

New York University

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.

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 HRPB 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:

- [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 \(IBC\)](#).
- [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.
- [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 USDL OSHA 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