB review via the expedited review mechanism.

Research that is determined to be Exempt has no expiration date; however, investigators are required to close-out their IRB study protocol when an Exempt study has ended. The IRB expects Investigators to cooperate in any compliance monitoring conducted by the HRC Office.

Categories of Exempt Research, Including Limited IRB Review subcategories (46.104)

The following categories of human subject research are exempt from IRB review, but must still be reviewed by the HRPP:

(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.

(2) Research that only includes interactions involving 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 §46.111(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 is 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.

(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.

(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

(NB Identifiable Health Information that is regulated under the HIPAA Privacy Rule that involves NYU PHI requires review by the NYU School of Medicine IRB/Privacy Board)

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research 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 USC. 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 USC. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 USC. 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 or 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 list 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 US Department of Agriculture.

Each of the exemptions above may be applied to research subject to research with pregnant women, fetuses, and neonates if the conditions of the exemption are met. The exemptions above do not apply to research with prisoners, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

Exemptions at (1), (4), (5), (6), (7), and (8) may be applied to research with children if the conditions of the exemption are met. Exemptions at (2)(i) and (ii) only may apply to research with children involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Exemptions at (d)(2)(iii) may not be applied to research with children.

The following two exemptions have not been adopted by the NYU IRB

(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.

Additional Protections for exempt research afforded by the Belmont Report

Although exempt research is not covered by the federal regulations, this research is not exempt from the ethical guidelines of the Belmont Report. The reviewer (either HRCO Staff or IRB Member) determining exemption will determine whether to require additional protections for participants in keeping with the guidelines of the Belmont Report.

3.5 EXPEDITED REVIEW

An experienced IRB member conducts expedited reviews at NYU. The IRB member conducting the expedited review may exercise the authority of the IRB, except that the reviewer may not disapprove or terminate the research. The reviewer must refer all research protocols that would have been disapproved to the convened IRB for review. The reviewer may also refer other research protocols to the convened IRB whenever the reviewer believes that the convened IRB review is warranted.

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 below categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110. 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.

The categories apply regardless of the age of subjects, except as noted.

The expedited review procedure may not be used where 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.
The expedited review procedure may not be used for classified research involving human subjects. **NYU DOES NOT PERMIT THE CONDUCT OF CLASSIFIED RESEARCH.**

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.

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**CATEGORIES OF EXPEDITED REVIEW**

**Category 1:** Clinical studies of drugs and medical devices only when condition (a) or (b) is met. *(NB: Research which meets the criteria for expedited review at category 1 cannot be reviewed by the NYU IRB and must be referred to the NYU Grossman School of Medicine IRB).*

(a) Research on drugs for which an investigational new drug application (21 CFR 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); or

(b) Research on medical devices for which (i) an investigational device exemption application (21CFR812) 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.

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

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

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

**Category 3:** Prospective collection of biological specimens for research purposes by noninvasive means. Examples include:
(a) hair and nail clippings in a non-disfiguring 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 gum base 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.

**Category 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 include:

(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.

**Category 5:** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research 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 research participants. 45 CFR 46.104(d)(4). This listing refers only to research that is not exempt.)

**Category 6:** Collection of data from voice, video, digital, or image recordings made for research purposes.

**Category 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 research participants. 45 CFR 46.104(d)(2) and (d)(3). This listing refers only to research that is not exempt.)

**Category 8:** Continuing review of research previously approved by the convened IRB as follows:

(a) where:
(i) the research is permanently closed to the enrollment of new participants;
(ii) all participants have completed all research-related interventions; and
(iii) the research remains active only for long-term follow-up of participants; or

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

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

**Category 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.

### 3.5.1 INFORMING THE IRB OF EXPEDITED REVIEW DETERMINATIONS

IRB members will be apprised of all expedited review approvals by means of a list in the meeting agenda. Any IRB member can request to review the full application for a study reviewed via expedited procedures by contacting the HRCO.

### 3.6 IRB MEETING SCHEDULE

The IRB meets on a regular basis throughout the year, typically monthly. The schedule for the IRB may vary due to holidays or lack of quorum. The IRB Meetings schedule for the academic year is posted on the HRCO website. Special meetings may be called at any time by the Chair or the Human Research Compliance (HRC) Director in consultation with the Chair.

### 3.6.1 PRELIMINARY REVIEW & ASSIGNMENT TO CONVENED IRB MEETINGS

Investigators submit applications electronically to the HRCO via Cayuse Human Ethics (IRB). Instructions for Cayuse Human Ethics (IRB) registration and the protocol submission process are available on the HRCO website.

Cayuse Human Ethics (IRB) smart forms are adaptable to all review levels. (e.g., Exempt vs. Limited IRB Review vs. Expedited review vs. Full-Board Review).

HRCO staff (e.g., IRB Administrators and Assistant IRB Administrators) perform preliminary reviews of all applications to ensure they contain the required components and associated documents. Only complete submissions will undergo a formal review under the NYU HRPP.

HRCO staff place applications on the agenda for the convened board when the non-exempt research proposes activities that do not meet the criteria for expedited review or expedited studies which cannot be approved by the designated expedited reviewer. HRCO staff may seek guidance from the Chair, HRC Director, and/or their designee to determine if an application requires convened IRB review.

Posted deadlines for full board review are on the HRCO website. The IRB will review applications of appropriate quality that contain all required components received by the posted deadline at its next convened meeting.
The IRB reviews applications that meet expedited review criteria or exempt-limited criteria on a rolling basis based on the submission date, except for the conditions described in the paragraph below.

Applications for research associated with a **Just-in-Time** or other sponsor requests that contain a specific deadline will receive a priority review. Investigators must attach the correspondence from the sponsor that reflects the deadline for IRB approval to their Cayuse Human Ethics (IRB) application. When submitting an application for research that has an impending funding deadline, the Investigator should note this in the study title of the Cayuse Human Ethics (IRB) application so that HRCO staff are alerted to the urgency of the review.

### 3.6.2 ASSIGNMENT AND CONDUCT OF REVIEWS

**Full Board review**

After determining that the protocol submission is complete and meets the criteria for review at a convened IRB meeting, HRC Office senior staff will assign protocols for review to the appropriate Board reviewers. The reviewer assignment will take into account the scientific content of the protocol and the required area of expertise. Each initial protocol will be assigned to two reviewers. At least one reviewer is assigned to each renewal and modification requiring review at a convened meeting. When the IRB is presented with a protocol that may be outside of the knowledge base of the NYU IRB, outside consultation will be sought.

Primary reviewers are responsible for:

- having a thorough knowledge of all of the details of the proposed research;
- performing an in-depth review of the proposed research;
- leading the discussion of the proposed research at the convened meeting and leading the IRB through the regulatory criteria for approval; and
- making suggestions for changes to the proposed research following regulatory criteria, where applicable.

If the primary reviewer is absent from the meeting, a new reviewer may be assigned, provided the new reviewer has reviewed the materials before the meeting.

Additionally, an absent reviewer can submit their written comments for presentation at the convened meeting, as long as there is another reviewer present at the convened meeting.
meeting who can serve as the primary reviewer. All IRB members have complete access to all of the research protocols for the meeting to ensure they can contribute to the deliberations and vote and must review all studies placed on the agenda, not just their assigned reviews.

Expedited and Limited IRB Review

Qualified IRB members conduct reviews of research that meet the criteria for expedited or Limited IRB Review. Frequently the reviewer is an IRB member who is also a member of the HRCO staff.

3.6.3 QUORUM REQUIREMENTS FOR FULL BOARD REVIEWS

A quorum for a convened IRB meeting consists of a majority of the voting membership, including at least one member whose primary concern is in a non-scientific area. When reviewing prisoner research, a prisoner representative must be present and counted towards the quorum. The IRB Chair, with the assistance of the HRCO staff, will confirm that an appropriate quorum is present before calling the meeting to order. The IRB Chair is responsible for ensuring that the meetings remain appropriately convened.

A quorum must be maintained for each vote to occur. The HRCO staff member assigned as the Board Secretary records when meeting membership reaches quorum and advises the Chair to call the meeting to order. After the meeting is called to order, the Board Secretary notes arrivals and departures of all members. If the quorum is lost, the meeting will adjourn. Protocols not reviewed by the quorum must be tabled and moved to the next meeting.

Members are considered present and counted towards the quorum if participating through teleconferencing or videoconferencing. All members, whether participating remotely or in-person, will receive all pertinent material prior to the meeting, and will be able to actively and equally participate in the discussion of all protocols.

The attending IRB members may consider the opinions of absent members transmitted in written form. However, they may not be counted as votes or to satisfy the quorum for convened meetings.

3.6.4 GUESTS AT CONVENED MEETINGS

When an Investigator’s application is reviewed at a convened IRB meeting, the Investigator is invited to attend the IRB meeting or remain available via phone to answer questions about the proposed research. Investigators may not be present for the discussion or vote on their research.
Other guests may be permitted to attend IRB meetings at the discretion of the IRB Chair and the HRC Director. Guests may not speak unless requested by the IRB and are required to sign a Confidentiality Agreement.

3.6.5 CONFLICTS OF INTEREST IN IRB REVIEW

Federal regulations prohibit IRB members from participating in the review of any research project in which they have conflicting interest, except to provide information that is requested by the IRB (45 CFR 46.107(e)). IRB members must comply with NYU institutional policies for the reporting and management of conflicts of interest. The NYU IRB works in conjunction with the NYU Conflict of Interest Review Board, which serves in an advisory capacity to interpret conflict of interest.

IRB Member's Disclosure of a Conflicting Interest

No IRB member, whether serving in the role of a convened IRB member or when serving as an expedited reviewer, with a declared conflict of interest may participate in the review except to provide information as requested.

This restriction includes a review of any materials submitted for the research project for the duration of the member's service on the IRB, such as:

- Initial IRB applications or Continuing review reports
- Modifications to approved research
- Reportable events/Incidents
- Allegations of non-compliance with regulations or requirements of the IRB

An expedited reviewer, who recognizes a conflicting interest with an item he or she is assessing under expedited review procedures, must have the item reassigned to a non-conflicted reviewer.

Convened IRB members who realize they have a conflicting interest when first assigned an item for review at an upcoming IRB meeting must notify the meeting staff or IRB Chairperson immediately so that the item can be reassigned before the meeting.

The IRB Chairperson begins each meeting with a reminder that each member must disclose any conflicting interest and recuse him or herself from the vote on the project by leaving the room or leaving the virtual meeting.

If the IRB Chairperson has a conflict, he or she may not chair the meeting during the consideration of the item in which the conflict resides and must leave the room or virtual meeting during the final discussion and vote.
If an IRB member recognizes a conflicting interest in an item under review at the IRB meeting, the IRB member must inform the Chairperson of the conflicting interest and leave the room or virtual meeting during the final discussion and vote on the item.

If other IRB members need to request information about the item from the IRB member with the conflicting interest, the IRB member may remain in the room during the presentation of the item. However, the IRB member must leave the room during the IRB's final discussion and vote.

**Consultant's Disclosure of a Conflicting Interest**

Conflicting interest, as defined above, extends to any Consultant asked to review an item under review by the IRB.

The IRB member or HRCO Staff member who contacts a Consultant to inquire about assisting with a review is responsible for asking if the Consultant has a conflicting interest in the project. If such a conflict exists, the individual may not serve as a consultant.

**Convened IRB Deliberation and Documentation**

An IRB member or Chairperson with a conflicting interest is required to leave the room or virtual meeting (i.e. recuse) for the final discussion and voting on the item under review.

The IRB member who must recuse due to a conflict of interest is not counted towards quorum.

When the IRB member recuses due to conflict of interest, the meeting minutes will reflect the name of the IRB member, and his/her absence from the vote due to a conflict of interest. Meeting minutes are recorded in the Cayuse Human Ethics (IRB) electronic system.

### 3.7 CRITERIA FOR IRB APPROVAL OF RESEARCH

To approve human research, the IRB must determine that the following requirements are satisfied:

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

(2) Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, 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 participants 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.

(3) Selection of participants is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

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

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

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.

(7) When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

3.7.1 RISK/BENEFIT ASSESSMENT

An assessment justifies that the risks to research participants posed by participation in research are balanced with or outweigh the anticipated benefits to the participants or society. The IRB must:

1. judge whether the anticipated benefit, either of new knowledge or improved conditions for the research participants, justifies asking any person to undertake the risks;
2. disapprove of research in which the risks are judged unreasonable in relation to the anticipated benefits.
Conducting the risk-benefits assessment to protect research participants is the primary responsibility of the IRB.

This assessment involves a series of steps:

- identify the risks associated with the research, as distinguished from other risks, such as the risks of therapies the participants would receive even if not participating in research;
- determine whether the risks will be minimized to the extent possible;
- identify the probable benefits to be derived from the research;
- determine whether the risks are reasonable in relation to the benefits to participants, if any, and assess the importance of the knowledge to be gained;
- ensure that potential participants will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits.

Risks to participants are minimized:

✓ by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk; and
✓ whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
✓ Risks to participants are reasonable in relation to anticipated benefits, if any, and to 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 participants 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 (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3.7.1.1 RESEARCH DESIGN

To assess the risks and benefits of proposed research, the IRB must determine that the study employs sound research design. Sound research design considers the overarching goals and tenets common to scientific research, the specific objectives of the research project, and the ethical standards of the relevant scientific discipline or disciplines. Investigators and the IRB must be
aware of and implement national and international ethical principles that guide scientific research such as the Belmont Report, the Nuremberg Code and the Declaration of Helsinki.

In making this determination, the IRB may draw on its knowledge and disciplinary expertise. The IRB may also draw on the knowledge and disciplinary expertise of others, such as peer reviews by a funding agency or a department. In the absence of peer review, the IRB must consider all aspects of the research design to ensure the safety of the research participants and the success of the research.

3.7.2 SELECTION OF PARTICIPANTS IS EQUITABLE
The IRB determines by viewing the application and associated documents that the selection of participants is equitable concerning sex, age, class, etc. The IRB will not approve a study that does not provide for the equitable selection of participants or has not provided an appropriate scientific and ethical justification for excluding classes of persons who might benefit from the research.

In making this determination, the IRB evaluates:

- the purpose(s) of the research;
- the setting in which the research occurs;
- the scientific and ethical justification for including vulnerable populations;
- the scientific and ethical justification for excluding classes of persons who might benefit from the research; and
- the inclusion/exclusion criteria.

3.7.2.1 RECRUITMENT OF PARTICIPANTS
The Investigator will provide the IRB with all recruiting materials for use in identifying participants, including recruitment methods, advertisements, and payment arrangements.

3.7.3 INFORMED CONSENT / PARENTAL PERMISSION / CHILD ASSENT
The IRB will ensure that informed consent will be sought from each prospective participant or the participant's legally authorized representative, unless the criteria for a waiver of consent are met. In research involving minor children, the assent of the child and parental permission will be sought, as appropriate. The IRB will further ensure that consent is documented or otherwise approve, as appropriate, a waiver of documentation of consent.

3.7.4 DATA SAFETY MONITORING
The IRB determines that, where appropriate, the research plan makes adequate provision for monitoring the data to ensure the safety of participants. For research in which risks are substantial, the IRB may require a general description of the data and safety monitoring plan to be submitted to the IRB as part of the application. This plan should contain procedures for reporting incidents that meet the criteria outlined in NYU's reporting incidents guidance. In general, it is desirable for a Data and Safety Monitoring Board (DSMB) to be established by the study sponsor for research that is blinded, involves multiple sites, involves vulnerable participants, or employs high-risk interventions.

For some studies, the National Institutes of Health (NIH) require a DSMB. The IRB has the authority to require a DSMB as a condition for approval of research where it determines that such monitoring is needed. When research uses DSMBs, the IRB, when conducting a continuing review of research, may rely on a current statement from the DSMB. The DSMB statement must indicate that it has reviewed, and will continue to review, study-wide adverse events, interim findings, and any recent literature that may be relevant to the research in place of requiring that this information be submitted directly to the IRB. Such reports must be attached to the protocol in the Cayuse Human Ethics (IRB) system.

3.7.5 PRIVACY AND CONFIDENTIALITY

The IRB will determine whether adequate procedures are in place to protect the privacy of participants and to maintain the confidentiality of the data.

Privacy is the control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. The evaluation of privacy also involves consideration of how the researcher accesses information from or about potential participants (e.g., recruitment process). IRB members consider strategies to protect privacy interests relating to contact with potential participants, and access to private information.

Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure. During the informed consent process, if applicable, subjects must be informed of the precautions that will be taken to protect the confidentiality of the data and be informed of the parties who will or may have access (e.g., research team, funding agency, OHRP). This information will allow subjects to decide about the adequacy of the protections and the acceptability of the possible release of private information to the interested parties.
At the time of initial review, the IRB assesses whether there are adequate provisions to protect participant privacy and maintain confidentiality. The IRB does this through the evaluation of the:

- methods used to obtain information about participants;
- methods used to obtain information about individuals who may be recruited to participate in studies;
- use of personally identifiable records; and
- methods to protect the confidentiality of research data.

In some cases, a Certificate of Confidentiality (CoC) will be recommended or required for the protection of research participants if the funding agency does not automatically grant the CoC. In reviewing confidentiality protections, the IRB shall consider the nature, probability, and magnitude of harms that would be likely to result from disclosure of collected information outside the research. It shall evaluate the effectiveness of proposed de-identification techniques, coding systems, encryption methods, storage facilities, access limitations, and other relevant factors in determining the adequacy of confidentiality protections.

### 3.7.6 VULNERABLE POPULATIONS

During the initial review, the IRB will consider the scientific and ethical reasons for including vulnerable participants in research. The IRB may determine and require that when appropriate, additional safeguards are put into place for vulnerable participants.

Per the federal regulations, vulnerable participants are individuals "vulnerable to coercion and undue influence, in recognition that coercion or undue influence refers to the ability to make an informed decision about participating in research." Included in this definition are individuals with impaired decision-making capacity, prisoners, and children.

The IRB carefully considers group characteristics, such as economic, social, physical, and environmental conditions, to ensure that the research incorporates additional safeguards for vulnerable participants.

### 3.8 ADDITIONAL CONSIDERATIONS DURING IRB REVIEW AND APPROVAL OF RESEARCH

**Determination of Risk**

At the time of initial and continuing review, when applicable, the IRB will weigh the risks associated with the research. Risks associated with the research will be classified as either "minimal" or "greater than minimal" based on the "absolute" interpretation of
Minimal Risk. The meeting minutes will reflect the Committee's determination regarding risk levels for Full Board research applications.

Minimal Risk generally means that the probability and magnitude of physical or psychological harm anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or routine medical, dental, or psychological examinations. In order to be considered Minimal Risk, research must meet this definition and fall within one or more of the federally-defined categories that qualify for "Expedited" review. The definition of "Minimal Risk" is somewhat different for research involving prisoners.

See Minimal Risk as an International Ethical Standard in Research

Period of Approval

Unless approved under expedited procedures, at the time of initial review and at continuing review, when applicable, the IRB will determine the frequency of review. All protocols will be reviewed by the IRB at intervals appropriate to the degree of Risk but no less than once per year (unless the research has progressed to the point that it meets criteria outlined in the Continuing Review section, below). In some circumstances, a shorter review interval (e.g., biannually, quarterly, or after the accrual of a specific number of participants) may be required. The meeting minutes will reflect the IRB's determination regarding review frequency.

Review More Often than Annually

Research that meets any of the following criteria may require review more often than annually:

- significant risk to research participants (e.g., death, permanent or long-lasting disability or morbidity, severe toxicity) without the possibility of direct benefit to the participants;
- the involvement of especially vulnerable populations likely to be subject to coercion (e.g., terminally ill)
- a history of serious or continuing non-compliance on the part of the PI.

The IRB should also consider the following factors when determining which studies require review more frequently than on an annual basis:

- the probability of and magnitude of anticipated risks to the research participants,
• the likely medical condition of the proposed participants,
• the overall qualifications of the PI and other members of the research team,
• the experience of the PI and other members of the research team conducting similar research, including nature and frequency of adverse events observed in similar research at this and other institutions,
• the novelty of the research making unanticipated adverse events more likely,
• and any other factors that the IRB deems relevant.

In specifying an approval period of less than one year, the IRB may define the period with either a time interval or a maximum number of participants either studied or enrolled. If a maximum number of participants studied or enrolled is used to define the approval period, the approval period cannot exceed one year and that the number of participants studied or enrolled determines the approval period only when that number of participants is studied or enrolled in less than one year.

3.8.1 INVESTIGATOR CONFLICTS OF INTEREST (COI)

The NYU IRB is dedicated to upholding the highest ethical standards of objectivity in research by identifying and evaluating financial conflicts of interest (FCOI) that may affect an investigator’s actions or an individuals' decision to participate in the research based on any perceived or actual risks associated with the FCOI.

The NYU Office of conflict of interest (OCI) coordinates COI review. Related financial interests disclosed through the IRB process will either have already been reviewed by the NYU COI Committee or will be referred to the COI Director for assessment. The OCI makes a determination regarding COI and, if applicable, management plan. The determination and management plan shared with the IRB.

The IRB determines if the protocol should include information and/or procedures relating to the COI, such as:

• disclosing the COI in the informed consent language; or
• prohibiting the investigator(s) with the conflict from recruiting participants, obtaining consent, or accessing identifiable data.

3.8.2 SIGNIFICANT NEW FINDINGS

During the research, significant new knowledge or findings of the topic under study may develop. The PI must report any significant new findings to the IRB, and the IRB will review them concerning the impact on the participants’ rights and welfare. Since the new knowledge or findings may affect the risks or benefits to participants or participants' willingness to continue in the research, the IRB may require, during the ongoing review process, that the PI contact the currently enrolled participants to inform
them of the new information. The IRB will communicate this to the PI. The informed consent should be updated, and the IRB may require that the currently enrolled participants be re-consented, acknowledging receipt of this new information and for affirming their continued participation.

3.8.3 PAYMENT TO RESEARCH PARTICIPANTS
Payment to research participants may be an incentive for participation or a way to reimburse a participant for travel and other experiences incurred due to participation. However, payment for participation is not a research benefit. Regardless of the form of remuneration, investigators must take care to avoid the undue influence payment may have for participants.

Payments should reflect the degree of risk, inconvenience, or discomfort associated with participation. The amount of compensation must be proportional to the risks and inconveniences posed by participation in the study.

Investigators who wish to pay research participants must indicate in their research application the justification for such payment. Such justification should:

- substantiate that proposed payments are reasonable and commensurate with the expected contributions of the participant;
- state the terms of the participation agreement and the amount of payment in the informed consent form; and
- substantiate that payments are fair and appropriate and that they do not constitute (or appear to constitute) undue pressure on the participant to volunteer for the research study.

The IRB must review both the amount of payment and the proposed method of disbursement to assure that neither raises issues of coercion or undue influence.

Credit for payment should accrue and not be contingent upon the participant completing the entire study. Whenever possible, the IRB does not allow the entire payment to be contingent upon completion of the entire study. Any amount paid as a bonus for completion of the entire study should not be so significant that it becomes coercive.

The consent form must describe the terms of payment and the conditions under which participants would receive partial payment (e.g., if they withdraw from the study before their participation is completed).

3.8.4 CERTIFICATES OF CONFIDENTIALITY (COC)
The NIH, the Centers for Disease Control and Prevention (CDC), the FDA, and other agencies (for example, HRSA and SAMHSA) issue Certificates of Confidentiality (CoCs) to protect the confidentiality of research subjects information that could be used to directly or indirectly identify them as participating in a research project.

CoCs are issued to institutions or universities where the research is conducted, and enable the Investigator and others who have access to research records to refuse to disclose identifying information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

As of October 1, 2017, NIH funded researchers will no longer have to apply for a CoC. A CoC will be issued automatically to NIH funded grants, cooperative agreements, and contracts, funded wholly or in part by the NIH if the research collects or uses identifiable, sensitive information. Compliance with the requirements of the CoC is a term and condition of award. All research that was started or ongoing on or after December 13, 2016, and is within the scope of the policy, is automatically issued a CoC through this policy.

NIH will continue to consider applications for CoCs for non-federally funded research submitted to NIH institutes and centers through the existing online CoC application system.

A study may receive protection under a CoC even if the project is not sponsored or funded by NIH, as long as, in NIH’s view, the subject matter of the study falls within a mission area of the NIH. The CDC only issues CoCs for research sponsored by the CDC or for the Agency for Toxic Substances and Disease Registry. Investigators may opt to apply for a CoC in these circumstances following approval by the NYU IRB. The IRB may also request that an investigator apply for a CoC if it determines that the data collected from participants should have the protections provided by a CoC.

Generally, any research project that collects personally identifiable, sensitive information and that has been approved by an IRB operating under either an approved FWA issued by the OHRP, or the approval of the FDA, is eligible for a CoC. Information is considered sensitive if disclosing it could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation.

All recipients of a CoC shall not:

- Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such
information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or

- Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

Certain disclosures are permitted even when a CoC has been issued. These include:

- Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;

- Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;

- Made with the consent of the individual to whom the information, document, or biospecimen pertains; or

- Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

The existence of a CoC, the protection it provides, and any limitations on that protection should be described in the informed consent form. [See the NIH Suggested Consent Language Describing the CoC Protections.]

### 3.8.5 COMPLIANCE WITH ALL APPLICABLE STATE AND LOCAL LAWS

The IRB follows and must adhere to all applicable state and local laws in the jurisdictions where the research is taking place. The HRPP and the IRB rely on the University’s General Counsel for the interpretation and application of State law and the laws of any other jurisdiction where research is conducted as they apply to human research.

All consent forms must be consistent with applicable state and local laws.
3.9 POSSIBLE IRB ACTIONS

The following are possible actions the IRB can take after reviewing a research application.

**Approved**: An IRB action taken when the required determinations are made that allows research involving human subjects to proceed consistent with federal regulations, state and local laws, and University policy.

**Approved with conditions**: An IRB action taken when the required determinations are made that allows research involving human subjects to proceed consistent with federal regulations, state and local laws, and University policy and the IRB specifies conditions under which research can be approved, pending the following:

- Confirmation of specific understandings by the IRB about how the research will be conducted, submission of additional documentation, precise language changes to the protocol and/or informed consent document(s), and/or substantive changes to documents with specific parameters the changes must satisfy.
- Verification that the Investigator’s response(s) satisfies the conditions for approval set by the IRB. The verification may be performed by the IRB Chair and/or other designated individual(s), including experienced HRCO staff.

**Requires modifications to secure approval**: An IRB action taken when the convened IRB cannot fully evaluate the research under review and make the determinations required for approval without modifications to the protocol and/or informed consent document, or submission of clarifications or additional materials prior to reconsideration of the research. Convened IRB review of the Investigator’s response(s) is required.

**Deferred**: An action taken when the convened IRB determines that certain critical information or significant changes are necessary before it can properly discuss the details of the protocol. Convened IRB review of the Investigator’s response(s) is required.

**Disapproved**: An IRB action taken when the determinations required for approval of research cannot be made, even with substantive clarifications or modifications to the protocol and/or informed consent process/document. Research cannot be disapproved by expedited review.
Tabled: An IRB “action” that indicates that review was not initiated or was not completed, resulting in postponement of IRB review, usually due to loss of quorum or other administrative issue. Research tabled at a convened meeting will be reviewed at a future convened meeting.

3.10 RESEARCH SUSPENSION AND TERMINATION

The NYU IRB may suspend or terminate some or all human subjects research activities if events are identified that represent serious or continuing noncompliance or unanticipated problems involving risk to subjects or others.

This action is most often determined by a convened board; however, the IRB Chair has the authority to suspend some or all research activities if exceptional human subject safety issues are identified. This authority is only exercised if an action is required prior to a convened meeting and it is not feasible to assemble an emergency meeting. When this authority is exercised, it will be reported at the next convened NYU IRB meeting. Research may be terminated only by the convened IRB. Terminations of research approved under expedited review must be made by the convened IRB.

The IRB shall notify the PI in writing of such suspensions or terminations and shall include a statement of the reasons for the IRB's actions. The terms and conditions of the suspension must be explicit. The Investigator shall be provided with an opportunity to respond in person or in writing.

When study approval is suspended or terminated by the convened IRB or IRB Chair, in addition to stopping all research activities, the convened IRB or IRB Chair suspension will consider notification of any participants currently enrolled in the study. The convened IRB or IRB Chair will consider whether procedures for withdrawal of enrolled participants are necessary to protect the rights and welfare of participants, such as: transferring participants to another investigator; making arrangements for care or follow-up outside the research; allowing continuation of some research activities under the supervision of an independent monitor, or requiring or permitting follow-up of participants for safety reasons.

If follow-up of participants for safety reasons is permitted/required by the convened IRB or IRB Chair, the participants should be informed and any adverse outcomes will be reported to the IRB and the sponsor.

3.11 CONTINUING REVIEW

Continuing review of approved research is not required for:
1. Research that is eligible for expedited review;
2. Exempt research conditioned on limited IRB review;
3. Research that has completed all interventions and now only includes analyzing data, even if the information or biospecimens are identifiable;
4. Research that has completed all interventions and now only includes accessing follow-up clinical data from clinical care procedures.

The NYU IRB can choose to require continuing review for the above-referenced research, as long as the IRB documents the decision and the rationale for this decision.

Unless it meets the criteria stipulated above, research that has undergone convened board review and approval is subject to continuing review.

Lapse in Approval

Investigators must allow sufficient time for IRB review before the expiration date.

The regulations permit no grace period or approval extension after approval expiration. Research that continues after the approval period has expired is research conducted without IRB approval. All research activities must stop, including recruitment, enrollment, consent, interventions, interactions, and data collection, unless the IRB finds that it is in the best interests of individual participants to continue participating in the research interventions or interactions.

Investigators receive renewal reminder notifications via Cayuse Human Ethics (IRB) at periodic prior to expiration as well as notification of study expiration.

The HRPP via Cayuse Human Ethics (IRB) promptly notifies the Investigator of the expiration of approval and that all research activities must stop. If research participants are currently enrolled in the research project and their participation is ongoing, once notified of the expiration of approval the PI must immediately submit to the IRB Chair a list of research participants for whom suspension of the research would cause harm. Enrollment of new participants cannot occur and continuation of research interventions or interactions for already enrolled participants should only continue when the IRB or IRB Chair finds that it is in the best interest of the individual participants to do so.

Conducting human subjects research activities after IRB approval is expired is considered non-compliance and will be handled under the procedures for reviewing instances of non-compliance.
3.12 AMENDMENTS TO AN APPROVED PROTOCOL

Investigators may wish to modify or amend their approved protocols. Investigators must seek IRB approval before making any changes to approved research - unless the change is necessary to eliminate an immediate hazard to the participant (in which case the IRB must then be notified promptly).

In order to obtain approval, investigators must submit a modification to the HRPP via Cayuse Human Ethics (IRB).

HRCO staff will determine the appropriate level of review for the proposed changes. The reviewer(s) using the expedited procedure has the ultimate responsibility to determine that the proposed changes may be approved through the expedited review procedure and, if not, must refer the amendment for convened board review.

The requested changes must not be implemented until IRB approval has been granted, which will be communicated to the Principal Investigator in writing.

3.13 REPORTING IRB ACTIONS

All IRB actions are communicated to the PI, and/or designated primary contact person for the protocol, in writing by the HRCO staff via Cayuse Human Ethics (IRB). For an approval, written notification of approval will be sent. For a deferral, the notification will include the modifications required for approval along with the basis for requiring those modifications. For a disapproval, termination, or suspension, the notification will include the basis for making that decision. The IRB reports its findings and actions to the University in the form of its minutes that are stored permanently and securely in Cayuse Human Ethics (IRB). Copies of minutes are accessible to the New York University Institutional Official (IO) via Cayuse Human Ethics (IRB) and can also be sent to the IO electronically.

3.14 APPEAL OF IRB DECISIONS

When research presented at a convened meeting of the IRB is disapproved, deferred, or requires modifications, the IRB will notify the PI in writing about the specific deficiencies and the modifications that are necessary for IRB approval. The IRB shall include in its written notification a statement of the reasons for its decision and give the Investigator an opportunity to respond in person or in writing.

In cases where there is disagreement between the IRB and the PI regarding the nature and extent of the requested changes and these disagreements cannot be resolved amicably in an informal manner, the PI and/or the IRB may make an appeal to the IO.
for a resolution of the matter. The IO may organize a meeting to help facilitate discussion between the IRB and the PI. While the IO may provide input and make recommendations to the IRB for expeditious resolution of the matter, final recommendations for approval remain under the purview of the IRB.

4. DOCUMENTATION AND RECORDS

4.1 IRB RECORDS

The IRB must prepare and maintain adequate documentation of the IRB’s activities including copies of all items reviewed, including, but not limited to:

- research applications
- recruitment materials
- scientific evaluations (if any) that accompany the proposals
- approved consent documents
- records of continuing review activities, including progress reports submitted by investigators
- any proposed amendments and the IRB action on each amendment
- reports of injuries to participants and serious and unexpected adverse events
- documentation of protocol violations
- documentation of noncompliance with applicable regulations
- statements of significant new findings provided to participants
- IRB membership roster(s)
- IRB meeting minutes
- Copies of all correspondence between the IRB and the investigator

IRB records must also document any determinations required by the regulations and protocol-specific findings supporting those determinations, including:

- waiver or alteration of the consent process
- research involving pregnant women, fetuses, and neonates
- research involving prisoners
- research involving children

4.2 IRB MEMBERSHIP ROSTER
A membership list of IRB members must be maintained. It must identify members sufficiently to describe each member's chief anticipated contributions to IRB deliberations. The list must contain the following information about members:

1. Name
2. Earned degrees
3. Affiliated or non-affiliated status (neither the member nor an immediate family member of the member may be affiliated with the university)
4. Status as scientist (physician-scientist, other scientist, non-scientist or social behavioral scientist). For purposes of this roster, IRB members with research experience are designated as scientists (including student and HRCO staff members). Research experience includes training in research (e.g., doctoral degrees with a research-based thesis) and previous or current conduct of research. Students being trained in research fields will be designated as scientists.
5. Indications of experience, such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations.
6. Representative capacities of each IRB member; which IRB member is a prisoner representative (as required by Subpart C), and which IRB members are knowledgeable about or experienced in working with children, pregnant women, individuals with impaired decision-making, and other vulnerable populations locally involved in research.
7. Role on the IRB (Chair, Vice Chair, etc.)
8. Voting status (Any ex officio members are non-voting members)
9. Alternate status, including the member they alternate with
10. Relationship (e.g., employment) between the individual IRB member and the organization

The HRPP must keep the IRB membership list current.

4.3 IRB MINUTES

Proceedings should be written and available for review by the next regularly scheduled IRB meeting date. Once approved by the IRB at a subsequent IRB meeting, the minutes must not be altered by anyone.

Minutes of IRB meetings must contain sufficient detail to show:
• Attendance:
  1. names of members present
  2. names of members or alternate members who are participating through videoconference or teleconference and documentation that those attending through videoconferencing or teleconferencing received all pertinent material prior to the meeting and were able to actively and equally participate in all discussions
  3. names of absent members
  4. names of alternates attending in lieu of specified (named) absent members. (Alternates may substitute for specific absent members only as designated on the official IRB membership roster)
  5. names of consultants present
  6. names of investigators present
  7. names of guests present

The initial attendance list shall include those members present at any point during the meeting. The minutes will indicate, by name, those members who enter or leave the meeting. The vote on each action will reflect the number of members present for the vote on that item.

• The presence of a quorum throughout the meeting, including the presence of one member whose primary concern is in a non-scientific area
• Business Items discussed, including review and approval of previous meeting’s minutes
• Continuing Education, if any
• Actions taken, including separate deliberations, actions, and votes for each protocol undergoing initial review, continuing review, or review of modifications by the convened IRB
• Votes on these actions (total number voting; number voting for; number voting against; number abstaining; number of those recused)
• Basis or justification for these actions including required changes in research
• Summary of controverted issues and their resolution
• Approval period for initial and continuing approved protocols, assumed to be 12 months unless otherwise indicated
• Risk level of initial and continuing approved protocols
• Review of interim reports, e.g. adverse event or safety reports, amendments, report of violation, etc.
• Review of Data and Safety Monitoring Board (DSMB) summary, if applicable
• Applications that have met or not met requested stipulations
• Protocol-specific documentation that the research meets the required criteria [45 CFR 46.116(d)] when approving a consent procedure that does not include or that alters some or all of the required elements of informed consent, or when waiving the requirement to obtain an informed consent
• Study-specific documentation that the research meets the required criteria [45 CFR 46.117(c)] when the requirements for documentation of consent are waived
• When approving research that involves populations covered by Subparts B, C, or D of 45 CFR 46, the minutes will document the IRB’s justifications and findings regarding the determinations stated in the Subparts or the IRB’s agreement with the findings and justifications as presented by the investigator on IRB forms.
• Review of COI Committee determinations of conflict of interest and COI management plans.
• Identification of any research for which there is need for verification from sources other than the investigator that no material changes are made in the research (e.g., Cooperative Studies, or other collaborative research).
• Special protections warranted in specific research projects for groups of participants who 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, regardless of source of support for the research.
• A list of research approved since the last meeting utilizing expedited review procedures
• Documentation of approval by the Chair or designee, or documentation of review and approval by a subcommittee of board members as designated by the convened board contingent on specific minor conditions in the minutes of the first IRB meeting that takes place after the date of the approval.
• An indication that, when an IRB member has a conflicting interest with the research under review, the IRB member was not present during the deliberations or voting on the proposal, and that the quorum was maintained.
• Key information provided by consultants will be documented in the minutes or in a report provided by the consultant.

A copy of the IRB-approved minutes for each IRB meeting will be made available to the Institutional Official or the IO’s designee.

4.4 DOCUMENTATION OF EXEMPTIONS
Documentation of verified exemptions consists of the reviewer’s citation of a specific exemption category and written concurrence that the activity described in the investigator’s request for exemption satisfies the conditions of the cited exemption category.

4.5 DOCUMENTATION OF EXPEDITED REVIEWS

IRB records for initial and continuing review by the expedited procedure must include: the specific permissible category, a description of action taken, if any, by the reviewer, and any determinations required by the regulations and study-specific findings supporting those determinations.

4.6 RECORD RETENTION

The above detailed records must be stored securely by the HRCO and must be retained for at least three years after final close-out of the research. IRB records not associated with research or for studies closed without participant enrollment will be retained at the facility for at least three years after closure.

After that time, those records may be securely destroyed. All records must be accessible for inspection and copying by authorized representatives of the OHRP, sponsors, and other authorized entities at reasonable times and in a reasonable manner.

Records are primarily maintained electronically on secure servers and are available only to IRB members, HRCO staff, and senior leadership, as necessary. Some historical documents are maintained in paper format.

5. OBTAINING AND DOCUMENTING INFORMED CONSENT FROM RESEARCH PARTICIPANTS

5.1 PURPOSE

The following procedures describe the requirements for obtaining and documenting consent from participants in research conducted under the auspices of New York University.

5.2 DEFINITIONS

Legally Authorized Representative (LAR):
A LAR is 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.

**Legal guardian:**

A person appointed by a court of appropriate jurisdiction.

**Clinical trial:**

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.

### 5.3 INFORMED CONSENT PROCESS

Informed consent must be obtained under the following circumstances:

1. Informed consent may only be obtained from participants who have the legal and decisional capacity to give consent. For participants without that capacity, consent must be obtained from a legal guardian or a legally authorized representative.
2. The informed consent process shall be sought under circumstances that provide the participant or LAR with sufficient opportunity to consider whether to participate.
3. The informed consent process shall be sought under circumstances that minimize the possibility of coercion or undue influence.
4. The informed consent information must be presented in language that is understandable to the participant or LAR given the target participant population and context of the research. Layman’s terms shall be used in the description of the research.
5. The informed consent process must give prospective subjects the information that a reasonable person would want to have in order to make an informed decision about whether to participate.
6. The information needs to be presented in sufficient detail and organized and presented in a way that facilitates an understanding of why one might, or might not, want to participate. The key information about the study must be provided at the beginning. This should include information about the purpose, the risks,
the benefits, and the alternatives, and explain to the person how to think about these pieces of information in terms of making a decision. It should be presented in a concise and focused manner.

7. For participants who are not competent to provide consent in English, informed consent must be obtained in a language that is understandable to the participant or the participant's LAR. The IRB requires that informed consent conferences include a reliable translator when the prospective participant does not understand the language of the person who is obtaining consent.

8. The informed consent process may not include any exculpatory language through which the participant is made to waive, or appear to waive, any of the participant’s legal rights or through which the investigator, the sponsor, the University, or University employees or agents are released from liability for negligence, or appear to be so released.

9. The PI is responsible for ensuring that each prospective participant is adequately informed about all aspects of the research and understands the information provided.

5.3.1 BASIC ELEMENTS OF INFORMED CONSENT

The basic elements of consent are:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's participation, a description of the procedures to be followed, and identification of any procedures which are experimental; a description of any reasonably foreseeable risks or discomforts to the participant;

2. A description of any benefits to the participant or to others which may reasonably be expected from the research;

3. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;

4. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;

5. For research involving more than minimal risk, an explanation as to the availability of medical treatment in the case of research-related injury, including who will pay for the treatment and whether other financial compensation is available;

6. An explanation of whom to contact on the research team for answers to pertinent questions about the research or to voice concerns or complaints about the research, and whom to contact in the event of a research-related injury to the participant;

7. Contact information for the IRB to obtain answers to questions about the research; to voice concerns or complaints about the research; to obtain answers to questions about their rights as a research participant; in the event the research staff could not
be reached; and in the event the participant wishes to talk to someone other than the research staff;

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled;

9. If the study involves the collection of identifiable private information or identifiable biospecimens, notice about whether participants’ information or biospecimens collected as part of the current research might be stripped of identifiers and used for other research in the future. Consent forms must indicate either that information or biospecimens collected for the research might be stripped of identifiers and used in other research in the future, or that this will not occur. Note that this is only about future research use of information and biospecimens that will be stripped of identifiers.

5.3.2 ADDITIONAL ELEMENTS OF INFORMED CONSENT

When appropriate, the following elements may be applied:

1. A statement that the particular procedure or treatment may involve risks to the participant which are currently unforeseeable.

2. A statement that if the participant is or becomes pregnant, the particular procedure or treatment may involve risks to the embryo or fetus, which are currently unforeseeable.

3. Anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent.

4. Any additional costs to the participant that may result from participation in the research.

5. The consequences of a participant’s decision to withdraw from the research.

6. Procedures for orderly termination of participation by the participant.

7. A statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided to the participant.

8. The approximate number of participants involved in the study.

9. Notice to participants that their biospecimens (even if identifiers are removed) may be used for commercial profit and whether they will or will not share in this commercial profit, whether clinically relevant research results will be returned to the participants, and whether research activities will or might include whole genome sequencing.
5.3.3 DOCUMENTATION OF INFORMED CONSENT

Informed consent must be documented by a written consent form (either in paper or in an electronic format) approved by the IRB unless a waiver of documentation of consent is approved.

1. Informed consent is documented by a written consent form approved by the IRB and signed and dated by the participant or the participant's LAR at the time of consent.

2. A copy of the signed and dated consent form shall be given to the person signing the form.

3. The consent form may be either of the following:

4. A written consent document that embodies the basic and required additional elements of informed consent. The consent form may be read to the participant or the participant's LAR, but the participant or representative must be given adequate opportunity to read it before it is signed; or

5. A short form written consent document stating that the elements of informed consent have been presented orally to the participant or the participant's LAR.

When this method is used:

• there must be a witness to the oral presentation; and

• the IRB must approve a written summary of what is to be signed by the participant or representative; and

• the witness must sign both the short form and a copy of the summary; and

• the person obtaining consent must sign a copy of the summary; and

• a copy of the summary must be given to the participant or representative, in addition to a copy of the short form.

5.4 WAIVER OF INFORMED CONSENT

The IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent, provided the IRB finds and documents that:
1. The research involves no more than minimal tangible or intangible risk to the participants;
2. The waiver or alteration will not adversely affect the rights and welfare of the participants;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the participants must be provided with additional pertinent information after participation.
5. For research with identifiable private information or identifiable biospecimens, the IRB must determine that the research could not practicably be carried out without using the information or biospecimens in an identifiable form.

6. In addition, an IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent, or waives the requirements to obtain informed consent, provided the IRB finds and documents that:

7. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
   a. public benefit or service programs
   b. procedures for obtaining benefits or services under those programs
   c. possible changes in or alternatives to those programs or procedures; or
   d. possible changes in methods or levels of payment for benefits or services under those programs.
8. The research could not practicably be carried out without the waiver or alteration.

5.5 WAIVER OF DOCUMENTATION OF INFORMED CONSENT
The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants if it finds that:

1. The only record linking the participant and the research would be the consent document and the principle risk would be potential harm resulting from a breach of confidentiality, and the research is not FDA-regulated. Each subject (or LAR) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.
2. The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context; or

3. The participants or LAR are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the documentation requirement is waived, the IRB requires the investigator to provide in the application materials a written summary of the information to be communicated to the participant, and the IRB will consider whether to require the investigator to provide participants with a written statement regarding the research.

5.6 SCREENING, RECRUITING, OR DETERMINING ELIGIBILITY

The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective participants without the informed consent of the prospective participant or the LAR, if either of the following conditions are met:

(1) The investigator will obtain information through oral or written communication with the prospective participant or LAR or

(2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

5.7 POSTING OF THE CLINICAL TRIAL CONSENT FORM

(1) For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll participants must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms.

(2) If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (e.g. confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.
(3) The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any participant, as required by the protocol.

6. QUALITY ASSURANCE: POST-APPROVAL MONITORING OF APPROVED HUMAN SUBJECT RESEARCH

This Standard Operating Procedure describes the policies and procedures for the post-approval monitoring of human subjects research under the NYU HRPP Post Approval Monitoring Program (PAM).

6.1 PURPOSE

The purpose of post-approval monitoring of studies involving human subject research is to confirm by observation, interviews with study staff and the PI, and documentation comparison, an accurate and consistent protocol performance, conducted in accordance with the IRB-approved protocol. Through its evaluation process, the program educates investigators on best practices for conducting their human subject research to maintain compliance with their IRB-approved protocol, NYU HRPP, and IRB policies and guidelines, and Federal regulations. The program helps investigators, their teams, and the University prepare for external audits by granting, regulatory, and accreditation agencies.

6.2 ROLES

The purpose of the IRB is to help researchers ensure that the rights and safety of human participants in their research are protected and that they conduct their research in compliance with applicable regulations. To achieve this, the IRB:

1. advises investigators in the design of research projects that minimize potential harm to participants,
2. reviews all planned research involving human participants before initiation of the research,
3. only approves research that meets established criteria for protection of human participants, and
4. monitors approved research to ensure the protection of the research participants.
The IRB has the authority to approve, require modifications in, disapprove, suspend, or terminate all human subject research activities at NYU. The IRB may determine whether post-approval monitoring is needed.

The Human Research Compliance Director (HRCD), provides oversight and management of the Post-Approval Monitoring Program (PAM) and assures that the IRB and the Institutional Official receive reports or updates on items of concern.

As part of NYU’s post-approval monitoring program, the IRB Chair or IRB Vice-Chair, in consultation with the HRCD or the convened IRB committee, may determine if post-approval monitoring is needed. This type of monitoring is considered “directed.” Additionally, the IRB Chair or Vice-Chair review PAM reports, and in consultation with the HRCD, determine if additional follow-up is needed.

Additionally, the IO or HRCD may determine a need for routine monitoring of specific research programs.

The role of the PAM is to meet with investigators and their teams to confirm by observation and documentation comparison that research activities comply with approved IRB protocols. The PAM reviews study records, observes research activities, prepares reports, provides recommendations for maintaining compliance, provides training or information on training options when needed, and assists in the implementation of corrective and preventative actions.

Categories of Monitoring Reviews:

**Routine:** The HRCD, in collaboration with the IRB Chair, may select studies to be monitored. Selection may include monitoring only some aspects of the research, such as observation of the informed consent process, study procedures, or study records.

**Informed consent:** This review is intended to support researchers in conducting the informed consent process. It may include observation of the consent process and a thorough review of the consent records. Monitoring may also include reviewing the process of how Principal Investigators train study personnel on administering consent to participants.

**Directed (For-cause Audits):** Directed reviews (for-cause audits) are not a routine compliance review and may be directed by the IRB, the Vice Provost for Research, Institutional Official, or a designee. A directed review may include but is not limited to a full study audit, a Corrective and Preventative Action Plan Assessment (CAPA), consent
form observation, or evaluation of other research activities. The following may trigger a directed review:

- Reportable new information that might affect the rights and welfare of research participants
- Any review of materials submitted via Cayuse Human Ethics (IRB)
- An allegation of non-compliance (perceived or confirmed)
- A suspension or termination of IRB approval
- Participant and employee complaints
- Whistleblower

**Investigator-Initiated:** A PI may request a review to help keep records and procedures in compliance with Federal regulations and institutional policies, or to prepare for an external audit by a sponsor or federal agency. Reviews of this nature are encouraged, as the goal of post-approval monitoring is to assist investigators in conducting compliant research. During these PI-requested reviews, the PAM focuses on areas of improvement, and if protocol deviations are found, counsels the PI on self-reporting the issue to the IRB, along with submitting a protocol modification, if needed.

### 6.3 PROTOCOL SELECTION

All studies, even those determined to qualify for exempt status, are subject to monitoring. Studies chosen for routine monitoring are randomly selected. However, emphasis may be placed on monitoring studies involving vulnerable populations, deception, confidentiality concerns, studies with more than minimal risks to subjects, or studies conducted by investigators with past IRB concerns.

### 6.4 THE POST-APPROVAL MONITORING PROCESS

The HRCO schedules monitoring with PI(s) and their staff, making every attempt to accommodate schedules. During scheduling, the HRCO staff provides the PI with a copy of the “PI Self-Assessment” to prepare for the visit.

During the post-approval monitoring visit, the monitor compares procedures conducted in the laboratory or study area with those listed in the IRB-approved protocol and any approved modifications. The visit may include activities such as reviewing study records, visiting with the PI to review current procedures and observation of the consent process.

The monitor brings documented discrepancies between observed and approved activities to the attention of the PI. The monitor reviews and assesses areas such as, but not necessarily limited to:
• Research team composition and training
• Recruitment procedures
• Screening procedures
• Consent process
• Study procedures
• Publications from the study
• Current enrollment and verification of informed consent
• Reports of adverse events
• Storage of study documents and data
• Privacy and confidentiality issues
• Subject payment
• Questions and concerns from the PI and research team

Post-Approval Monitoring as a Pedagogic Vehicle

The primary goal of the post-approval monitoring program is research compliance through education. The HRCO staff can explain the IRB process, the importance of following the IRB-approved protocol, and what the HRPP expects from investigators and their team. Additionally, the HRCO staff is a resource for investigators, providing best practice ideas for conducting their human subjects research in compliance with NYU HRPP policies and educating the research team on HRPP guidance documents, policies, and Federal regulations. The HRCO staff also assists the principal investigator in identifying any protocol deviations, unanticipated problems, provides guidance for self-reporting any deviations or unapproved changes to the IRB protocol, and implementing any necessary actions, such as submitting a protocol modification.

Most potential non-compliance issues uncovered during post-approval monitoring are a result of a lack of understanding of the roles and responsibilities of individuals involved in research and inadequate training of staff. In many cases, minor discrepancies observed during PAM can be addressed through modification of an existing protocol, or reverting to procedures that were originally approved; however, more serious discoveries such as protocol deviations and unanticipated problems must be reported to the HRCD and IRB (see the process below).
6.6 INFORMATION SHARING AND FOLLOW-UP

Issues that pose an immediate threat to research participants or that may constitute serious non-compliance are brought to the immediate attention of the HRCD, the IRB Chair, and Vice-Chair, as needed. The monitor prepares a written report of the post-approval monitoring. The goal of this report is to outline any discrepancies from the IRB-approved protocol and offer recommendations for areas of improvement, including any required protocol modifications identified. A draft copy of the report will be shared with the PI for their comments and review. The PI reviews the report, the report is finalized, and a copy is shared with the PI for their records. The final report is then shared with the HRCD, the IRB Chair, and Vice-Chair. They review the report to determine whether additional follow-up is needed. If warranted, the HRCD, or their designee, contacts the PI to investigate any potential non-compliance found during PAM. Following this investigation, the HRCD, or their designee, prepares a report of potential non-compliance to share with the IRB. The IRB discusses both the PAM report and the potential non-compliance report (if warranted) at a convened IRB meeting.

Any determinations of non-compliance or requests for additional follow-up are made at this time. In the case of non-compliance or protocol deviations, periodic monitoring may be necessary to ensure that required corrective and precautionary actions have been taken to prevent protocol deviations in the future, or as directed by the HRCD, IRB Chair(s), and IRB as needed. HRCO staff members assist investigators, if needed, in the completion of required actions resulting from the PAM or IRB-determined corrective actions. Assistance may include guiding protocol modifications and direction to appropriate training.

6.7 INVESTIGATOR APPEAL PROCESS

PIs who disagree with the findings of the post-approval monitoring or required actions are invited to address these concerns with the monitor during the discussion period at the end of the visit. If the monitor and the PI cannot reach a satisfactory resolution, the PI may then contact the HRCD to discuss these issues within 30 days of the visit. Again, if no satisfactory resolution is agreed upon, the PI may address the IRB in writing within a second 30-day period.

6.8 POST-APPROVAL MONITORING AND RECORDKEEPING

The HRCO retains a copy of the final post-approval monitoring assessment report by attaching it to the applicable Cayuse Human Ethics (IRB) study file or files.
7. UNANTICIPATED PROBLEMS INVOLVING RISKS TO PARTICIPANTS AND OTHERS, COMPLAINTS, NONCOMPLIANCE AND SUSPENSION OR TERMINATION OF IRB APPROVAL OF RESEARCH

7.1 UNANTICIPATED PROBLEMS

Federal regulations require organizations to have written policies and procedures to ensure the prompt reporting of unanticipated problems involving risks to subjects or others to the IRB, appropriate institutional officials, and regulatory agencies and departments.

Not all unanticipated problems involve direct harm to subjects. Events can occur which are unexpected and result in new circumstances that increased the risk of harm to subjects without directly harming them. In addition, the event may have presented unanticipated risks to others (e.g., the sexual partners of the subjects, individuals the subject may come in contact with, family members, research personnel, etc.) in addition to the subjects. In each case, while the event may not have caused any detectable harm or adverse effect to subjects or others, they nevertheless represent unanticipated problems and should be promptly reported.

7.1.2 DEFINITIONS

Unanticipated Problem Involving Risks to Participants or Others (Unanticipated Problem):

Any incident, experience, or outcome that meets all the following criteria:

1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

2. related or possibly related to participation in the research (related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Adverse Event
Any physical, psychological, or social harm to subjects during the course of research. An adverse event can be any unfavorable or unintended event.

7.1.3 REPORTING
Principal investigators must report via an incident report to the IRB as soon as possible any:

- an unanticipated event related to the research that exposes research participants or individuals other than the research participants (e.g., investigators, research assistants, students, the public, etc.) to potential risk
- information that indicates a change to the risks or potential benefits of the research.
- a breach of confidentiality, including the loss of digital storage devices
- change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant
- complaint of a participant when the complaint indicates unexpected risks or cannot be resolved by the research team
- protocol violation (meaning an accidental or intentional change to the IRB approved protocol) that harmed participants or others or that indicates participants or others may be at increased risk of harm
- event that requires prompt reporting to the sponsor
- sponsor imposed suspension for risk

7.1.4 IRB REVIEW
Upon receipt of an Incident Report from a Principal Investigator, the HRCD or designee checks the form for completeness. If any applicable sections of the form are incomplete or have been answered unsatisfactorily, the HRCD or designee will contact the investigator to obtain additional information. Corrections are documented in the IRB file.

The IRB Administrator assigns the report provided by the investigator to the Chair for review.

Based on the information received from the Principal Investigator and upon the advice of the Administrator or other reviewers, the IRB Chair may suspend research to ensure protection of the rights and welfare of participants. In making a determination whether to direct suspension, the Chair may consider whether the PI has voluntarily put the research on hold. Suspension directives made by the IRB Chair must be reported to a meeting of the convened IRB.

The Chair (or their designee) or the convened IRB determines whether additional information is necessary, including information from individuals other than the principal
investigator (e.g., other research staff, research participants, site administrators). The IRB may conduct the investigation itself or request assistance from others (e.g., post approval monitors).

The Chair determines whether the report should be reviewed by the convened IRB or whether it can be reviewed under expedited procedures. If reviewed under expedited procedures, then the Chair or their designee may make requested changes to the protocol but may not terminate the study or make a finding of an unanticipated problem involving risk to subjects or others, serious noncompliance, or continuing noncompliance.

If referred to the convened IRB, then it may make all applicable determinations, including a finding of unanticipated problems involving risks to subjects or others, serious noncompliance, or continuing noncompliance. The results of the convened IRB review are recorded in the IRB minutes, protocol record, communicated to the investigator and referred to the HRCO to be handled according to the reporting procedures.

7.2 COMPLAINTS

As part of its commitment to protecting the rights and welfare of human subjects in research, the IRB reviews all complaints and allegations of noncompliance and takes any necessary action to ensure the ethical conduct of research.

Complaints reported to the IRB will be evaluated as possible unanticipated problems involving risks to participants or others.

The Chair of the IRB (or designee) will investigate all complaints, concerns, and appeals received by the IRB. This includes complaints, concerns, and appeals from investigators, research participants, and others.

All complaints, written or verbal (including telephone complaints), and regardless of point of origin, are recorded and forwarded to the IRB Chair and HRC Director.

Upon receipt of the complaint, the Chair will make a preliminary assessment whether the complaint warrants immediate suspension of the research project. If a suspension is warranted, the procedures in suspension will be followed.

If the complaint meets the definition of noncompliance, it will be considered an allegation of noncompliance according to noncompliance.

If the complaint meets the definition of an unanticipated problem involving risk to subjects or others, it will be handled according to Unanticipated Problems.
Upon receipt of the complaint, the IRB Chair and/or HRC Director shall generate a letter to acknowledge that the complaint has been received and is being investigated, providing a follow-up contact name.

7.3 NONCOMPLIANCE

All members of the NYU community involved in human subject research are expected to comply with the highest standards of ethical and professional conduct in accordance with federal and local regulations and institutional and IRB policies governing the conduct of research involving human subjects.

Investigators and their study staff are required to report instances of possible noncompliance. The Principal Investigator is responsible for reporting any possible noncompliance by study personnel to the IRB. Common reports to the IRB that are not serious or continuing are typically viewed as protocol violations and do not have to be reported to OHRP when federally funded, unless they result in the IRB suspending or terminating its approval. Any individual or employee may report observed or apparent instances of noncompliance to the IRB. In such cases, the reporting party is responsible for making these reports in good faith, maintaining confidentiality, and cooperating with any IRB and institutional review of these reports.

If an individual, whether Investigator, study staff or other, is uncertain whether there is cause to report noncompliance, he or she may contact the IRB Chair or HRCO directly to discuss the situation informally.

Reports of noncompliance should be submitted to the IRB promptly. The report must include a complete description of the noncompliance, the personnel involved and a description of the noncompliance.

Complainants may choose to remain anonymous.

7.3.1 DEFINITIONS

Noncompliance is a failure to comply with any of the regulations and policies described in this document and failure to follow the determinations of the IRB. Noncompliance may be minor, sporadic, or it may be serious or continuing.

Serious Noncompliance is a failure to follow any of the regulations and policies described in this document or failure to follow the determinations of the IRB and which, in the judgment of the convened IRB, increases risks to participants, decreases potential benefits, or compromises the integrity of the human research protection program. Research being conducted without prior IRB approval or participation of
subjects in research activities without their prior consent (in studies where consent was not explicitly waived by the IRB) is considered serious noncompliance.

Continuing Noncompliance is a pattern of noncompliance that, in the judgment of the convened IRB, suggests a likelihood that instances of noncompliance will continue without intervention. Continuing noncompliance also includes failure to respond to a request to resolve an episode of noncompliance.

An Allegation of Noncompliance is an unproved assertion of noncompliance.

A Finding of Noncompliance is an allegation of noncompliance that is proven true or a report of noncompliance that is true. (For example, a finding on an audit of an unsigned consent document, or an admission of an investigator that the protocol was willfully not followed would represent reports of noncompliance that would require no further action to determine their truth and would, therefore, represent findings of noncompliance.) Once a finding of noncompliance is proven, it must be categorized as serious and/or continuing, or neither serious nor continuing.

7.3.2 IRB REVIEW OF ALLEGATIONS OF NON-COMPLIANCE

The IRB Chair, or designee, will review all allegations of noncompliance, and will examine all pertinent materials, such as:

- all documents relevant to the allegation
- the last approval letter from the IRB
- the last approved IRB protocol
- the last approved consent document
- the grant (if applicable)
- any other pertinent information (e.g., questionnaires, etc.)

The HRCO will provide the Investigator with notice of the allegation along with a list of the charges/allegations.

The individual has 10 days to respond in writing to the HRCO.

The IRB Chair or designee will make a determination as to the truthfulness of the allegation and the response. They may request additional information from either party or an audit of the research in question.

When there is a determination that noncompliance did not occur because the incident was within the limits of an approved protocol for the research involved, the determination is reported in writing to the Principal Investigator and, if applicable, the
reporting party. The Chair or designee may also determine that the letter be copied to
the Institutional Official and other relevant officials.

If the reported allegation of noncompliance is determined to be not true, no further
action will be taken. If the reported allegation of is determined to be accurate, the
noncompliance will be processed according to Review of Findings of Noncompliance.

If, in the judgment of the IRB Chair, any allegation or findings of noncompliance
warrants suspension of the research before completion of any review or investigation to
ensure the protection of the rights and welfare of participants, the IRB Chair may
suspend the research as described in below in with subsequent review by the convened
IRB.

The Chair may determine that additional expertise or assistance is required to make
these determinations and may form an ad hoc committee to assist with the review and
fact-gathering process. When an ad hoc committee assists in the review process, the
Chair is responsible for assuring that minutes of the meeting are generated and kept to
support any determinations or findings made by the ad hoc committee.

7.3.3 REVIEW OF FINDINGS OF NONCOMPLIANCE

If, in the judgment of the IRB Chair, the reported finding of noncompliance is not
serious, not continuing, and the proposed corrective action plan seems adequate, no
further action is required, and the IRB is informed at the next convened meeting.
Otherwise, the matter will be presented to the IRB at a convened meeting with a
recommendation that a formal inquiry (described below) will be held.

If an allegation of noncompliance is referred to the convened IRB, then IRB members
will receive all pertinent materials/information, such as:

- all documents relevant to the allegation
- all documents relevant to the response
- the last approval letter from the IRB
- the last approved IRB protocol
- the last approved consent document
- At this stage, the IRB may:
  - find that there is no issue of noncompliance
  - find that there is noncompliance that is neither serious nor continuing and an
    adequate corrective action plan is in place
  - find that there may be serious or continuing noncompliance and direct that a
    formal inquiry (described below) be held
- request additional information
- find that there is serious or continuing noncompliance
- suspend or terminate IRB approval

7.3.4 INQUIRY PROCEDURES
A determination may be made by the IRB that an inquiry is necessary based on several issues that may include but are not limited to:

- subject's complaint(s) that rights were violated
- report(s) that Investigator is not following the protocol as approved by the IRB;
- unusual and/or unexplained adverse events in a study
- repeated failure of Investigator to report required information to the IRB

7.3.5 FINDINGS OF SERIOUS OR CONTINUING NONCOMPLIANCE
If the results of the inquiry substantiate a finding of serious or continuing noncompliance, the IRB's possible actions could include, but are not limited to:

- request a correction action plan from the Investigator
- verification that participant selection is appropriate and observation of the actual informed consent
- require an increase in data and safety monitoring of the research activity
- request a directed audit of targeted areas of concern
- request a status report after each participant receives an intervention
- modify the continuing review cycle
- request additional Investigator and staff education
- require notification of current subjects if the information about the noncompliance might affect their willingness to continue participation
- request modifications to the protocol
- request modifications to the information disclosed during the consent process
- require current participants to re-consent to participation
- suspend IRB approval (see below)
- terminate IRB approval (see below)

In cases where the IRB determines that the event of noncompliance also meets the definition of an unanticipated problem involving risks to subjects or others, the policy and procedure for review of such events will also be followed.

The Investigator is informed of the IRB determination and the basis for the determination in writing and is given a chance to respond. If the IRB determines that
the noncompliance was serious or continuing the results of the final review will be reported as described below in Reporting.

7.3.6 ADDITIONAL ACTIONS

A finding of serious or continuing noncompliance may also result in the following sanctions, among others:

• suspension or termination of IRB approval of specific research protocols or of all research involving human subjects in which the Investigator participates
• the IRB may impose additional requirements on the Investigator or other personnel involved in a study, according to IRB policies and procedures.

Failure to secure necessary NYU IRB approval before commencing may result in disciplinary action from the University.

Investigators should also be aware that, in general, NYU indemnifies them from liability for adverse events that may occur in NYU studies approved by the NYU IRB. Failure to follow approved procedures may compromise this indemnification and make the Investigator personally liable in such cases.

7.3.7 SUSPENSION OR TERMINATION

An IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Suspension of IRB approval is a directive of the convened IRB or IRB Chair to stop temporarily, or permanently, some or all previously approved research activities. Suspended protocols remain open and require continuing review. Termination of IRB approval is a directive of the convened IRB to stop all activities permanently in a previously approved research protocol. Terminated protocols are considered closed and no longer require continuing review.

The IRB Chair may suspend research to ensure the protection of the rights and welfare of participants. Suspension directives made by the IRB Chair must be reported to a meeting of the convened IRB. The convened IRB determines if the suspension should continue.

Research may only be terminated by the convened IRB. Terminations of protocols approved under expedited review must be made by the convened IRB.

After review of the allegation and possible response from the Investigator, the IRB shall notify the Principal Investigator in writing of such suspensions or terminations and shall
include a statement of the reasons for the IRB’s actions. The terms and conditions of
the suspension must be explicit. The Investigator shall be provided with an opportunity
to respond in person and in writing.

The convened IRB or individual ordering the suspension or termination of a study will
consider whether procedures for withdrawal of enrolled subjects are necessary to
protect the rights and welfare of the subjects, such as:

- transferring participants to another investigator;
- making arrangements for care or follow-up outside the research;
- allowing continuation of some research activities under the supervision of an
  independent monitor; or
- requiring or permitting follow-up of participants for safety reasons.

If follow-up of subjects for safety reasons is permitted/required by the convened IRB or
individual ordering the suspension, the convened IRB or individual ordering the
suspension will require that the subjects should be so informed and that any adverse
events/outcomes be reported to the IRB and the sponsor.

Investigators must continue to provide reports on unanticipated problems and
noncompliance to both the IRB and sponsor, as needed, just as if there had never been
a suspension (i.e., all events that need to be reported during a study need to continue to
be reported during the suspension period.)

### 7.3.8 REPORTING

Serious or continuing noncompliance with regulations or the requirements or
determinations of the IRB, suspensions or terminations of IRB approval, and findings of
unanticipated problems involving risks to subjects or others will be reported to the
appropriate regulatory agencies and institutional officials according to the procedures
below.

### 7.3.9 REPORTING TO REGULATORY AGENCIES AND INSTITUTIONAL
OFFICIALS

Federal regulations require prompt reporting to appropriate institutional officials, OHRP,
and the department or agency head of (i) any unanticipated problems involving risks to
subjects or others; (ii) any serious or continuing noncompliance of federal regulations
or the requirements or determinations of the IRB; and (iii) any suspension or termination
of IRB approval. The IRB will comply with this requirement, and the following
procedures describe how these reports are handled.

The HRCO will initiate these procedures when the IRB takes any of the following
actions:
• Determines that an event may be considered an unanticipated problem involving risks to participants or others
• Determines that noncompliance was serious or continuing
• Suspends or terminates approval of research

The Human Research Compliance Director or designee prepares a letter about the finding that may contain the following information:

• the nature of the event (unanticipated problem involving risks to participants or others, serious or continuing noncompliance, suspension or termination of approval of research)
• name of the institution conducting the research
• title of the research project and/or grant proposal in which the problem occurred
• name of the principal investigator on the protocol
• number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement)
• a detailed description of the problem including the findings of the organization and the reasons for the IRB's decision
• actions the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.)
• plans, if any, to send a follow-up or final report by the earlier of specific date when an investigation has been completed or a corrective action plan has been implemented

The IRB Chair and the Institutional Official review the letter and modify the letter as needed. The Institutional Official signs the letter and returns it to the HRC Director or designee

The HRC Director or designee sends a copy of the report to:

• the IRB by including the letter in the next agenda as an information item
• the Institutional Official
• Principal Investigator
• department or agency head, if the study is funded by a Common Rule department or agency
• OHRP, if the study is funded by a Common Rule department or agency.

The Institutional Official and/or IRB may determine that a copy of the report be sent to others, such as:
• chairman or supervisor of the principal investigator or student investigator
• other sites engaged in the research
• sponsor, if funded by an entity other than a Common Rule agency.

The HRC Director ensures that all steps of this policy are completed promptly after the initiating action. For more serious actions, the HRC Director will expedite reporting.

The above reporting is not required if the event occurred at a site that was not subject to the direct oversight of NYU IRB.

8. VULNERABLE POPULATIONS

When some or all of the participants in a protocol are likely to be vulnerable to coercion or undue influence or to specific risks, the IRB should include additional safeguards to protect the rights and welfare of these participants. Some of the vulnerable populations that might be involved in research studies include children, pregnant women, fetuses, prisoners, persons with impaired decision-making capacity, or economically or educationally disadvantaged persons.

If the IRB reviews research that involves categories of vulnerable participants, the review process will include one or more individuals who are knowledgeable about or experienced in working with these participants.

The subparts within 45 CFR Part 46 provide extra protections for specific vulnerable populations. These populations have additional review requirements for IRBs. For research funded by DHHS agencies, there are also other reporting requirements.

**Subpart B:** Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

**Subpart C:** Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

**Subpart D:** Additional Protections for Children Involved as Subjects in Research

Researchers conducting human subject research must check with the IRB to determine the applicability of and how to apply the subparts.

NYU recognizes individuals who have a unique relationship with investigators or cooperating sites, such as students and employees, as vulnerable due to the potential for undue influence and coercion in certain conditions.

8.1 PI RESPONSIBILITIES

The Principal Investigator is responsible for identifying the potential for enrolling vulnerable subjects in the research protocol and for adherence to the additional
requirements for the population, including any approvals from cooperating institutions, such as schools and penal institutions.

8.2 IRB RESPONSIBILITIES
The IRB shall include representation, either as members or ad hoc consultants, individual(s) interested in or who have experience with the vulnerable populations involved in a research proposal.

The IRB reviews the PI's justifications for including vulnerable populations in the research to assess the appropriateness of the research proposal and may require that additional safeguards be included to protect the rights and welfare of vulnerable participants as needed.

8.2.1 INITIAL REVIEW OF RESEARCH PROPOSALS
The Principal Investigator should identify the potential to enroll vulnerable participants in the proposed research at the initial review and provide the justification for their inclusion in the study.

The IRB evaluates the proposed plan for the consent of the specific vulnerable populations involved. If the research involves adults unable to consent, the IRB evaluates the proposed plan for permission of legally authorized representatives.

The IRB evaluates and approves the proposed plan for the assent of participants.

The Principal Investigator should provide appropriate safeguards to protect the participant's rights and welfare, which may include the addition of an independent monitor. The independent monitor is a qualified individual not involved in the research study who will determine the participant's capacity to provide voluntary informed consent.

The IRB assesses the adequacy of additional protections for vulnerable populations provided by the Principal Investigator.

8.2.2 CONTINUING REVIEW AND MONITORING
For research that requires an annual review, the Principal Investigator should identify the number of vulnerable participants enrolled and any that needed an independent monitor in the progress report.
8.3 RESEARCH INVOLVING PREGNANT WOMEN OR FETUSES

NYU applies the Federal Regulations 45 CFR Subpart B to all research regardless of funding source as applicable. Although this subpart is primarily directed at medical interventions, the IRB will take additional care to review any social and behavioral research projects that specifically target this group to ensure that the requirements for approval are met.

The NYU IRB does not review research involving neonates or involving, after delivery, the placenta, the dead fetus, or fetal material.

8.3.1 DEFINITIONS PERTINENT TO RESEARCH INVOLVING PREGNANT WOMEN OR FETUSES

Pregnant

Pregnancy encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

Fetus

Fetus means the product of conception from implantation until delivery.

8.3.2 FINDINGS REQUIRED FOR THE APPROVAL OF RESEARCH WITH PREGNANT WOMEN OR FETUSES

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

(b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

(c) Any risk is the least possible for achieving the objectives of the research;

(d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of
benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions;

(e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions, except that the father’s consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest;

(f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

(g) For children as defined in §46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions for the involvement of children as research participants;

(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

(i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

(j) Individuals engaged in the research will have no part in determining the viability of a neonate.

8.4 RESEARCH INVOLVING PRISONERS

There are special federal regulations that govern research involving prisoners enrolled as participants. Subpart C of 45 Code of Federal Regulation (CFR) 46 applies when are target participant population are prisoners.

8.4.1 DEFINITIONS PERTINENT TO PRISONER RESEARCH

Secretary:

For DHHS-funded research, Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

DHHS:
DHHS means the Department of Health and Human Services.

**Prisoner:**

A prisoner is defined as any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

**Minimal Risk**

Minimal Risk for prisoners is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

8.4.2 COMPOSITION OF THE BOARD WHEN REVIEWING PRISONER RESEARCH STUDIES

When the IRB reviews study protocols that will involve the use of prisoners as participants, a prisoner representative must participate in all types of these reviews (e.g., initial, continuation, modification, and adverse events)

A majority of the Board Members (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

8.4.3 FINDINGS REQUIRED FOR APPROVAL OF PRISONER RESEARCH

For the IRB to approve a study, there research must meet certain criteria:

1. The research under review represents one of the categories of research permissible under §46.306(a);
2. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
3. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
(4) Procedures for the selection of participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control participants must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

(5) The information is presented in language which is understandable to the participant population;

(6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(7) Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) For DHHS supported research, the Board shall carry out such other duties as may be assigned by the Secretary.

(c) For DHHS supported research, the institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

Permitted research involving prisoners at 45 CFR 46.306(a):

   (i) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than an inconvenience to the participants;

   (ii) Study of prisons as institutional structures or of prisoners as incarcerated persons provided that the study presents no more than minimal risk and no more than an inconvenience to the participants;

   (iii) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults), and, for DHHS supported research, provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or
(iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. For DHHS supported research, in cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research.

A certification report must be submitted to OHRP for all HHS funded projects involving prisoners. A certification letter from OHRP must be received before a research study can commence.

8.5 RESEARCH INVOLVING CHILDREN

The following applies to all research involving children, regardless of funding source. The requirements in this section are consistent with [Subpart D of 45 CFR 46].

8.5.1 DEFINITIONS PERTINENT TO RESEARCH INVOLVING CHILDREN

Children:

Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

Guardian:

Guardian means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

Assent:

Assent is a child's affirmative agreement to participate in research. Mere failure to object, absent affirmative agreement, should not be construed as assent.

Permission:

Permission is an agreement from the parent(s) or legal guardian for their child or ward to participate in research.

Parent:

A parent is a child's biological or adoptive parent.

8.5.2 ALLOWABLE CATEGORIES OF RESEARCH WITH CHILDREN
Research on children must be reviewed and categorized by the IRB into one of the following groups:

Research not involving physical or emotional risk greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (i.e., minimal risk). [45 CFR 46.404]

Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participant. [45 CFR 46.405]

Research involving greater than minimal risk and no reasonable prospect of direct benefit to the individual participant, but likely to yield generalizable knowledge about the participant's disorder or condition. [45 CFR 46.406]

Research not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. [45 CFR 46.407] HHS will conduct or fund research that the IRB does not believe meets the requirements of 46.404, 46.405, or 46.406 only if: (a) the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and (b) the Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either: (1) that the research in fact satisfies the conditions of §46.404, §46.405, or §46.406, as applicable, or (2) the following: (i) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; (ii) the research will be conducted in accordance with sound ethical principles; (iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in §46.408.

8.5.3 PERMISSION AND ASSENT

Parental Permission

In accordance with [45 CFR 46.408(b)], the IRB must determine that adequate provisions have been made for soliciting the permission of each child’s parents or guardians. The criteria for obtaining and documenting permission from each child's parents or guardians follow the provisions for obtaining informed consent, including the criteria for waiving consent and/or waiving documentation of consent.

In addition to the provisions for waiving consent, the IRB may waive the requirement for obtaining permission from a parent or legal guardian if the IRB determines that the research protocol is designed for conditions or a participant population for which
parental or guardian permission is not a reasonable requirement to protect the participants (for example, neglected or abused children), and an appropriate mechanism for protecting the children who will participate as participants in the research is substituted and that the waiver is not inconsistent with Federal, State, or local law.

The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research participants, and their age, maturity, status, and condition.

Assent from Children

For research activities involving children whose capacity to understand resembles that of adults, the assent procedure should likewise include information similar to what would be provided for informed consent by adults. For children whose age and maturity level limits their ability to fully comprehend the nature of the research activity but who are still capable of being consulted about participation in research, it may be appropriate to focus on conveying an accurate picture of what the actual experience of participation in research is likely to be (for example, what the experience will be, how long it will take, whether it might involve any pain or discomfort). The assent procedure should reflect a reasonable effort to enable the child to understand, to the degree they are capable, what their participation in research would involve.

The IRB presumes that children ages four and older should be given an opportunity to provide assent. Generally, oral assent using a script in language appropriate for the child's age should be obtained from children 4-11 years of age. Written assent using a written document for the children to read should be sought for children aged 12 and older. If the child's assent is not obtained, the Principal Investigator may either re-approach the child at a later time or not enroll the child.

At times, there may be an inconsistency between parent permission and child assent. Usually, a "no" from the child overrides a "yes" from a parent. There are individual exceptions to these guidelines (such as when the use of an experimental treatment for a life-threatening disease is being considered). The general idea, however, is that children should not be forced to be research participants, even when their parent gives permission for it.

If the IRB determines that the capability of some, or all, of the children, is so limited that they cannot reasonably be consulted, or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research.
Even when the IRB determines that the participants are capable of assenting, the IRB may still waive the assent requirement under the provisions for waiving informed consent.

8.5.4 THE ASSENT FORM

When the IRB determines that assent is required, it shall also determine whether and how assent must be obtained and documented.

8.5.5 CHILDREN WHO ARE WARDS

Children who are wards of the State or any other agency, institution, or entity can be included in research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition, only if such research is:

- related to their status as wards; or
- conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards.

If the research meets the condition(s) above, an advocate must be appointed for each child who is a ward (one individual may serve as advocate for more than one child), in addition to any other individual acting on behalf of the child as legal guardian or in loco parentis.

The advocate must be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

8.6 VULNERABLE POPULATIONS RECOGNIZED BY THE NYU HRPP: STUDENTS AND EMPLOYEES AS RESEARCH PARTICIPANTS

When researchers recruit students and employees as potential participants, researchers must ensure that there are additional safeguards for these participants. The voluntary nature of their participation must be primary and without undue influence on their decision.

Researchers must emphasize to participants that neither their academic status nor grades nor employment will be affected by their participation decision. Records of participation cannot be linked to an academic record and, whenever possible, an employer should not be told whether an employee participates in the research.
To minimize coercion and undue influence, investigators should avoid, whenever possible, the use of their students and employees in procedures that do not hold the possibility of direct benefits to the participants. Investigators should solicit participants through means such as bulletin board notices, flyers, advertisements in newspapers, and announcements in classes other than their own.