NYU Shanghai
Institutional Review Board
Procedures for Human Subjects Research Protection

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1. Definitions

Legally Authorized Representative

Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

Common Rule

The Common Rule refers to the "Federal Policy for the Protection of Human Subjects" adopted by a number of US federal agencies. Although the Common Rule is codified by each agency separately, the text is identical to US HHS regulations in 45 CFR 46 Subpart A. For the purposes of this document, references to the Common Rule will cite the US HHS regulations.

Clinical Trial*

Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Human Subject

Under the Common Rule, a human subject means a living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

In China, Research Participants include subjects for human research and individuals who provide personal biological samples, information data, health records and behaviors for life science and medical research involving human being.

For the purposes of this document, the terms "subject" and "participant" will be used interchangeably and are equivalent.

Intervention*

Intervention means both physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction*

Interaction means communication or interpersonal contact between investigator and subject.

Private Information*

Private information means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.

Identifiable Private Information*

Identifiable private information means private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Identifiable Biospecimen*

Identifiable biospecimen means a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Research

Research means a **systematic investigation**, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**.

- **Systematic investigation** is an activity that involves a prospective study plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a study question;
- **Generalizable knowledge** relates to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings.

Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

For purposes of the Common Rule, **the following activities are deemed not to be research**: (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters). (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes. (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions. [45 CFR 46.102(l)]

Life Science and Medical Research involving Human Being

Under Chinese regulations, the Measures for Ethical Review of Life Science and Medical Research Involving Human Subjects (2023 Measures), life science and medical research involving human being refers to the following research activities carried out with biological samples and information data (including health records, behaviors, etc.) with human beings as subjects or users (collectively referred to as “research participants”):
(1) Carrying out activities of research on human reproduction, growth, development and senescence by physics, chemistry, biology and traditional Chinese medicine and other means.
(2) Carrying out activities of research on human physiological and psychological behaviors, pathological phenomena, etiology and pathogenesis of diseases, as well as prevention, diagnosis, treatment and rehabilitation of diseases by physics, chemistry, biology, traditional Chinese medicine, psychology and other means.
(3) Carrying out activities of experimental research on human subjects by using new technologies or new products.
(4) Carrying out activities of collecting, recording, using, reporting or storing biological samples, information data (including health records, behaviors, etc.) and other scientific research materials on life science and medical problems involving human being by epidemiology, sociology, psychology, and other means.

Study/Protocol

A study is a research project involving or possibly involving human subjects. The protocol is the documentation of a study submitted to the IRB. IRB approval only applies to the study activities described in the documentation submitted in the protocol.

Institutional Official (IO)

The IO is responsible for ensuring that the IRB at the Organization has the resources and support necessary to comply with all federal regulations and guidelines that govern human subjects' research. The IO is legally authorized to represent the institution, is the signatory official for all Assurances, and assumes the obligations of the institution's Assurance.

IRB

IRB means 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 this institution. For the purpose of the document, the term IRB will be used to indicate any Ethics Committee performing the same function.

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, US federal, Chinese and local requirements.

Minimal Risk*

Minimal risks means 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.

Research under the Auspices of the Organization

Research conducted at this institution, conducted by or under the direction of any employee or agent of this institution (including students) in connection with his or her institutional responsibilities, conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or involving the use of this institution's non-public information to identify or contact human subjects.

Principal Investigators

At NYU Shanghai, only tenured and tenure track faculty with full-time appointments may serve as the Principal Investigator (PI) or as the faculty sponsor on an externally-funded research project. PI status requests for Full Time Continuing Contract Faculty and Professional Research Personnel, as well as for those individuals whose appointments do not fall within the above-stated categories, though not guaranteed, may be requested by following the guidance provided in the NYU Shanghai Statement on PI Eligibility. The University requires that every investigator conducting human subjects research, whether funded or not funded, must submit a proposed research plan to the institutional review board (IRB) for review. The same PI eligibility considerations are therefore applicable for non-funded human subjects research also. The approval obtained is applicable for a designated program/project only. The PI status cannot be carried over to another project. Hence a new approval must be sought for each new application.

Any investigator whose status is considered to be "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.

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

Protocols that require skills beyond those held by the Principal Investigator must be modified to meet the investigator's skills or have one or more additional qualified faculty as Co-investigator(s).

Investigators

The US HHS regulations at 45 CFR part 46 uses the term “investigator” to refer to an individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB. For the purposes of the US HHS regulations, the US Office for Human Research Protections (OHRP) interprets an “investigator” to be any individual who is involved in conducting human subjects research studies. Such involvement would include:

- obtaining information about living individuals by intervening or interacting with them for research purposes;
- obtaining identifiable private information or biospecimens about living individuals for research purposes;
- obtaining the voluntary informed consent of individuals to be subjects in research; and
- studying, interpreting, or analyzing identifiable private information or biospecimens for research purposes.

Investigators can include physicians, scientists, nurses, administrative staff, teachers, and students, among others. Some research studies are conducted by more than one investigator, and usually one investigator is designated the “principal investigator” with overall responsibilities for the study. In every human subjects research study, investigators have certain responsibilities regarding the ethical treatment of human subjects.

**Definition taken directly from 45CFR46*

2. Institutional Authority

The NYU Shanghai Provost serves as the Institutional Official ("IO") responsible for compliance with laws and regulations applicable to research carried out under the auspices of NYU Shanghai. The IO is authorized to establish IRB(s) and to assure compliance with applicable laws, regulations and University policy in the review, approval and monitoring of human subjects research. The IO is responsible for maintaining a Federal-wide Assurance (FWA) with the Office of Human Research Protections of the United States Department of Health and Human Services and the NYU Shanghai IRB to be registered with the National Medical Research Registration and Recordation Information System by the National Health Commission of the People's Republic of China.

The NYU Shanghai Research Compliance Office is responsible for the day-to-day operations of the IRB. The IRB functions in coordination with NYU Shanghai officials and other review committees but at all times maintains its independence to appropriately review, approve and monitor research with human subjects.

The NYU Shanghai IRB has jurisdiction over all human subject research (as defined above) conducted under the auspices of NYU Shanghai. Research under the auspices of NYU Shanghai includes research conducted at NYU Shanghai, conducted by or under the direction of any employee or agent of NYU Shanghai (including students) in connection with his or her institutional responsibilities, conducted by or under the direction of any employee or agent of NYU Shanghai using any property or facility of NYU Shanghai, or involving the use of NYU Shanghai's non-public information to identify or contact human subjects.

2.1. Assurance of Compliance

NYU Shanghai has provided written assurance that it will comply with Federal regulations protecting human subjects (a Federal-wide Assurance, or FWA). The FWA is an assurance of compliance with the federal regulations for the protection of human subjects in federally funded research. Other departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects may rely upon the FWA for the research that they conduct or support. NYU Shanghai maintains these same standards for all human research regardless of funding status.

2.2. Regulatory Compliance

The IRB is responsible for ensuring compliance with all applicable regulations (US and Chinese), local laws and customs and institutional policies. All human subjects' research at NYU Shanghai is conducted in accordance with the US policy and regulations found in 45CFR46, and Chinese regulations found in the Measures for Ethical Review of Life Science and Medical Research Involving Human Subjects (2023 Measures).

In the event of conflict between applicable standards of protection, NYU Shanghai follows the standard that provides greater protection to human subjects.

2.3. Management of pre-existing studies once the revised Common Rule goes into effect

For research subject to the Common Rule (whether due to support or organization policy), the following outlines when the old rule or the revised rule will apply to research conducted at NYU Shanghai.

I. **Research subject to the old rule (pre-2018 requirements).** The old rule will apply to the following studies.

- All studies initially approved, waived under 45CFR46.101(i), or determined exempt before January 21, 2019 will be subject to the old rule through the close of study.

II. **Research subject to the revised rule (2018 requirements).** The revised rule will apply to the following studies.

- All studies initially approved, waived under 45CFR46.101(i), or determined exempt on or after January 21, 2019 will be subject to the revised rule.

3. NYU Shanghai Institutional Review Board

The NYU Shanghai 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 this institution. The IO and the Chair of the IRB review the activity of the IRB periodically and make a determination as to the appropriate number of review boards and meetings that are needed for NYU Shanghai.

3.1. Authority of the IRB

The IRB at the NYU Shanghai reviews and has the authority to approve, require modifications to secure approval, or disapprove human subjects research activities conducted under the auspices of NYU Shanghai, including exempt research activities under 45 CFR 46.104 for which limited IRB review is a condition of exemption. The IRB also has the authority to suspend, place restrictions on, or terminate approvals of research activities that fall within its jurisdiction that are not being conducted in accordance with IRB requirements, or that have been associated with unexpected serious harm to subjects.

The IRB ensures that appropriate safeguards exist to protect the rights and welfare of research subjects [45 CFR 46.111]. IRB review and approval of proposed research involving human subjects must take place before research is initiated. In fulfilling its responsibilities, the IRB reviews all research documents and activities that bear directly on the rights and welfare of the subjects of proposed research. Examples of IRB review documentation include, *inter alia:* protocols, consent/assent document(s), tests, surveys, questionnaires and similar measures, and recruiting documents.

Before any human subject becomes involved in research at NYU Shanghai, an IRB will properly consider:

- risks to the subject
- anticipated benefits to the subject and others
- importance of the knowledge that may reasonably be expected to result from the study
- informed consent process to be employed

The IRB has the authority to suspend, place restrictions upon, or terminate approval of research activities that fall within its jurisdiction that

- are not being conducted in accordance with IRB requirements, or
- that have been associated with serious harm to subjects

The IRB has the authority to observe (or delegate a third party to observe) the consent process and the research if the IRB deems this necessary.

3.2. Jurisdiction of the IRB

The IRB jurisdiction extends to all research (funded and unfunded) involving human subjects conducted under the auspices of NYU Shanghai.

3.2.1. IRB Relationships

The IRB functions independently of, but in coordination with, other institutional regulatory committees. The IRB, however, makes independent determinations regarding approval or disapproval of a protocol based upon whether or not human subjects are adequately protected. The IRB retains review jurisdiction over all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency that adopted the human subjects' regulations. Human research must have IRB approval before the research can begin.

3.3. Roles and Responsibilities

3.3.1. Institutional Official

The ultimate responsibility of the IRB resides with the NYU Shanghai Provost who serves as the Institutional Official (IO) of the program. The IO is responsible for ensuring the IRB has the resources and support necessary to comply with all institutional policies and with federal regulations and guidelines that govern human subjects research. The IO is legally authorized to represent the IRB.

The IO also holds ultimate responsibility for oversight over the:

- Institutional Review Board (IRB); and
- conduct of human research conducted by all NYU Shanghai investigators.

3.3.2. Associate Provost for Research

The Associate Provost for Research reports to the IO and is responsible for:

- developing, managing and evaluating policies and procedures that ensure compliance with all local, and federal regulations governing research. This includes monitoring changes in regulations and policies that relate to human research protection and overseeing all aspects of NYU Shanghai's Human Research Protection Program (HRPP);
- advising the IO on key matters regarding research at NYU Shanghai;
- implementing the organization's HRPP policies and procedures;
- assisting investigators in their efforts to carry out Organization's research mission;
- developing and implementing needed improvements and ensuring follow-up of actions, as appropriate, for the purpose of managing risk in the research program;
- overseeing the day-to-day operation of the Research Compliance Office, including supervision of Research Compliance Manager; and
- performing other duties as may be delegated by the IO.

3.3.3. Research Compliance Manager

The Research Compliance Manager reports to the Associate Provost for Research and is responsible for:

- submitting, implementing and maintaining an approved FWA through the IO and the Department of Health and Human Services Office of Human Research Protection (OHRP);
- submitting, and maintaining the registration and reporting requirements in the National Medical Research Registration and Recordation Information System by the National Health Commission of the People's Republic of China;
- managing the finances of the IRB;
- developing training requirements as required and as appropriate for investigators, subcommittee members and research staff, and ensuring that training is completed on a timely basis;
- serving as the primary contact at NYU Shanghai for the OHRP of the U.S. Department of Health and Human Services and other federal regulatory agencies;
- serving as the primary contact at NYU Shanghai for the Shanghai Municipal Education Commission (China) and other regulatory authorities regarding human subjects protection;
- responding to faculty and student questions regarding the protection of human subjects;
- working closely with the Chair of the IRB on the review of policy and procedures, as well as organizing and documenting the review process.

The Research Compliance Manager serves as the secretary to the IRB.

Research Compliance Office/IRB Staff
The Research Compliance Manager may delegate functions to other staff in the Research Compliance Office. For the purpose of this document all administrative IRB functions will be indicated for the Research Compliance Manager but may be performed by other appropriate staff.

3.3.4. Institutional Review Board (IRB)

The IRB prospectively reviews and makes decisions concerning all human research conducted at NYU Shanghai facilities by its employees or agents, or under its auspices. The IRB is responsible for the protection of rights and welfare of human research subjects at all NYU Shanghai facilities. It discharges this duty by complying with the requirements of the Common Rule and the Measures for Ethical Review of Life Science and Medical Research Involving Human Being (2023 Measures); local regulations, the FWA and institutional and federal policies.

3.3.5. Chairperson of the IRB

The IO will appoint a Chair and Vice Chair of the IRB to serve for renewable one-to-three-year terms. Any change in appointment, including reappointment or removal, requires written notification.

The IRB Chair should be a highly respected tenured faculty member of an involved discipline or a highly respected individual specifically designated to fulfill this role who is fully capable of managing the IRB and the matters brought before it with fairness and impartiality. Moreover, the IRB Chair must be prepared to resist pressure from the institution's administration, the investigators whose protocols are brought before him/ her, and other professional and nonprofessional sources.

The IRB Chair is responsible for conducting convened IRB meetings.

The IRB Chair may designate other IRB members to perform duties, as appropriate, for review, signature authority, and other IRB functions.

The IRB Chair advises the IO about IRB member performance and competence.

3.3.6. Vice Chair of the IRB

A Vice Chair serves as the Chair of the IRB in the absence of the Chair or in instances where the Chair has a real or perceived conflict of interest with the research under review by the IRB, A Vice Chair maintains equivalent qualifications, authority, and duties as the IRB Chair.

3.3.7. The Principal Investigator

The Principal Investigator (PI) has primary responsibility for carrying out the human research protection program. The PI is expected to abide by the highest ethical standards and to develop a protocol that incorporates the principles of the Belmont Report and Declaration of Helsinki. He/she is expected to conduct research in accordance with the approved research protocol and to oversee all aspects of the research by providing supervision of support staff, including oversight of the informed consent process. The PI is responsible for obtaining prior IRB review and approval for any proposed changes to research methodology, recruitment, consent procedures, etc. to a previously approved protocol, except where an immediate change in protocol is warranted to protect the health and welfare of subject(s).

All subjects must give informed consent (unless a waiver has been approved by the IRB) and the PI and other Investigators must establish and maintain an open line of communication with all research subjects within his/her responsibility. In addition to complying with all the policies and standards of the

governing regulatory bodies, the Investigator must comply with institutional and administrative requirements for conducting research. The Investigator is responsible for ensuring that all research staff complete appropriate training and must obtain all required approvals prior to initiating research.

While the PI may delegate responsibilities to others, including Co-Investigators, the PI has the ultimate responsibility for the conduct of research involving human subjects.

3.4. Resources for the IRB

The NYU Shanghai Office of Research provides resources to the IRB, including adequate meeting and office space, and staff for conducting IRB business. Office equipment and supplies, including technical support, file cabinets, computers, internet access, and copy machines (etc.) will be made available to the IRB and staff.

Periodically, the IO will review the activity, workload and resources of the IRB. The resources provided for the IRB will be reviewed during the NYU Shanghai annual budget review process.

4. IRB Membership

Appointments are made by the IO for renewable terms of between one and three years.

In accordance with the governing regulations, IRB members are selected based on appropriate diversity, including consideration of race, gender, cultural backgrounds, specific community concerns in addition to representation by multiple, diverse professions, knowledge and experience with vulnerable subjects, and inclusion of both scientific and non-scientific members. The structure and composition of the IRB must be appropriate to the amount and nature of the research that is reviewed. Every effort is made to have member representation that has an understanding of the areas of specialty that encompass most of the research performed at NYU Shanghai. The IRB has procedures that specifically outline the requirements of protocol review by individuals with appropriate expertise.

In addition, the IRB will include members who are knowledgeable about and experienced working with subjects vulnerable to coercion or undue influence (e.g., children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons) that are regularly included in the research under its review.

The IRB must promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects; 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.

Changes in membership will be reported to OHRP.

4.1. Composition of the IRB

The IRB will at all times consist of at least seven members with a guiding principle to promote complete and adequate review of research activities commonly conducted by the institution.

In addition to possessing the professional competence necessary to review specific research activities, the IRB will be able to ascertain the acceptability of proposed research in terms of institutional policies and regulations, applicable law, and standards of professional conduct and practice. The IRB will therefore include persons knowledgeable in these areas.

Since the IRB will regularly review research that involves vulnerable categories of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration is given to the inclusion of one or more individuals on the IRB who are knowledgeable about, and experienced in, working with vulnerable populations. In fact, 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. Prior to the meeting, the Research Compliance Manager and IRB Chair will review the agenda to ensure that the membership present for the meeting has the appropriate expertise and experience with any vulnerable populations that are included in the protocols being reviewed.

The IRB shall be selected from experts in the fields of life science, medicine, bioethics, law and other fields as well as from social elites, and shall not consist entirely of members of one profession. There shall be members of different genders.

The IRB includes at least one member whose principal concerns are in scientific areas and at least one member whose principal concerns are in nonscientific areas. According to OHRP, members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist, while members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist.

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.

On an ongoing basis the Associate Provost for Research and the IO will monitor the membership and composition of the IRB in order to meet regulatory and organizational requirements.

4.2. Alternate Members

The appointment and function of alternate members is the same as that for principal IRB members. The role of the alternate member is to serve as a voting member of the IRB when the regular principal member is unavailable to attend a convened meeting. When an alternate member substitutes for a principal member, the alternate member will receive and review the same materials prior to the IRB meeting that the principal member received or would have received.

The alternate member will not be counted as a voting member unless the principal member is absent. The IRB minutes will document when an alternate member replaces a principal member.

4.3. Use of Consultants (Outside Reviewers)

When necessary, the IRB Chair may solicit individuals with competence in specialized areas to assist in the review of issues or protocols requiring expertise beyond, or in addition to, that available on the IRB.

4.4. Attendance Requirements

Members should attend all meetings for which they are scheduled. If a member is unable to attend a scheduled meeting, that member should inform the IRB Chair, Vice Chair, or the Research Compliance Manager, preferably with sufficient advance notice to assure quorum attendance. If the inability to attend will be prolonged, a request for an alternate to be assigned may be submitted to the Chair or the Research Compliance Manager. If an IRB member is to be absent for an extended period of time, such as for a sabbatical, he or she should notify the IRB at least 30 days in advance so that an appropriate replacement can be obtained. The replacement can be temporary, for the period of absence, or permanent if the member is not returning to the IRB. If the member has a designated alternate, the alternate can serve during the Principal member's absence, providing that the IRB receives advance notice.

4.5. Training / Ongoing Education of Chair and IRB Members in Regulations, Procedures

A vital component of a comprehensive human research protection program is an education program for the IRB Chairs and the IRB members. NYU Shanghai is committed to providing training and an on-going educational process for IRB members and the staff of the IRB, related to ethical concerns and regulatory and institutional requirements for the protection of human subjects, as described below.

4.5.1. Orientation

New IRB members, including alternate members, will meet with an IRB Chair and the Research Compliance Manager for an informal orientation session. After the initial session, all new IRB members will meet with the Research Compliance Manager for a formal introduction to the IRB and members' responsibilities. All new members will be given an orientation handbook that includes:

- The Belmont Report and Declaration of Helsinki
- NYU Shanghai Procedures for Human Subjects Research Protection

- US Federal regulations relevant to the IRB
- Chinese regulations relevant to the IRB

New members are required to complete the initial education requirement (discussed in the next section) prior to serving as Primary Reviewer.

4.5.2. Initial Education

All new IRB members will complete "IRB Members Course" found in the CITI online program, as well as the SBR investigator track. All new members are required to attend an initial orientation session and should be knowledgeable about all documents referenced in these Standard Operating Procedures prior to reviewing any IRB study protocols.

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

- in-service training at IRB meetings
- training workshops
- review of appropriate publications
- identification and dissemination by the Research Compliance Manager of new information that might affect the human research protection program, including emerging laws, regulations, policies, procedures, and ethical and scientific issues to IRB members via email, mail, or during IRB meetings.

4.5.3. Staff Training

All new IRB staff will meet with the Research Compliance Manager for a formal introduction to the IRB and staff members' responsibilities. At this session, the new staff will be given an orientation handbook that includes:

- The Belmont Report and Declaration of Helsinki
- NYU Shanghai Procedures for Human Subjects Research Protection
- US Federal regulations relevant to the IRB
- Chinese regulations relevant to the IRB

All new Research Compliance Office staff members are trained in the appropriate purpose and use of all IRB forms, documents, and procedures, such as Application for New Protocol Review forms, Request for Continuing Review or Notice of Study Closure form, Reviewer Checklist forms, etc.

4.6. Reporting and Investigation of Allegations of Undue Influence

If an IRB Chair, member, or staff person feels that the IRB has been unduly influenced by any party, he/she shall make a confidential report to the Institutional Official (IO) or designee, depending on the circumstances. The official receiving the report will conduct a thorough investigation and corrective action, when appropriate and necessary, will be taken to prevent additional occurrences.

5. 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 proposals; recruitment materials; scientific evaluations (if any) that accompany the proposals; approved consent documents; any proposed amendments and the IRB action on each amendment; reports of injuries to subjects and serious and unexpected adverse events; documentation of protocol violations, and documentation of non-compliance with applicable regulations

IRB records must also include continuing review activities and copies of all correspondence between the IRB and investigators.

Documentation of verified exemptions consists of the reviewer's written concurrence that the activity described in the investigator's request satisfies the conditions of the cited exemption category.

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

IRB records must document any determinations required by the regulations and protocol-specific findings supporting those determinations.

All records must be accessible for inspection and copying by authorized representatives of OHRP, sponsors, and other authorized entities at reasonable times and in a reasonable manner.

5.1. IRB Records

IRB records include, but are not limited to:

- IRB Bylaws
- Written operating procedures
- IRB membership rosters
- Training records
- IRB correspondence (other than protocol related)
- IRB study files
- Documentation of exemptions and when limited IRB review is a condition of exemption
- Documentation of convened IRB meetings minutes, including voting records for all IRB actions
- Documentation of review by another institution's IRB when appropriate
- Documentation of cooperative review agreements, e.g. Memoranda of Understanding (MOUs)
    - For nonexempt research involving human subjects covered by the 2018 revised Common Rule (or exempt research for which limited IRB review takes place as described in Section 6.2.2) that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB shall document the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this policy (e.g., in a written agreement between the institution and the IRB, by implementation of an institution-wide policy directive providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution, or as set forth in a research protocol);
- Federal Wide Assurances
- Protocol violations submitted to the IRB

5.2. IRB Study Files

The IRB will maintain a separate IRB study file for each research application (protocol) that it receives for review. These files may be maintained electronically. Protocols will be assigned a unique identification number by the Research Compliance Manager and entered into the IRB tracking system.

Accurate records are maintained of all communications to and from the IRB. The IRB maintains a separate file for each research protocol that includes, but is not limited to:

- Protocol and all other documents submitted as part of a new protocol application
- Protocol and all other documents submitted as part of a request for continuing review/closure of research application, including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in Section 6.6;. This also includes progress reports
- Documents submitted and reviewed after the study has been approved, including reports of modifications to research/amendments and adverse event reports
- Copy of IRB-approved Consent Form
- Documentation of the type of IRB review
- For expedited review, documentation of 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
    - research involving persons with impaired cognitive function
- Documentation of the rationale for an expedited reviewer's determination under 45 CFR 46.110(b)(1)(i) that some or all the research appearing on the expedited review list described in 45 CFR 46.110(a) is more than minimal risk
- Documentation of all IRB review actions
- Notification of suspension of research
- Correspondence pertaining to appeals
- Copies of approval letters and forms that describe what Principal Investigator must have before beginning the study
- IRB correspondence to and from research investigators
- All other IRB correspondence related to the research
- Reports of unanticipated problems involving risk to subjects or others and adverse events

5.3. Minutes of an IRB Meeting

Proceedings must be written and available for review by the next regularly scheduled IRB meeting date. After ratification of the minutes by the Board members, if it is determined that revisions/corrections are necessary, the Minutes will be amended and presented at the following IRB meeting.

Minutes of IRB meetings must contain sufficient detail to show:

- The basis for requiring changes in research
- The basis for disapproving research
- The presence of a quorum throughout the meeting, including the presence of one member whose primary concern is in a non-scientific area
- Attendance at the meetings, including documentation of those members or alternate members who are participating through videoconference or teleconference, including documentation that

those attending through videoconferencing or teleconferencing received all pertinent materials prior to the meeting and were able to actively and equally participate in all discussions
- Alternate members attending the meeting and for whom they are substituting
- Names of consultants present
- Name of investigators present
- Names of guests present
- The initial attendance list shall include those members present at the beginning of the meeting. The minutes will indicate, by name, those members who enter or leave the meeting. The vote on each action will reflect those members present for the vote on that item
- Business items discussed
- Separate deliberations, actions, and votes for each protocol undergoing initial review, continuing review, or review of modifications by the convened IRB
- Documentation that the research meets each of the required criteria [45 CFR 46.116(e) or (f)] along with protocol-specific information containing justification as to why the IRB considers the research to meet each criterion 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 informed consent
- Documentation that the research meets each of the required criteria [45 CFR 46.117(c)] along with protocol-specific information justifying why the IRB considers the research to meet each criterion when the requirements for written 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 protocol-specific 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
- The vote on actions, including the number of members voting for, against, and abstaining
- Number of those excused, Number of those recused
- Notations indicating an IRB member's conflicting interest with the research under review, as defined by NYU Shanghai policy as described in this document at Section 6.5.3
- A conflicted IRB member may be present at the meeting to respond to IRB member questions, etc. during review/discussion but must leave the meeting during deliberations and voting
- A written summary of the discussion of controvertedl issues and their resolution
- Review of additional safeguards to protect vulnerable populations if entered as study subjects when this is not otherwise documented in IRB records
- Approval period for initial and continuing reviews, when applicable, including identification of research that warrants review more often than annually and the basis for that determination
- The rationale for requiring continuing review of research that otherwise would not require continuing review as described in Section 6.6
- Risk level of initial and continuing approved protocols
- Review of interim reports, e.g., unanticipated problems or safety reports; amendments; report of violation/deviations; serious or continuing non-compliance; suspensions/terminations, etc.
- Relevant information provided by consultants will be documented in the minutes or in a report provided by the consultant
- Determinations of conflict of interest management plans, when relevant and that the IRB found it acceptable
- 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
- A list of exempt determinations and research approved under expedited review procedures, including limited IRB reviews conducted using expedited procedures, since the time of the last such report

5.4. Membership Rosters

A membership list of IRB members must be maintained and must identify members sufficiently to describe each member's chief anticipated contributions to IRB deliberations. The list must contain the following information about members (IRB Membership Roster)

- Name
- Earned degrees
- Affiliated or non-affiliated status (neither the member him/ herself nor an immediate family member of the member may be affiliated with the NYU Shanghai)
- Status as scientist or non-scientist
- Indications of experience, such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations
- Representative capacities of each IRB member, including naming the IRB member prisoner representative (as required by Subpart C), and naming the IRB members knowledgeable about or experienced in working with children, pregnant women, adults with impaired decision-making capacity, and other vulnerable populations commonly involved in NYU Shanghai research
- Role within the IRB (Chair, Vice-Chair, etc.)
- Alternate status
- Relationship (e.g., employment) between the individual IRB member and the organization

The Research Compliance Office must keep the IRB membership list current.

5.5. Documentation of Expedited Reviews

IRB records for initial and continuing review by the expedited review procedures must include: the reviewer's verification that the study qualifies for expedited review including the specific permissible category(ies) or status as exempt but requiring limited IRB review, documentation that the activity satisfies the criteria for approval, the period of approval (when applicable), and any determinations required by the regulations including protocol-specific findings supporting those determinations.

5.6. Access to IRB Records

The IRB has policies and procedures to protect the confidentiality of research information:

- IRB protocol files are secured in the IRB electronic system with administrative access controlled by the IRB office. Likewise, investigators control access to investigator records in the electronic system. All other IRB records (e.g., membership rosters) are kept secure in a limited access file on NYU Shanghai's servers, locked filing cabinets or locked storage rooms;
- Ordinarily, access to all IRB records is limited to the IO, IRB Chair/Vice Chair, IRB members, Research Compliance Manager, IRB Staff, authorized institutional officials, and officials of US Federal and Chinese regulatory agencies. Research investigators are provided reasonable access to files related to their research. Appropriate accreditation bodies are provided access and may recommend additional procedures for maintaining security of IRB records. All other access to IRB records is limited to those who have legitimate need for them, as determined by the IO and Research Compliance Manager;
- Records are accessible for inspection and copying by authorized representatives of US Federal and Chinese regulatory agencies during regular business hours;
- Records may not be removed from the Research Compliance Office; however, the Research Compliance Manager will provide copies of records for authorized personnel if requested in writing and approved by the Research Compliance Manager;

- All other access to IRB study files is prohibited.

5.7. Written Procedures and Guidelines

The NYU Shanghai Procedures for Human Subjects Research Protection detail the policies and regulations governing research with human subjects, and further set forth the requirements for submitting research protocols for review by the NYU Shanghai IRB.

The written procedures and guidelines are updated as needed. The Institutional Official will approve additions and substantive updates to the policies and procedures, and the Associate Provost for Research will approve revisions and non-substantive edits of the policies and procedures. The Research Compliance Manager will keep the NYU Shanghai research community apprised of any new information that may affect the human research protection program, including laws, regulations, policies, procedures, and emerging ethical and scientific issues. Such notification will be given via electronic mail, displayed on the IRB's website.

These procedures and guidelines apply to all research involving human subjects, regardless of sponsorship and performance site, conducted under the auspices of NYU Shanghai.

6. IRB Review Process

6.1. Human Subjects Research Determination

The responsibility for the initial determination as to whether an activity constitutes human subjects research rests with the PI. The PI should make this determination based on the definitions of "human subject" and "research" as provided by the Common Rule and using the Human Subjects Research Determination form.

The PI will be held responsible by NYU Shanghai to make the proper human subjects research determination. As such, the PI may request a confirmation that an activity does not constitute human subjects research from the Research Compliance Office. The request should be made via NYU Shanghai electronic submission system. All requests must include sufficient documentation of the research activity to support the determination.

For purposes of the Common Rule, the following activities are deemed not to be research: (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters). (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes. (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions. [45 CFR 46.102(l)]

6.2. Exempt Research

6.2.1. Categories of Research Permissible for Exemption

The categories of research permissible for Exemption are defined in 45 CFR 46.104(d)(1)-(6) and are described on the IRB Application for Exemption. NYU Shanghai has not adopted broad consent, and therefore research is not eligible for review under exempt categories 7 & 8.

The Exempt Reviewers are required to use the *Checklist for Exemption Determination* to make a determination.

6.2.2. How to Submit an Exemption Application

Any investigator submitting an IRB Application for Exemption Review must include with that application the following documentation:

- a summary of the research
- a description of the research procedures
- consent documents (if applicable)
- plan for privacy and confidentiality
- plan for dissemination of findings

- a copy of the proposal if the research is externally funded, and
- expected date of completion

The Application for Exemption must be signed and dated by the Principal Investigator.

The Research Compliance Manager (or designee) reviews all requests for exemptions, except for research for which limited IRB review is a condition of exemption under 45 CFR 46.104(d)(2)(iii) and (d)(3)(i)(C). The Research Compliance Manager determines whether the request meets the criteria for exempt research and may designate an IRB member to review requests submitted to the IRB.

When the research requires limited IRB review, the review may be conducted using expedited review procedures by either an IRB Chair themselves along with one or more IRB members designated by the Chair or two or more IRB members who have designated by the Chair. As with all other research subject to IRB review requirements, when conducting limited IRB review the IRB has the authority to approve, require modifications in (to secure approval), or disapprove all research activities; and to suspend or terminate IRB approval. Actions of disapproval may only be made by the convened IRB. [45 CFR 46.109(a), 45 CFR 46.110]

Proposed modifications to the aspects of research subject to limited IRB review must be submitted to and approved by the IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to the subject(s), in which case the change must be promptly reported to the IRB (i.e., within 5 business days). [45 CFR 46.108(a)(3)(iii)]

Continuing review is generally not required for research determined to be exempt, even when that research is subject to limited IRB review. However, the IRB may determine that continuing review is required for a particular study subject to limited IRB review, in which case it shall document the reasons for its determination in the IRB record and communicate the requirement to the investigator in the IRB determination letter. [45 CFR 46.109(f)(ii), 45 CFR 46.115(a)(3)]

To document the IRB reviewer's determination of exempt status, he/she completes the Exemption Determination Form. The reviewer indicates whether the request for exemption was approved or denied, and if approved, the rationale for the determination and category under which it was permitted.

When an exemption includes limited IRB review, the documentation will include this fact and the IRB action taken on those aspects of the research subject to limited IRB review in accordance with the procedures described for the review procedures used (expedited or convened board) elsewhere in this manual.

6.3. Expedited Review of Research

The IRB may use an expedited review procedure to review the following: (A) some or all of the research appearing on the list of categories of research eligible for expedited review described in 45 CFR 46.110(a) unless the reviewer determines that the research involves more than minimal risk; (B) minor changes in research previously approved by the convened IRB; and (C) Research for which limited IRB review is a condition of exemption under 45 CFR 46.104(d)(2)(iii) and (d)(3)(i)(C).

A minor change is one which, in the judgment of the IRB reviewer, makes no substantial alteration in (i) the level of risks to subjects; (ii) the research design or methodology (e.g., an addition of a procedure which would increase risk to subjects); (iii) the number of subjects enrolled in the research (e.g., increases representing greater than 10%); (iv) the qualifications of the research team; (v) the facilities available to support safe conduct of the research, or (vi) any other change in the research that would otherwise warrant review of the proposed changes by the convened IRB. Adding procedures that are not eligible for expedited review would not be considered a minor change.

Under an expedited review procedure, the review may be carried out by either an IRB Chair themselves along with one or more IRB members designated by the Chair or two or more IRB members who have designated by the Chair. Expedited review may also be carried out by the full IRB at a convened meeting, when appropriate. When expedited review is carried out by the full IRB, the IRB minutes should indicate that the review was done under expedited review and indicate the appropriate expedited review category.

When reviewing research under an expedited review procedure, the IRB Chair, or designees, should receive and review all documentation that would normally be submitted for a full-board review including the complete protocol, for ongoing research, a continuation review form summarizing the research to date (including modifications and adverse events), notes from the pre-screening conducted by the Research Compliance Manager, and the current consent documentation. The IRB Chair or designees shall determine the review criteria for use of such a review procedure by using the Reviewer Checklist.

The Principal Investigator will indicate on the *Application for New Protocol Review* the specific category under which the investigator believes the research is eligible for expedited review. The reviewer(s) shall evaluate the Principal Investigator's request and determine whether the expedited review process is appropriate. If the research appears to qualify for expedited review, the reviewer shall conduct the expedited review. If the research does not qualify for expedited review, the reviewer shall refer the application to the IRB for a full board review at its next convened meeting. (PI shall be informed by Research Compliance Manager that the protocol has been referred to the full IRB committee for review.)

The reviewer(s) conducting the initial or continuing review will complete the appropriate *Institutional Review Board Protocol Reviewer Checklist* in order to determine whether the research meets the expedited procedure criteria and, if so, whether the research meets the regulatory criteria for approval. When a reviewer determines that research subject to the Common Rule falls within the expedited categories but involves more than minimal risk, the reviewer will document the rationale for that determination in the checklist and refer the research for review by the convened IRB. If the research does not otherwise meet the criteria for expedited review, then the reviewer will indicate that the research requires a full board review by the IRB and the protocol will be placed on the next agenda for an IRB meeting.

In reviewing the research, the reviewers will follow the Review Procedures described in Section 6.5 and may exercise all of the authorities of the IRB except for disapproval of the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth below.

Reviewers will indicate approval, required modifications or disapproval on the Protocol Review/ Initial Review form and return it to the Research Compliance Manager. If modifications are required, the reviewer or Research Compliance Manager will inform the investigator via electronic mail. If the modifications are minor, the reviewer(s) may determine if the investigator has sufficiently addressed the modifications. Upon the discretion of the reviewer(s) and/ or the IRB Chair or IRB Vice Chair, the protocol may be submitted to the IRB for a full board review.

In the event that expedited review is carried out by more than one IRB member and the expedited reviewers disagree on the resolution of the application, the IRB Chair/Vice Chair may make a final determination.

6.3.1. How to Submit an Expedited Review

The Principal Investigator should indicate on the *Application for New Protocol Review* the specific category under which the investigator believes the research is eligible for expedited review.

Investigators must submit a completed IRB *Application for New Protocol Review* and include the following documentation:

- a summary of the research
- description of the research procedures
- consent documents (if applicable)
- plan for privacy and confidentiality
- plan for dissemination of findings
- a copy of the proposal if the research is externally funded
- a human subjects application protocol
- expected date of completion date, and
- any conflict of interest disclosure

The application must be signed and dated by the Principal Investigator.

6.3.2. Informing the IRB

All members of the IRB will be apprised of all expedited review approvals, including limited IRB reviews conducted using expedited review procedures, by means of the agenda for the next scheduled meeting. The expedited review approvals will be made available for review at the request of any IRB member.

6.4. Convened IRB Meetings

Except where an expedited review procedure is followed, the IRB will conduct initial and continuing reviews of all non-exempt research at convened meetings at which a quorum of the members is present. This may also include exempt research subject to limited IRB review.

6.4.1. IRB Meeting Schedule

The IRB meets on a regular basis throughout the year (usually once per month except one month in the summer where the quorum is difficult to obtain due to holidays). The schedule for the IRB may vary due to holidays or lack of quorum. The schedule for IRB meetings will be published on the IRB website. Special meetings may be called at any time by the Chair.

6.4.2. Quorum

A quorum consists of a simple majority of the voting membership, including at least one member whose primary concern is in a non-scientific area. The IRB Chair, with the assistance of the Research Compliance Manager, will confirm that an appropriate quorum is present before calling the meeting to order. The IRB Chair will be responsible in ensuring that the IRB meetings remain appropriately convened.

Votes may only occur when a quorum is present. Research Compliance Manager takes note of arrivals and departures of all members and notify the IRB Chair if a quorum is not present. If a quorum is not maintained, the proposal must be tabled or the meeting must be terminated. All members present at a convened meeting have full voting rights, except in the case of a conflict of interest.

In order for the research to be approved, it must receive the approval from more than half of all members of the IRB.

While it is preferred that IRB members be physically present at the meeting, if physical presence is not possible, a member may be considered present if participation occurs via teleconference or videoconference. In such cases, the member must have received all pertinent materials prior to the meeting and must be able to participate actively and equally in all discussions.

Opinions of absent members that are transmitted by mail, telephone, facsimile or email may be considered by the attending IRB members but may not be counted as votes or to satisfy the quorum for convened meetings.

6.4.3. Pre-Meeting Distribution of Documents

The location and time of each IRB meeting is set forth on the agenda cover sheet distributed to all IRB members.

The agenda, including all review assignments, all protocols and supporting documentation to be reviewed, are provided to IRB members electronically prior to each meeting.

6.4.4. Meeting Procedures

The IRB Chair, or Vice-Chair in the event that the IRB Chair is absent, will call the meeting to order, once it has been determined that a quorum is in place. The Chair or Vice-Chair will remind IRB members to recuse themselves from the discussion and vote by leaving the room where there is a conflict. The IRB will review and discuss the IRB Minutes from the prior meeting and determine if there are any revisions/corrections to be made. If there are no changes to be made, the Minutes will be accepted as presented and considered final. If it is determined that revisions/corrections are necessary, the Minutes will be amended and presented at the following IRB meeting. The IRB reviews all submissions for initial and continuing review, as well as requests for modifications. The Primary and Secondary Reviewer present an overview of the research and lead the IRB through the completion of the regulatory criteria for approval.

Guests

At the discretion of the IRB, the Principal Investigator may be invited to the IRB meeting to answer questions about his or her proposed or ongoing research. The Principal Investigator may designate another person to attend the meeting. The Principal Investigator may not be present for the discussion or vote on his or her research.

Other guests may be permitted to attend IRB meetings at the discretion of the IRB Chair. Guests may not speak unless requested by the IRB and must sign the IRB's *Confidentiality Agreement*.

6.4.5. Primary Reviewers

The Research Compliance Manager assigns a primary reviewer for all protocols requiring initial full board review, continuing full board review and for all protocols requiring full board review of modifications to previously approved research. When making reviewer assignments, Research Compliance Manager will assign a member or members of the IRB, and will take into consideration the vulnerable populations involved in the research and the scientific or scholarly expertise required to review the research. Such protocols will then be assigned to at least one IRB member who has the appropriate expertise. If the IRB cannot identify a primary reviewer with appropriate expertise, the IRB Chair will solicit consultants from the Institution or the community with competence in such specialized areas to assist in the review of the issues or protocols requiring appropriate scientific or scholarly expertise beyond or in addition to that available on the IRB.

Prior to the convened IRB meeting, each protocol application (including background information, scientific protocol and informed consent) is reviewed in depth by the assigned Primary reviewer(s). All other IRB members have access to these materials electronically. IRB Members are expected to have reviewed all provided materials in order to have a meaningful discussion of the presented information during the convened IRB meeting.

At the meeting, the Primary Reviewer presents an overview of the goals, design, study procedures, safety procedures, and qualifications of the investigators. The IRB reviews the protocol application using *Reviewer Checklists* appropriate for the type of review (e.g., initial, continuing, amendment).

Both primary reviewers and other IRB members who are not assigned as primary reviewers of proposed studies that require copies of protocols and/or any documentation have access to them via NYU Shanghai's currently established electronic system and/or can request them from the Research Compliance Manager. Further, upon request, copies of minutes and or physical protocol files can be obtained through the Research Compliance Manager.

6.5. Review Process

6.5.1. Research Compliance Office Pre-review

Applications are screened by the Research Compliance Manager for completeness and ensuring regulatory compliance prior to the placement of the application on the full board agenda by the Research Compliance Manager. The Research Compliance Manager will perform comprehensive pre-reviews of all new protocol full board submissions. Investigators will submit their applications to the Research Compliance Office via the currently established electronic system. The Research Compliance Manager will check for completeness of submissions and the Research Compliance Manager will further identify the pertinent issues for the IRB. The Research Compliance Manager will identify questions and deficiencies before the protocol is added to an agenda for full board review. Changes to the protocol made after the agenda packets have been delivered to IRB members will be forwarded to the full board prior to consideration of the protocol application at the convened meeting.

The Principal Investigator will be informed of missing materials and the necessary date of receipt for inclusion on that meeting's agenda. Specific questions about the IRB policies and procedures, determination of whether a particular protocol is human research or not and what particular forms are required for a particular study can be submitted to the Research Compliance Office for information and/or clarification. Individual appointments with the Research Compliance Office are strongly recommended for first-time submitters.

6.5.2. Materials Received by the IRB for the Initial Review of Research

Each IRB member will receive the following documentation, as applicable:

- complete protocol application form
- protocol summary
- proposed consent / parental permission / assent form(s)
- recruitment materials
- subject information
- data collection instruments (including all surveys and questionnaires)

If an IRB member requires additional information to complete the review, that member may contact the Research Compliance Manager to make the request of the Principal Investigator.

When a protocol is reviewed by the expedited procedure process, reviewers are provided with and expected to review all information that the convened IRB would have received. For expedited review protocols, any IRB member can request to review the full protocol by contacting the Research Compliance Manager.

6.5.3. IRB Member Conflicts of Interest

IRB members and consultants will not participate in any IRB action, including the initial and continuing review of any project, in which the member has a conflicting interest, except to provide information requested by the IRB. IRB members are expected to self-identify conflicting interests. A Primary Reviewer or expedited reviewer with a conflict of interest must notify the IRB Chair or Research Compliance Manager, who will re-assign the protocol to another IRB member.

Real or perceived conflicts of interest on the part of any individual associated with the use of human subjects in research, and the protection of the subjects, can seriously undermine the credibility of the process and must be avoided. The IRB strives to avoid conflicts of interest in performing its obligations. A conflict of interest may take many forms, but arises when members of the NYU Shanghai community are in a position to influence the University's business, research, or other decisions in ways that could lead directly or indirectly to financial gain for the member or his or her family, or give improper advantage to others. For example, an IRB member who is named as Co-Investigator on a protocol is considered to have a Conflict of Interest for purposes of consideration of that protocol.

6.5.4. Possible IRB Actions Taken by Vote

Approved

The research, proposed modification to previously approved research, or other item is approved. The IRB has made all of the determinations required for approval [i.e., approval criteria and any applicable special determinations (e.g., waivers, alterations, vulnerable population determinations, etc.)]. No further action is needed.

Conditionally Approved

The research, proposed modification to the previously approved research, or other item is approved, but conditions must be satisfied before the approval becomes effective.

The IRB may approve research with conditions if, given scope and nature of the conditions, the IRB is able, based on the assumption that the conditions are satisfied, to make all of the determinations required for approval [i.e., approval criteria and any applicable special determinations (e.g., waivers, alterations, vulnerable population determinations, etc.)]. Any time the IRB cannot make one or more of the determinations required for approval, the IRB may not approve the study with conditions.

When the convened IRB approves research with conditions, the IRB may designate the IRB Chair or another IRB member to review responsive materials from the investigator and determine that the conditions have been satisfied. If the conditions have not been satisfied, or are only partially satisfied, the responsive materials must be referred to the convened IRB for review.

The IRB may require the following as conditions of approval of research:

- Confirmation of specific assumptions or understanding on the part of the IRB regarding how the research will be conducted (e.g., confirmation that research excludes children)
- Submission of additional documentation (e.g., certificate of training)
- Precise language changes to the study, consent, or other study documents, or
- Substantive changes to the study, consent, or other study documents along with clearly stated parameters that the changes must satisfy

When the IRB approves research with conditions, the conditions will be documented in the IRB minutes for research reviewed at a convened meeting.

After verification, the following will be documented in IRB records and written communication to the investigator:

- The date when the IRB determined that the criteria for approval were satisfied (i.e., the "approval date")
- The date when verification was made that all IRB conditions have been satisfied (i.e., the “effective date”)
- For initial approval and continuing reviews, the date by which continuing review must occur (i.e., the “expiration date”), and
- The expiration date is determined to be the anniversary of the convened IRB review of the study, excluding any amendments made during the approval period

The IRB will be informed of the outcome of the review of the investigator’s response in the agenda of the next meeting.

Deferred for Substantive Issues

Substantive issues regarding the protocol and /or consent form must be addressed. This action is taken if substantial modification or clarification is required, or insufficient information is provided to judge the protocol application adequately (e.g., the risks and benefits cannot be assessed with the information provided). IRB approval of the proposed research may not occur outside of a convened meeting of the IRB. If the application is deferred the following will occur:

- the IRB informs the investigator in writing of the IRB's decision, setting forth the IRB’s questions and concerns;
- the investigator's response is sent to the IRB;
- in order to receive approval for a deferred protocol, the protocol must be submitted for full board review at a subsequent, convened meeting of the IRB. The Research Compliance Manager will provide to the IRB members the investigator’s response, the revised protocol and/or consent with highlighted changes, all original submission materials (inclusive of changes, if any were required), and the previous IRB written decision (relayed to the Principal Investigator by the Research Compliance Manager) signed by the Principal Investigator. The amended protocol is then placed on the agenda for the following meeting;
- the amended protocol application is given a full board review;
- the outcome of the IRB's deliberations is once again communicated to the Principal Investigator in writing; and
- the IRB's determination concerning the subsequent amended submission will be documented in the minutes of that meeting.

Disapproved

Questions and issues are of such a magnitude that the IRB determines approval of the study is unwarranted. Approval of a previously disapproved protocol requires a full board review (see Section 6.11. Appeal of IRB Decisions).

Approval in Principle [45 CFR 46.118]

There are two circumstances in which the IRB may grant approval required by a sponsoring agency without having reviewed all of the study procedures and consent documents:

- if study procedures are to be developed during the course of the research, but human subjects approval is required by the sponsoring agency;

- if the involvement of human subjects depends on the outcomes of work with animal subjects.

The IRB may then grant Approval in Principle without having reviewed the, as yet undeveloped, recruitment, consent, and intervention materials. Approval in Principle is granted to satisfy sponsoring agency requirements or to allow sponsor consideration of a proposal or to allow investigators to have access to funding to begin aspects of the project that do not involve human subjects. The PI must attain full approval before commencing human subjects research.

6.5.5. Independent Verification Regarding Material Changes

Protecting the rights and welfare of subjects may require the IRB to independently verify information about various aspects of the study utilizing sources other than the investigator. Independent verification includes, but is not limited to:

- adverse event reporting
- information in the scientific literature
- confirmation that no material changes occurred since the previous IRB review

The IRB may determine the need for verification from outside sources on a case-by-case basis based upon the following criteria:

- protocols where concern about possible material changes occurring without IRB approval have been raised based on information provided in continuing review reports or annual status reports or from other sources
- protocols conducted by Principal Investigators who have previously failed to comply with federal regulations and/or the requirements or determinations of the IRB
- protocols randomly selected for internal audit, and
- whenever else the IRB deems verification from outside sources is relevant

The following factors may also be considered when determining whether or not a study requires independent verification:

- the probability and magnitude of anticipated risks to subjects, and
- the probable nature and frequency of changes that may ordinarily be expected in the type of research proposed

In making independent verification determinations, the IRB may prospectively require that such verification take place at predetermined intervals during the approval period, may retrospectively require such verification at the time of continuing review, review of amendments and/or unanticipated problems, or may require such verification at any time during the approval period in the light of new information.

If any material changes have occurred without IRB review and approval, the IRB will decide the corrective action to be taken.

6.5.6. Reporting IRB Actions

All IRB actions are communicated directly, in writing, from the Research Compliance Office to the Principal Investigator in a timely way. When approving a protocol, the IRB will forward written notification of approval. The approval notice will contain date(s) of IRB approval and the IRB expiration date (when applicable). When no continuing review is required for Common Rule research, the approval notice will indicate the date an Annual Status Update is due in place of an expiration date. When deferring a protocol, the IRB notification will include the modifications required for approval along with the reasoning for requiring such modifications. When disapproving, terminating or suspending a protocol, the IRB notification will include the reasoning behind such decision.

6.6. Continuing Review of Active Protocols

For research subject to the revised Common Rule (2018 requirements), the IRB will conduct continuing review of ongoing research requiring review by the convened IRB at intervals that are appropriate to the level of risk of the research, but not less than once per year, except as described below. The date by which continuing review must occur will be recorded in the IRB electronic system and on initial and continuing review approval letters.

Unless the IRB determines otherwise, continuing review of research subject to the revised Common Rule (2018 requirements) is not required in the following circumstances:

- Research eligible for expedited review in accordance with 45 CFR 46.110
- Research reviewed by the IRB in accordance with the limited IRB review described in Section 6.2.2, and
- Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
    - Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
    - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care

The IRB may determine that continuing review is required for any research protocol that falls within the above criteria. For example, the IRB may determine that continuing review is required when any of the following apply:

- Required by other applicable regulations;
- Required by the terms of a grant, contract, or other agreement;
- The research involves topics, procedures, or data that may be considered sensitive or controversial;
- The research involves particularly vulnerable subjects or circumstances that increase subjects' vulnerability;
- An investigator has minimal experience in research or the research type, topic, or procedures; and/or
- An investigator has a history of non-compliance.

When the IRB determines that continuing review is required for such research, it will document the rationale in the IRB record and communicate the requirement to the investigator in the IRB determination letter.

Research studies that are determined to not require continuing review are still subject to prompt reporting requirements (e.g., proposed amendments, personnel changes, unanticipated problems involving risk to subjects or others, and protocol deviation/violations/non-compliance). They are also subject to the requirement of an annual status report that will collect information regarding status of the research activities. Investigators will receive courtesy reminder email notices for completion of the status report. Research Compliance Manager will review the report for compliance with institutional policies (verification of human subjects training, etc.). Failure to submit an annual status report as required will constitute non-compliance with NYU Shanghai's IRB SOPs and may result in suspension of the study until compliance with this policy is confirmed.

6.6.1. Continuing Review/Approval Period

At NYU Shanghai, determination of the approval period and the need for additional supervision and/ or participation is made by the IRB on a case-by-case basis. 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 a subcommittee of the IRB 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 subjects.

For each initial or continuing protocol approval, the IRB will indicate an approval period with an approval expiration date specified. Not all ongoing research will have an IRB expiration date (i.e., where no continuing review is required for Common Rule research). For research subject to the Common Rule, the IRB will conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk of the research, but not less than once per year, except as described in Section 6.6. IRB approval is considered to have lapsed at midnight on the expiration date of the approval. For a study approved by the convened IRB, the approval period starts on the date that the IRB conducts its final review of the study; that is, the date that the convened IRB approved the research or the date the convened IRB granted conditional approval noting minor non-substantive issues. For a study approved under expedited review, the approval period begins on the date the IRB Chair or IRB member(s) designated by the Chair gives final approval to the protocol.

The approval date(s) and approval expiration date are clearly noted on all IRB notifications sent to the Principal Investigator and must be strictly adhered to. Investigators should allow sufficient time for development and review of renewal submissions.

Review of a change in a protocol ordinarily does not alter the date by which continuing review must occur. This is because continuing review is review of the full protocol, not simply a change to it.

No grace periods extending the conduct of research beyond the expiration date of IRB approval will be permitted. Therefore, continuing review and re-approval of research must occur by midnight of the date when IRB approval expires.

It is the investigator's responsibility to ensure that the continuing review of ongoing research is approved prior to the expiration date. By federal regulation, no extension to that date can be granted.

6.6.2. Continuing Review Process

In order to avoid interruption of the research, investigators must submit a Request for Continuing Review far enough in advance that it can be reviewed by the IRB prior to the review expiration date.

In conducting continuing review of research ineligible for expedited review, all IRB members are provided with and review all of the above-referenced material. The Primary Reviewer and IRB Chair will also receive a copy of the most recent protocol version. At the convened IRB Board meeting, the Primary Reviewer will lead the IRB through the completion of the regulatory criteria for approval in the *Reviewer Checklists*.

In the case of expedited review, the IRB members may request the Research Compliance Manager to provide them with any additional materials required for the review.

Review of currently approved or newly proposed consent documents may occur during the scheduled continuing review of research by the IRB, but informed consent documents should be reviewed whenever new information becomes available that would require modification of information in the informed consent document.

A new protocol version that has not been previously approved by the IRB will not be accepted at the time of continuing review unless the protocol is also submitted through a *Request for Amendment* form with all accompanying materials for amendments.

Generally, if research did not qualify for expedited review at the time of initial review, it does not qualify for expedited review at the time of continuing review, unless it has progressed to the point that it involves only one or both of the following:

- data analysis, including analysis of identifiable private information or identifiable biospecimens, or
- accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care;

and in limited circumstances described by expedited review categories (8) and (9). It is also possible that research activities that previously qualified for expedited review, have changed or will change, such that expedited continuing review would no longer be permitted.

6.6.3. Lapse in Continuing Reviews

The IRB and investigators must plan ahead in order to meet required continuing review dates. If the IRB has not reviewed and approved a research study by the end of the approval period specified by the IRB, all research activities involving human subjects must cease, including recruitment and enrollment of subjects, consent, interventions, interactions, and data collection, unless the IRB concludes that it is in the best interests of individual subjects to continue participation in the research interventions or interactions. This interruption will occur even if the investigator has provided the continuing information before the expiration date. Therefore, investigators must allow sufficient time for IRB review before the expiration date.

Once suspended, IRB review and re-approval must occur prior to re-initiation of the research.

6.7. Modification of an Approved Protocol

Principal Investigators may wish to modify or amend their approved applications. **Investigators must seek IRB approval before making any changes, no matter how minor, in approved research** unless the change is necessary to eliminate an apparent immediate hazard to the subject (in which case the IRB must then be notified at once).

Modifications may be approved by the IRB if they are within the scope of what the IRB originally authorized. For example, if a researcher wishes to add a population to an existing study, but not alter the study procedures or purpose, a modification request is usually appropriate. Likewise, modifying a procedure without changing the study's purpose or study population may also be appropriate. Investigators must submit documentation to inform the IRB about the changes in the status of the study, including, but not necessarily limited to:

- completed Request for Amendment form
- revised approved consent/parental permission/assent documents (if applicable) or other documentation that would be provided to subjects when such information might relate to their willingness to continue to participate in the study
- revised recruitment materials
- any other relevant documents provided by the investigator

All changes must be accompanied by a detailed summary of the changes and a rationale (if applicable).

The IRB Chair (or designee) will determine whether the proposed changes may be approved through an expedited review process, if the changes are minor, or whether the modification warrants full board review. The reviewer(s) using the expedited procedures may determine whether the proposed changes may be approved through the expedited review and, if not, must refer the protocol for full board review.

6.7.1. Expedited Review of Protocol Modifications

An IRB may use expedited review procedures to review minor changes in ongoing previously-approved research during the period for which approval is authorized. An expedited review may be carried out by the IRB Chair and/or designee(s) among the IRB. Minor changes/modifications would not include the addition of procedures involving more than minimal risk to participants or changes that do not fall in categories (1) - (7) of research that could be reviewed using the expedited procedure. (*see: Categories of Research Eligible for Expedited Review*)

The reviewer(s) complete the *Checklist for Amendment Review Determination* to determine whether the modifications meet the criteria allowing review using the expedited procedure, and if so, whether the research with the proposed modifications meets the regulatory criteria for approval.

6.7.2. Full Board Review of Protocol Modifications

When a proposed change in a research study is not minor (e.g., procedures involving increased risk or discomfort are to be added), then the IRB must review and approve the proposed change at a convened meeting before the change can be implemented. The only exception is a change necessary to eliminate apparent immediate hazards to the research subjects. In such a case, the IRB should be promptly informed of the change following its implementation and should review the change to determine that it is consistent with ensuring the subjects' continued welfare.

Major changes/modifications would include the addition of procedures involving more than minimal risk to participants or changes that do not fall in categories (1) - (7) of research that could be reviewed using the expedited procedure. (*see: Categories of Research Eligible for Expedited Review*)

All IRB members are provided and review all documents provided by the investigator.

At the meeting, the Primary Reviewer presents an overview of the modifications and leads the IRB through the completion of the regulatory criteria for approval.

When the IRB reviews modifications to previously approved research, the IRB considers whether information about those modifications might relate to participants' willingness to continue to take part in the research and if so, whether to provide that information to participants.

6.7.3. Closure of Protocols

The completion or termination of the study is a change in activity and must be reported to the IRB. Although subjects will no longer be "at risk" under the study, a notice of study closure allows the IRB to close its files.

Investigators may submit closure applications to the IRB as a study closure of a protocol (Request for Study Closure). Investigators may submit study closures to the IRB on a Continuing Review application or Annual Status Report.

In cases where studies have expired, Research Compliance Office will send out notice of study expiration to investigators. Investigators must submit a Request for Continuing Review Form to reactivate the study within 30 calendar days. If a response is not received within 30 calendar days, the study will be administratively closed.

Research Compliance Manager should administratively acknowledge study closure and notify the Full Board at the next meeting by listing as a notice of study closure on the agenda. In cases where problems/concerns are identified and cannot be resolved by clarification from the study team, the Request for Study Closure form will be forwarded to the IRB Chair.

6.8. Umbrella Protocol

On a case-by-case basis, the NYU Shanghai IRB may accept an IRB application that will cover multiple projects which have a common overarching theme of exploration, aims, design, study procedures, data sources, and set of investigators and for which details of the study procedures will only change minimally, if at all.

6.8.1. Definitions

Umbrella Protocol

An umbrella protocol is an administrative term to describe a protocol in which a single investigator submits an IRB application that will cover multiple projects which have a common hypothesis, set of investigators, or data set and for which details of the study procedures will only change minimally, if at all. Unlike the more usual procedure of requiring separate IRB review and approval for each study, the IRB approves the procedures to be used in all studies under the umbrella protocol and individual studies under the umbrella protocol do not need to be submitted to the IRB. Such an approval is designed to minimize the burden on both the investigators and the IRB.

Umbrella Protocol Principal Investigator

The investigator who is ultimately responsible for oversight of the umbrella protocol and any project that falls under the umbrella protocol.

Project

Specific research studies that are conducted in accordance with parameters outlined in the umbrella protocol.

6.8.2. Criteria for Umbrella Protocols

- The research must involve no more than minimal risk;
- Research procedures must be limited to activities that qualify as exempt or for expedited IRB review under categories (1) – (7). (see: *Categories of Research Eligible for Expedited Review*);
- The subject population may not include individuals vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. Pregnant women, fetuses, or neonates may not be included;
- Research that does not fall within the Common Elements of the umbrella protocol requires submission of a separate new study application to the IRB; and
- An umbrella protocol is not to be considered a protocol which covers an entire school/department.

6.8.3. Additional Requirements for Umbrella Protocols

The IRB application must include and address each of the following:

- **Identifying Statement**: Indicate the proposal is for an umbrella protocol;
- **Common Elements**: Describe the overarching theme of exploration, aims, design, study procedures, data sources, and set of investigators which will apply to all projects conducted under the umbrella protocol;
- **Proposed Sub-Analyses**: List and describe the proposed sub-analyses that will occur under the umbrella protocol;
- **Consent Document**: Provide an informed consent document that accurately reflects the study;

- **Notifying the IRB of Changes**: Any proposed change to the IRB-approved application/documents will require IRB approval. Minor changes within the scope of the umbrella may be eligible for IRB review as an amendment. Major changes or changes that are outside of the scope of the umbrella may require submission of a brand-new protocol. Clearly outline the process that project investigators will follow for recommending new projects or other changes to the Umbrella Principal Investigator and for seeking IRB approval of any proposed changes prior to implementation;
- **Project Certification Process**: Describe the certification process that the Umbrella Principal Investigator will follow when determining if a project is eligible to be conducted under the umbrella. The Umbrella Protocol Principal Investigator must find that the project is consistent with the Common Elements and the IRB-approved Consent Document. Project certification documentation requirements are described in the section below.

6.8.4. Documentation of Project Certification

The NYU Shanghai IRB project certification form must be used when documenting whether a proposed project is consistent with the approved umbrella protocol or not. Certification forms must be kept in the Umbrella Protocol Principal Investigator's files and do not need to be submitted to the Research Compliance Office at the time of certification unless a confirmation or consultation is necessary.

6.8.5. Additional Documentation Required at the Time of Continuing Review or Annual Status Report

The Umbrella Protocol Principal Investigator must provide project certification forms to the IRB at the time of continuing review (when IRB continuing review is required) or submission of an annual status report, along with a summary of individual project activity since the last review (please see the NYU Shanghai IRB umbrella protocol project summary form). When considering approval of an umbrella protocol, the IRB may determine that continuing review is required more often than annually. The approval period will be communicated in the determination letter.

6.8.6. Routine Quality Assurance Assessment of Umbrella Protocols

This type of submission requires a great deal of oversight. As a service to investigators, the Research Compliance Office may conduct routine assessments to provide feedback regarding the conduct of the study in accordance with these requirements.

6.8.7. Amendments

The Umbrella Protocol Principal Investigator must submit an amendment for any proposed change to the IRB-approved application/documents. Examples include changes in or adding new research activities, subject populations, investigators, funding sources, etc.

6.8.8. Unanticipated Problems Involving Risks and Instances of Non-compliance

The Umbrella Protocol Principal Investigator must submit any/all reportable unanticipated problems or instances of non-compliance related to any individual projects under the umbrella protocol, according to the standard IRB reporting policies.

6.9. 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.

Events which harm subjects are referred to as "Adverse Events." Although adverse events occur most commonly in the context of biomedical research, adverse events can occur in the context of social and behavioral research. Only unanticipated adverse events that are related to the research need to be reported. For instance, if a research subject were to die due to causes that are clearly unrelated to the study, it is not necessary to report the death as an adverse event.

6.9.1. Definitions

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

Any event, any incident, experience, outcome, or new information that (1) was unforeseen and (2) indicates that the research procedures caused harm to participants or others or indicates that participants or others are at increased 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 research subjects or participants during the course of research. An adverse event can be any unfavorable or unintended event.

Unanticipated

An event is "unanticipated" when its specificity and severity are not accurately reflected in the informed consent document, protocol and/or Investigator's Brochure.

The incident, experience or outcome is not expected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent documents; and the characteristics of the subject population being studied;

Related to the Research

An event is "related to the research procedures" if in the opinion of the Principal Investigator, it was more likely than not related to the research procedures, or if it is more likely that not that the event affects the rights and welfare of current participants, or if it is unclear whether or not the event may have been related to the research procedures.

6.9.2. Reporting

Principal investigators must report to the IRB as soon as possible any:

- adverse events which in the opinion of the principal investigator are both unexpected and related

- an unanticipated event related to the research that exposes 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
- incarceration of a participant in a protocol not approved to enroll prisoners
- 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 unintentional 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, and
- sponsor imposed suspension for risk

6.9.3. IRB Review

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

The Research Compliance Manager submits the *Unanticipated Event Report* and all supporting documents provided by the investigator to the Chair for review.

Based on the information received from the Principal Investigator and upon the advice of the Research Compliance Manager 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 results of the IRB review are recorded in the IRB minutes, protocol record, communicated to the investigator and referred to the Research Compliance Manager to be handled according to the reporting procedures.

6.10. Further Review/Approval of IRB Actions by Others within the Institution

Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution; however, those officials may not approve research if it has been not been approved by the IRB. [45 CFR 46.112]

6.11. Appeal of IRB Decisions

NYU Shanghai will consider appeal(s) of IRB decisions. The Principal Investigator may appeal an IRB decision in writing. All appeals must be addressed to the IRB Chair (or Vice Chair when appropriate) and should be accompanied by a letter detailing the reason for the appeal. The Principal Investigator should be prepared to attend the meeting of the IRB to address issues raised by the Board. The IRB makes the final determination in all appeals.

6.12. Exemptions in Emergency Situations

In the event of an emergency or disaster (e.g., public health or weather-related), the procedures in these IRB policies and procedures may be modified as appropriate for the situation. Such modifications may include alternative meeting procedures, alternative procedures for the submission and review of modifications, alternative procedures for prompt reporting, and any other changes necessary to ensure appropriate ongoing oversight and conduct of research. Because procedural modifications may vary based on the nature of the event, these cannot be anticipated and described in these IRB policies and procedures. Instead, such procedural modifications will be recorded in an addendum to the IRB policies and procedures, note-to-file, or other appropriate means of documentation and communicated to the research community. This documentation will be maintained in accordance with applicable record retention requirements.

7. Criteria for IRB Approval of Research

In order to approve human subjects research, the IRB must determine that the following requirements are satisfied:

- risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk;
- risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility;
- selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons;
- informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by [45 CFR §46.116];
- informed consent will be appropriately documented, in accordance with, and to the extent required by [45 CFR §46.117];
- when appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;
- when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data;
- when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

7.1. Scientific Merit

In order to assess the risks and benefits of the proposed research, the IRB must determine that the science is adequate to provide sufficient benefit to justify the risks, including:

- research uses procedures consistent with sound research design;
- research design is sound enough to reasonably expect the research to answer its proposed question; and
- knowledge expected to result from this research is sufficiently important to justify the risk.

7.2. Selection of Subjects is Equitable

The IRB will review the inclusion/exclusion criteria for the research to ensure equitable selection of subjects. In making this assessment the IRB takes into account the purposes of the research and the setting in which the research will be conducted, and is particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, individuals with impaired decision-making capacity, or persons who are economically or educationally disadvantaged.

7.2.1. Recruitment of Subjects

The investigator will provide the IRB with all recruiting materials to be used in identifying participants.

The IRB must approve all advertisements prior to posting and/or distribution.

This information should be submitted to the IRB with the initial application or as an addendum to the protocol.

Once approved by the IRB, an advertisement cannot be altered or manipulated in any way without prior IRB approval.

7.3. Privacy and Confidentiality

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

7.3.1. Definitions

Privacy

Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

Confidentiality

Methods used to ensure that information obtained by researchers about their subjects is not improperly divulged.

Private Information

Information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Identifiable Private Information

Identifiable private information means private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. [45 CFR 46.102(e)(5)].

Identifiable Biospecimen

Identifiable biospecimen means a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen [45 CFR 46.102(e)(6)]

7.3.2. Privacy

The IRB must determine whether the activities in the research constitute a violation of privacy. The IRB must be provided with information regarding how the investigators obtain access to subjects or subjects' information and the subjects' expectations of privacy in the situation. Investigators must have appropriate authorization to access the subjects or the subjects' information.

7.3.3. Confidentiality

Confidentiality and anonymity are not the same. If anyone, including the investigator, can readily ascertain the identity of the subjects from the data, then the data are not anonymous and the IRB must determine if appropriate protections are in place to minimize the likelihood that the information will be inappropriately divulged. The level of confidentiality protections should be commensurate with the potential of harm from inappropriate disclosure.

The IRB will review all information received from the Principal Investigator and determine whether or not the privacy and confidentiality of research subjects is sufficiently protected.

In reviewing confidentiality protections, the IRB shall consider the nature, probability, and magnitude of harms that would be likely to result from a 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.

7.4. Vulnerable Populations

At the time of initial review, modification (when an investigator proposes to add inclusion of a vulnerable population after research has already been approved by the IRB) and continuing review, the IRB will consider the scientific and ethical reasons for including vulnerable subjects in research. The IRB must determine if appropriate additional safeguards are in place to protect the rights and welfare of subjects if they are likely to be members of a vulnerable population (e.g., persons with diminished autonomy).

7.5. Informed Consent Process

No investigator may involve a human being as a subject in research without obtaining the legally effective informed consent of the subject or the subject's legally authorized representative except as provided in Section 7.7.

The requirement to obtain the legally effective informed consent of individuals before involving them in research is one of the central protections provided by the IRB. When informed consent is required, it must be sought prospectively, and properly documented.

The informed consent process involves three key features:

- disclosing to the prospective human subject sufficient information needed to make an informed decision
- facilitating the understanding of what has been disclosed, and
- promoting the voluntariness of the decision about whether or not to participate in the research

The IRB will consider where the consent process will take place and the individual who will be obtaining consent (e.g. the investigator, collaborator, or qualified designee) in its determination regarding the appropriateness of the consent process. When the potential participant's understanding of the research may be impaired due to the timing, location, or individuals participating in the proposed consent process, the IRB will require an alternative process.

The information that is given to the subject or the representative must be in language understandable to the subject or the representative.

No informed consent, whether oral or written, may include exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights.

If someone other than the investigator conducts the interview and obtains consent, the Principal Investigator needs to formally delegate this responsibility and the person so delegated must have received appropriate training to perform this activity.

7.6. Requirements of Informed Consent

General Requirements

Except as provided elsewhere in these Standard Operating Procedures:

- Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative (LAR);
- An investigator shall seek informed consent only under circumstances that provide the prospective subject or the LAR sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence;
- The information that is given to the subject or the LAR shall be in language understandable to the subject or the LAR;
- The prospective subject or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information;
- Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension;
- Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate;
- No informed consent may include any exculpatory language through which the subject or the LAR is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

These informed consent requirements are not intended to preempt any applicable federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that have additional requirements for informed consent to be legally effective.

Additional Requirements

Informed consent must be obtained under the following circumstances:

1. Informed consent may only be obtained from subjects who have the legal and mental capacity to give consent. For subjects without that capacity, permission must be obtained from a legal guardian with appropriate authority to make decisions regarding the activities called for in the research or a legally authorized representative (LAR);
2. The informed consent information must be presented in language that is understandable to the subject (or LAR/guardian). To the extent possible, layman's terms shall be used in the description of the research. The IRB may require or allow different readability standards based upon the characteristics of the target subject population;
3. For subjects with *Limited English/Chinese Proficiency,* informed consent must be obtained in a language that is understandable to the subject (or LAR/guardian). In accordance with this policy, the NYU Shanghai IRB requires that informed consent discussions include a reliable interpreter when the prospective subject does not understand the language of the person who is obtaining consent, and, in most circumstances, that consent materials are translated;
4. The investigator is responsible for ensuring that each prospective subject is adequately informed about all aspects of the research and understands the information provided.

Basic Elements of Informed Consent

To be valid, the consent process must provide the following basic elements of information described at 45 CFR 46.116(b).

Additional Elements of Informed Consent

Additional elements of informed consent to be applied, as appropriate, are described at 45 CFR 46.116(c).

Broad Consent
NYU Shanghai is not adopting the Broad Consent option described in the Common Rule. Therefore, Broad Consent regulatory requirement described at 45 CFR 46 111(a)(8), 116(a)-(b), and 116(d) do not apply.

7.7. Waiver of Informed Consent

General Waiver or Alteration:

An IRB may waive the requirement to obtain informed consent, provided the IRB finds and documents that the below criteria are satisfied.

Likewise, an IRB may approve a consent procedure that omits some, or alters some or all, of the basic and additional elements of informed consent set forth at 45 CFR 46.116(b) and (c) (an "alteration"), provided that the IRB finds and documents that the below criteria are satisfied. An IRB **may not** omit or alter any of the general requirements for informed consent (See Section 7.6).

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

Public Benefit or Service Programs Waiver or Alterations:

An IRB may waive the requirement to obtain informed consent, provided the IRB finds and documents that the below criteria are satisfied.

Likewise, an IRB may approve a consent procedure that omits some, or alters some or all, of the basic and additional elements of informed consent set forth at 45 CFR 46.116(b) and (c) (an "alteration"), provided that the IRB finds and documents that the below criteria are satisfied. An IRB **may not** omit or alter any of the general requirements for informed consent (See Section 7.6).

1. 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; and
2. The research could not practicably be carried out without the waiver or alteration.

This option **does not** apply to FDA-regulated research.

7.7.1. Screening, Recruiting, or Determining Eligibility

An 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 subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

- The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative; or
- The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

7.8. Documentation of Informed Consent (Signed Consent)

Informed consent must be appropriately documented, in accordance with, and to the extent required by [45 CFR 46.117] and local regulations.

- Informed consent is documented by the use of a written consent form approved by the IRB and signed and dated (including in an electronic format) by the subject or the subject's legally authorized representative at the time of consent;
- A written copy of the signed consent form must be given to the person signing the form;
- The consent form may be either of the following:
    - A written consent document that embodies the basic and required additional elements of informed consent. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative; or
    - a short form written consent document stating that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative and that the key information required by Section 7.6 #5 was presented first to the subject, before other information, if any, was provided. When this method is used:
        i. there must be a witness to the oral presentation or video record; and
        ii. the IRB must approve a written summary of what is to be signed by the subject or representative; and
        iii. the witness must sign both the short form and a copy of the summary; and
        iv. for subjects who do not speak English, the witness must be conversant in both English and the language of the subject.
        v. the person actually obtaining consent must sign a copy of the summary; and
        vi. a copy of the summary must be given to the subject or representative, in addition to a copy of the short form.

7.9. Waiver of Documentation of Informed Consent (Waiver of Signed Consent)

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds any of the following:

- The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality (e.g., domestic violence research where the primary risk is discovery by the abuser). Each subject (or legally authorized representative) will be asked whether they want documentation linking them with the research, and their wishes must govern. (This option does not apply to FDA-regulated research);

- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Procedures such as non-sensitive surveys, questionnaires and interviews generally do not require written consent when conducted by non-researchers;
- If the subjects or legally authorized representative 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. (This option does not apply to FDA-regulated research).

Unless the IRB has granted a full waiver of the requirement to obtain informed consent, investigators who seek and receive approval for a waiver of documentation of consent still must perform an appropriate consent process.

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

7.10. Surrogate Consent

This policy is designed to protect human subjects from exploitation and harm and, at the same time, make it possible to conduct essential research on problems that are unique to persons who are incompetent, or who have an impaired decision-making capacity.

Unless waived by the IRB, informed consent must be obtained directly from the individual subject. Under appropriate conditions, investigators instead may obtain informed consent from a legally authorized representative of a subject.

> Legally Authorized Representative: 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 [45 CFR 46.102(i)].
>
> 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 nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

Obtaining consent from a representative of an adult subject rather than directly from the subject (i.e., surrogate consent) by any NYU Shanghai investigator requires the prior approval of the IRB. The IRB will allow use of surrogate consent in accordance with NYU Shanghai policy only for subjects who lack the capacity to provide their own consent. Capacity is determined by a physician, often a psychiatrist and not the judiciary. Capacity refers to an assessment of the individual's abilities to understand, appreciate, and manipulate information and form rational decisions. An Investigator is responsible, however, to ensure that the subject both understands the procedures and his/her rights as a research subject.

If a subject previously determined to lack capacity to consent regains capacity during the study, the investigator must obtain the consent of the individual for the remaining part of the study. The consent process must disclose all research procedures performed to date and allow the individual an opportunity to continue in or withdraw from the study. The subject must sign the IRB-approved consent document and the research record should document what research procedures were already performed or remain to be performed.

The IRB must approve any use of surrogate consent prospectively during review of the protocol or modification of the protocol. The submission to the IRB must include details of how the investigator will verify the authority of the individual to serve as the legally authorized representative designated to provide surrogate consent.

If feasible, the investigator must explain the proposed research to the prospective research subject even when the surrogate gives consent. Under no circumstances may a subject be forced or coerced to participate in a research study.

7.11. Consent and Language Barriers

Researchers should prepare both English (Chinese) language and translated consent forms for proposals that include non-English-speaking (non-Chinese-speaking) subjects. The IRB may consult with language experts or require a "back-translation" into English (Chinese). When non-English speaking (non-Chinese-speaking) subjects enroll, they sign the translated document. The subjects are given a copy of the signed translated consent document.

If a non-English-speaking (non-Chinese-speaking) subject is enrolled unexpectedly, researchers may rely on an oral translation of the English (Chinese) language consent form, but should take extra care in the informed consent process to ensure that the subject has understood the project. A statement in the research records [and on the English (Chinese) language consent form] should indicate that the translation took place, identify the translator, and document the translator's belief that the subject understands the study and the consent process. Researchers should try to provide a written translation of the vital emergency contact information.

If the subject does not clearly understand the information presented at the signing of the consent document or in subsequent discussions, his/her consent may not be informed, and therefore, not effective.

If a Principal Investigator decides to enroll a subject into a protocol for which there is not an existing IRB-approved informed consent document in the prospective subject's language, the Principal Investigator must receive IRB approval to follow the procedures for a “short form” written consent [see*: Documentation of Informed Consent (Signed Consent)].*

7.11.1. Use of Interpreters in the Consent Process

Unless the person obtaining consent is fluent in the prospective subject’s language, an interpreter will be necessary to deliver information in the IRB-approved script and to facilitate the consent conversation. Preferably someone who is independent of the subject (i.e., not a family member) should assist in presenting information and obtaining consent. Whenever possible, interpreters should be provided copies of the short form and the IRB-approved consent script well before (24 to 48 hours if possible) the consent conversation with the subject. If the interpreter also serves as the witness, she/he may sign the short form consent document and script as the witness and should note “Interpreter” under the signature line. The person obtaining consent must document that the “short form” process was used in the progress notes of the subject's medical record, including the name of the interpreter.

7.11.2. Braille Consent

For blind subjects who read Braille, the IRB may approve a consent document prepared in Braille. In order to assure itself that a Braille consent document is accurate, the IRB may require a transcription into print text or review of the document by an IRB member or other person who reads Braille. If possible, the subject will sign the Braille consent; otherwise verbal consent will be obtained, witnessed and documented as described below.

7.11.3. Oral Consent

When subjects are unable to read a written consent form (such as blind or illiterate subjects), the IRB may approve an oral consent process, provided the subject (1) retains the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study when it is explained verbally and (2) is able to indicate approval or disapproval to study entry.

For research that is no more than minimal risk, documentation of consent may be waived according to the criteria in *Waiver of Documentation of Informed Consent (Waiver of Signed Consent)*.

For more than minimal risk research, the consent form must be read to the subjects and the subjects must be given an opportunity to ask questions. An audiotape approved by the IRB may be used. If capable of doing so, the subject signs, or marks an X to signify consent. If that is not possible, the subject will provide verbal consent. The person obtaining consent and a witness will sign the written study consent form with a statement that documents that an oral process was used and, if necessary, that the subject gave verbal consent. Signed copies of the consent form are given to the subject and, whenever possible, these documents should be provided to the subject on audio or video tape.

7.12. Continuing Review on More than an Annual Basis

Unless specifically waived by the IRB, research that meets any of the following criteria may require review more often than annually:

- Significant risk to research subjects (e.g., death, permanent or long lasting disability or morbidity, severe toxicity) without the possibility of direct benefit to the subjects;
- The involvement of especially vulnerable populations likely to be subject to coercion (e.g., institutionalized psychiatric patients, incarcerated minors); or
- A history of serious or continuing non-compliance on the part of the Principal investigator;
- The following factors will also be considered when determining which studies require review more frequently than on an annual basis:
    - The probability and magnitude of anticipated risks to subjects;
    - The likely medical condition of the proposed subjects;
    - The overall qualifications of the Principal Investigator and other members of the research team;
- The specific experience of the responsible Principal Investigator and other members of the research team in conducting similar research;
- The nature and frequency of adverse events observed in similar research at this and other institutions;
- The novelty of the research, thereby increasing the possibility of unanticipated adverse events, 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 enrolled subjects. If a maximum number of subjects is used to define the approval period, it is understood that the approval period in no case can exceed one year unless the study does not require continuing review. If an approval period of less than one year is specified by the IRB for research that is subject to continuing review, the reason for more frequent review must be documented in the minutes or the expedited reviewer's checklist.

7.13. Posting of Clinical Trial Consent Forms

For each clinical trial conducted or supported by a U.S. federal department or agency, one IRB approved informed consent form used to enroll subjects must be posted by the awardee or the U.S. federal department or agency component conducting the trial on a publicly available U.S federal website that will be established as a repository for such informed consent forms.

If the U.S. federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a U.S. federal website (e.g. confidential commercial information), such U.S. federal department or agency may permit or require redactions to the information posted.

The informed consent form must be posted on the U.S. federal website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

7.14. Study Registration for Life Science and Medical Research involving Human Being

Under the Chinese regulations, Measures for Ethical Review of Life Science and Medical Research Involving Human Subjects (2023 Measures), researchers must register the applicable studies approved by the IRB in the National Medical Research Registration and Recordation Information System in China before implementing the research. This registration includes details about the research study, ethical review opinions, and other relevant review opinions. As the research progresses, researchers should promptly upload updates and changes to the system to ensure that registration information remains up to date. Researchers are responsible for updating the system on a timely basis. For the IRB-approved studies, researchers should refer to the Determination of Study Registration page in the exempt application form or follow the Registration Requirements stated in the decision letters for expedited or full-board reviewed studies to confirm the study registration requirements.

8. Vulnerable Populations

When some or all of the participants in a protocol are likely to not have the capacity to consent without representation or are vulnerable to coercion or undue influence, the IRB should include additional safeguards to protect the rights and welfare of these participants.

If the IRB reviews research that involves categories of participants vulnerable to coercion or undue influence, the review process will include one or more individuals who are knowledgeable about or experienced in working with these participants. When the IRB does not have the relevant expertise among its membership, expertise may be sought through the use of consultants.

[45 CFR 46] has additional subparts designed to provide extra protections for certain defined vulnerable populations which also have additional requirements for IRBs, where research is funded by the US Department of Health and Human Services:

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 applicability of and how to apply the subparts.

8.1. PI or Co-PI Responsibilities

The Principal Investigator is responsible for identifying the potential for enrolling vulnerable subjects in the research proposal. The Principal Investigator is responsible for identifying subjects who may be mentally disabled.

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 appropriateness of the research proposal, and may require that additional safeguards be included to protect the rights and welfare of vulnerable subjects as needed.

8.2.1. Initial Review

The Principal Investigator should identify the potential to enroll vulnerable subjects in the proposed research at initial review and provide the justification for their inclusion in the study.

The IRB evaluates the proposed plan for 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 subject'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 subject's capacity to provide voluntary informed consent.

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

8.2.2. Continuing Review and Monitoring

At continuing review, the Principal Investigator should identify the number of vulnerable subjects enrolled and any that needed an independent monitor in the progress report.

8.3. 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] and the Chinese local rule. For research conducted under other international jurisdictions, researchers should consult with the local jurisdiction to ensure compliance with applicable regulations and guidelines.

8.3.1. Definitions

Child

Under HHS regulations "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.

Law of the People's Republic of China on the Protection of Minors: Article 2 Minors as used in this Law refer to citizens under the age of eighteen.

Guardian

Under HHS regulations "guardian" means an individual who is authorized under applicable local law to consent on behalf of a child to general medical care.

Under the Civil Code of the People's Republic of China, Section II "Guardianship" defines that the parents of a minor shall be his/her guardians.

> Where both parents of a minor are dead or incapable of acting as a guardian, the following persons capable of acting as a guardian shall act as the guardian of the minor in the following order:
>
> (1) paternal or maternal grandparent of the minor;
>
> (2) elder brothers or sisters of the minor;
>
> (3) Other individuals or organizations willing to act as the guardian, provided that it is approved by the urban residents' committee, villagers' committee, or civil affairs department of the place of the minor's domicile.

Assent

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

Permission

The agreement of parent(s) or legal guardian to the participation of their child or ward in research.

Parent

A child's biological or adoptive parent.

8.3.2. Allowable Categories

Research on children must be reviewed and categorized by the IRB into one of the following groups:

1. 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]

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

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

4. 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].

When the IRB does not believe that the research meets the requirements of categories 1 - 3, and the IRB finds and documents 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, the IRB shall refer the research for further review as follows:

- US funded research in this category will be referred for review by the Secretary of Health and Human Services. However, before doing so the IRB must determine that the proposed research also meets all of the requirements of the Common Rule.
- For research that is not US funded, the IRB will consult with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, and law). Based on the recommendation of the panel, the IRB may approve the research based on either that:
    - the research in fact satisfies the conditions of the previous categories, as applicable; or
    - 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 accord with sound ethical principles; and
        iii. adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.

8.3.3. Parental 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 IRB may waive the requirement for obtaining consent from a parent or legal guardian if:

- the research meets the provisions for waiver in [45 CFR 46.116(f)(1-5)]; or
- for research that is not FDA-regulated, if the IRB determines that the research is designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children) provided that an appropriate mechanism for protecting the children who will participate as subjects 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/research plan, the risk and anticipated benefit to the research subjects, and the child's age, maturity, status, and condition.

Permission from parents or legal guardians must be documented unless waived by the IRB.

8.3.4. Assent from Children

For research activities involving adolescents 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 or for parental permission. 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 4 and older should be given an opportunity to provide assent. Generally, oral assent through the use of a script in appropriate language 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 sign 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 inconsistency between parent permission and child assent. Usually a "no" from the child overrides a "yes" from a parent, but a child typically cannot decide to be in research over the objections of a parent. Obviously, 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 subjects, even when their parents consent to 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 subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances detailed in the *Waiver of Informed Consent*.

The Assent Form

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

8.3.5. 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 subjects, but likely to yield generalizable knowledge about the subject'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 subjects 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.

8.4. Research Involving Pregnant Women or Fetuses

NYU Shanghai 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 which specifically target this group to ensure that the requirements for approval are met. Women who are pregnant will not be enrolled in any study which involves the use of MRI/fMRI or any other device which does not hold out a direct benefit to the woman and her unborn child.

9. Complaints, Non-Compliance and Suspension or Termination of IRB Approval of Research

9.1. 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 non-compliance 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 under Section 6.9.

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 Research Compliance Manager.

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 Section 9.3 will be followed.

If the complaint meets the definition of non-compliance, it will be considered an allegation of non-compliance according to Section 9.2.

If the complaint meets the definition of an unanticipated problem involving risk to subjects or others, it will be handled according to Section 6.9.

Within 3 business days of receipt of the complaint, the IRB Chair and/or Research Compliance Manager shall generate a letter to acknowledge that the complaint has been received and is being investigated, providing a follow-up contact name.

9.2. Non-Compliance

All members of the NYU Shanghai 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 non-compliance using the Event Report Form. The Principal Investigator is responsible for reporting any possible non-compliance 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. However, any individual or employee may report observed or apparent instances of non-compliance 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/or institutional review of these reports.

If an individual, whether investigator, study staff or other, is uncertain whether there is cause to report non-compliance, he or she may contact the IRB Chair directly to discuss the situation informally.

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

Complainants may choose to remain anonymous.

9.2.1. Definitions

Non-Compliance

Failure to comply with any of the regulations and policies described in this document and failure to follow the determinations of the IRB. Non-compliance may be minor or sporadic or it may be serious or continuing.

Serious Non-Compliance

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 either the IRB Chair or 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 specifically waived by the IRB) is considered serious non-compliance.

Continuing Non-Compliance

A pattern of non-compliance that, in the judgment of the IRB Chair or convened IRB, suggests a likelihood that instances of non-compliance will continue without intervention. Continuing non-compliance also includes failure to respond to a request to resolve an episode of non-compliance.

Allegation of Non-Compliance

An unproved assertion of non-compliance.

9.2.2. Finding of Non-Compliance

An allegation of non-compliance that is proven true or a report of non-compliance that is clearly true. (For example, a finding on an audit of an unsigned consent document, or an admission of an investigator of that the protocol was willfully not followed would represent reports of non-compliance that would require no further action to determine their truth and would therefore represent findings of non-compliance.) Once a finding of non-compliance is proven, it must be categorized as serious, non-serious, or continuing.

9.2.3. IRB Review of Allegations of Non-Compliance

All allegations of non-compliance will be reviewed by the IRB Chair or designee, who will review:

- all documents relevant to the allegation
- the last approval letter from the IRB
- initial approved IRB application and all subsequent amendment submissions
- the last approved consent document
- the last approved Investigator's Brochure, if applicable
- the grant (if applicable)
- any other pertinent information (e.g., questionnaires, etc.)

The Research Compliance Office 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 Research Compliance Office.

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 non-compliance 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 determination letter will be copied to the Institutional Official and the Associate Provost for Research.

If, the reported allegation of non-compliance is determined to be not true, no further action will be taken. If the reported allegation of non-compliance is determined to be true, the non-compliance will be processed according to *Review of Findings of Non-Compliance*.

If, in the judgment of the IRB Chair, any allegation or findings of non-compliance warrants suspension of the research before completion of any review or investigation to ensure protection of the rights and welfare of participants, the IRB Chair may suspend the research as described in below in *Suspension or Termination* with subsequent review by the 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 help support any determinations or findings made by the ad hoc committee.

9.2.4. Review of Findings of Non-Compliance

If, in the judgment of the IRB Chair, the reported finding of non-compliance 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.

All findings of non-compliance referred to the IRB will be reviewed at a convened meeting. All IRB members will receive:

- all documents relevant to the allegation
- all documents relevant to the response
- the last approval letter from the IRB
- the last approved IRB application
- the last approved consent document

At this stage, the IRB may:

- find that there is no issue of non-compliance
- find that there is non-compliance that is neither serious nor continuing and an adequate corrective action plan is in place
- find that there may be serious or continuing non-compliance and direct that a formal inquiry (described below) be held
- request additional information

9.2.5. 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:

- subjects' 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

9.2.6. Final Review

If the results of the inquiry substantiate the finding of serious or continuing non-compliance, 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 intervention
- modify the continuing review cycle
- request additional Investigator and staff education
- notify current subjects, if the information about the non-compliance might affect their willingness to continue participation
- modify the protocol
- modify the information disclosed during the consent process
- require current participants to re-consent to participation
- suspend the study (see below)
- terminate the study (see below)

In cases where the IRB determines that the event of non-compliance also meets the definition of 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 non-compliance was serious or continuing, the results of the final review will be reported as described below in *Reporting to Regulatory Agencies and Institutional Officials*.

9.2.7. Additional Actions

A finding of serious or continuing non-compliance 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
- IRB may impose additional requirements on the Investigator or other personnel involved in a study, pursuant to IRB policies and procedures.

Failure to secure necessary NYU Shanghai IRB approval before commencing may result in disciplinary action.

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

9.3. 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. The IRB's authority to suspend or terminate research applies to all research subject to IRB approval, including exempt research with limited IRB review and research for which continuing review is

no longer required. Suspension of IRB approval is a directive of the convened IRB or IRB Chair either to temporarily or permanently stop some or all previously approved research activities short of permanently stopping 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 permanently all activities 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 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.

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 the 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 or in writing.

The convened IRB or individual ordering the suspension or termination will consider whether procedures for withdrawal of enrolled subjects are necessary to protect their rights and welfare of 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 or termination, the convened IRB or individual ordering the suspension or termination will require that the subjects should be so informed and that any adverse events/outcomes be reported to the IRB and the sponsor.

Investigator MUST continue to provide reports on adverse events and unanticipated problems to both the IRB and sponsor 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.)

9.4. Reporting

Serious or continuing noncompliance with regulations or the requirements or determinations of the IRB; and suspensions or terminations of IRB approval will be reported to the appropriate regulatory agencies and institutional officials according to the procedures in *Reporting to Regulatory Agencies and Institutional Officials*.

10. Reporting to Regulatory Agencies and Institutional Officials

US 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 non-compliance with this policy 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 Research Compliance Manager will initiate these procedures as soon as 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 non-compliance was serious or continuing
- Suspends or terminates approval of research

The Research Compliance Manager or designee prepares a letter that contains the following information:

- the nature of the event (Unanticipated problem involving risks to participants or others, serious or continuing non-compliance, 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 (a) a specific date, or (b) 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 Research Compliance Manager or designee.

The Research Compliance Manager or designee sends a copy of the report to:

- the IRB by including the letter in the next agenda packet as an information item
- the Institutional Official
- the OHRP or the head of the agency as required by the agency, if the study is conducted or funded by any federal agency other than HHS that is subject to "the Common Rule"
    - reporting to a regulatory agency is not required if the event occurred at a site that was not subject to the direct oversight of the organization, and the agency has been notified of the event by the investigator, sponsor, another organization, or other mechanisms
- the OHRP, if the study is subject to HHS regulations or subject to a HHS FWA
- the principal investigator
- the sponsor, if the study is sponsored
- the chairman or supervisor of the principal investigator
- others as deemed appropriate by the Institutional Official

Reports are not submitted to federal departments or agencies such as OHRP unless the research is subject to federal regulations or another mandate that necessitates such reporting.

The Research Compliance Manager ensures that all steps of this policy are completed within 10 business days of the initiating action. For more serious actions, the Research Compliance Manager will expedite reporting.

11. Investigator Responsibilities

Principal Investigators are ultimately responsible for the conduct of research. Principal Investigators may delegate research responsibility. However, investigators must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibility.

In order to satisfy the requirements of this policy, investigators who conduct research involving human subjects must:

- develop and conduct research that is in accordance with the ethical principles in the *Belmont Report and Declaration of Helsinki*
- develop a research plan that is scientifically sound and minimizes risk to the subjects
- have sufficient resources necessary to protect human subjects, including:
    - access to a population that would allow recruitment of the required number of subjects
    - sufficient time to conduct and complete the research
    - adequate numbers of qualified staff
    - adequate facilities
    - a process to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions
    - availability of medical or psychological resources that subjects might require as a consequence of the research
- assure that all procedures in a study are performed with the appropriate level of supervision and only by individuals who are licensed or otherwise qualified to perform such under the applicable laws and the policies of NYU Shanghai
- assure that all key personnel are educated in the regulatory requirements regarding the conduct of research and the ethical principles upon which they are based
- protect the rights and welfare of prospective subjects
- ensure that risks to subjects are minimized:
    - by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
    - whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes
- recruit subjects in a fair and equitable manner
- have plans to monitor the data collected for the safety of research subjects
- protect the privacy of subjects and maintain the confidentiality of data
- have a procedure to receive complaints or requests for additional information from subjects and respond appropriately
- ensure that pertinent laws, regulations, and institution procedures and guidelines are observed by participating faculty and research staff
- obtain and document informed consent as required by the IRB and ensure that no human subject is involved in the research prior to obtaining their consent, unless IRB has approved exception to elements of informed consent or waiver of the documentation requirement
- ensure that all research involving human subjects receives IRB review and approval in writing before commencement of the research
- comply with all IRB decisions, conditions, and requirements
- ensure that submissions for IRB review are submitted in a timely manner
- report problems that require prompt reporting to the IRB
- obtain IRB review and approval in writing before changes (i.e. amendments) are made to approved protocols or consent forms
- seek IRB assistance when in doubt about whether proposed research requires IRB review

- ensure that life science and medical research involving human being is registered the National Medical Research Registration and Recordation Information System in China before implementing the research; and any changes and updates to research are promptly uploaded to the system.

11.1. Investigator Classifications

Principal Investigators (PIs)

At NYU Shanghai, tenured or tenure track faculty with full-time appointments and Full Time Continuing Contract Faculty who have been approved to be PIs may serve as the Principal Investigator or as the faculty sponsor on a research project involving human subjects. PI status may be granted to other faculty whose appointments do not fall within the above-stated categories. Please refer to NYU Shanghai Statement on PI Eligibility for details and guidance on requesting approval for PI status.

Any investigator whose status is considered to be “in training” (i.e. students and post-doctoral researchers who are under the direct supervision of a faculty member) may not serve as a Principal Investigator but may serve as a co-investigator.

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

Protocols that require skills beyond those held by the Principal Investigator must be modified to meet the investigator's skills or have one or more additional qualified faculty as Co-investigator(s).

Student Investigators (Investigators in Training)

Students may not serve as sole Investigators. They must have a faculty sponsor who fulfills the Principal Investigator eligibility criteria and who will serve as Principal Investigator and faculty advisor on the study.

Research Team

The Principal Investigator and other individuals (also known as key personnel) who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the protocol. The research team also consists of individuals who intervene or interact directly with human subjects (including the recruitment or consenting thereof), or who analyze data and/or tissue derived from humans for the purposes of the activity in question.

11.2. Protocol Development

When developing a protocol, the Principal Investigator or a member of the protocol research team may contact the Research Compliance Office for advice regarding whether the proposed project constitutes human subjects research, and if so, what level of review would be required.

Investigators must provide complete answers to all questions on the *Application for New Protocol Review* and make certain that consent information is in agreement with the research plan.

Proposed consent/assent form (if applicable) must include or address:

- the required elements of informed consent
- translated consent documents, as necessary, considering likely subject population(s)
- NYU Shanghai IRB-approved formats for consent forms and assent forms
- Rationale for waiver of consent, if applicable

11.3. Continuing Review or Annual Status Report after Protocol Approval

It is the responsibility of the Principal Investigator (PI) to submit a timely continuing review application when IRB continuing review is required or a timely annual status report when IRB continuing review is not required. The investigator should allow sufficient time for development and review of renewal submissions or status report. By U.S. federal regulation, no extension can be granted to the expiration date of an approved research.

11.4. Required Reports to the IRB

11.4.1. Unanticipated Problems

Principal investigators must report to the IRB as soon as possible of any:

- adverse events involving direct harm to participants which in the opinion of the principal investigator are both unexpected and related
- an unanticipated event related to the research that exposes individuals other than the research participants (e.g., investigators, research assistants, students, the public, etc.) to potential risk but that does not involve direct harm to participants
- new information that indicates a change to the risks, conduct of the trial or potential benefits of the research. For example:
    - an interim analysis or safety monitoring report indicates that frequency or magnitude of harms or benefits may be different than initially presented to the IRB
    - a paper is published from another study that shows that the risks or potential benefits of your research may be different than initially presented to the IRB
- a breach of confidentiality
- incarceration of a participant in a protocol not approved to enroll prisoners
- changes that increase the risk to subjects and/or affect significantly the conduct of the trial
- 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 unintentional 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
- any other event that indicates participant or others might be at risk of serious, unanticipated harms that are reasonably related to the research

The IRB will accept other reports when the investigator is unsure whether the event should be reported. The investigator may first contact the Research Compliance Office by email or telephone to determine if the reporting is necessary.

Principal Investigators should report the above events using the *Unanticipated Event Report*. Reports may be accepted by other means such as email, or phone.

11.4.2. Submission of Reports

Investigators must report possible unanticipated problems to the IRB promptly.

Investigators must report possible unanticipated problems to the Research Compliance Office in writing. The written report should contain the following:

- detailed information about the possible unanticipated problems, including relevant dates
- any corrective action, planned or already taken, to ensure that the possible unanticipated problems is corrected and will not occur again
- an assessment of whether any subjects or others were placed at risk as a result of the event or suffered any physical, social, or psychological harm and any plan to address these consequences
- any other relevant information
- any other information requested by the Research Compliance Office

11.4.3. Complaints and Non-Compliance

Investigators must report all complaints and concerns from subjects, non-compliance by research staff, and any protocol deviations to the IRB promptly as described in for evaluation as possible unanticipated problems involving risks to subjects or others.

11.5. Investigator-Required Record Keeping

Investigators must retain copies of approved IRB documents, and implement a system to comply with approval expiration dates.

In addition to providing a copy of the signed and dated consent form to each subject, a copy must be stored securely by the Principal Investigator for a minimum of 3 years after completion of the research.

11.6. Training & Ongoing Education of Principal Investigator and Research Team

As stated above, one component of a comprehensive human research protection program is an education program for all individuals involved with research subjects. NYU Shanghai is committed to providing training and an on-going educational process for investigators and members of their research team related to ethical concerns and regulatory and institutional requirements for the protection of human subjects.

11.6.1. Orientation

All Principal Investigators and members of their research team (also known as “key personnel”) must review core training documentation including the *NYU Shanghai IRB Procedures for Human Subjects Research Protection*, and the “*Belmont Report: Ethical Principals and Guidelines for the Protection of Human Subjects of Research* “

11.6.2. Initial Education

All investigators and their research teams must complete an appropriate human subjects training course (as currently designated on the IRB website).

New research protocols and applications for continuing review will not be accepted from Principal Investigators who have not completed the initial education requirement.

While research protocols and applications for continuing review will be accepted and reviewed if the Principal Investigator holds a current certification of training, final approval will not be granted until all co-investigators and members of the research team have completed the initial education requirement (or the continuing education requirement once the initial education requirement has been satisfied).

When IRB continuing review is not required, the continuing education requirement will be verified at the time of annual status report submission.

11.6.3. Waiver of Initial Education

If investigators or members of their research team can verify that they have successfully completed human subjects research training equivalent to that required by the NYU Shanghai, they may request a waiver of the requirement for initial education. However, all investigators or members of their research team must complete the requirements of continuing education.

11.6.4. Continuing Education and Recertification

It is recommended that all investigators and members of their research teams take an NYU Shanghai refresher course every three (3) years after completing Initial Education certification. Maintaining certification is especially important for investigators who have or wish to seek federal funding for their research. Additional human subjects research educational opportunities are available as well and may include attendance at PRIM&R or OHRP seminars and conferences, attendance at an IRB sponsored seminar, or review of appropriate refresher modules at the CITI web-based training site.

Investigators who are also IRB Chair, IRB members, or Research Compliance Manager will satisfy the training requirements for IRB members and staff described in this policy under *Training / Ongoing Education of Chair and IRB Members in Regulations, Procedures*.

11.6.5. Additional Resources

Human research protection information will be made available on the IRB website on an ongoing basis to ensure that the NYU Shanghai research community is apprised of current regulatory and policy requirements and training opportunities.

11.7. Investigator Conflict of Interest

Conflicts of interest at NYU Shanghai are subject to the "NYU Policy on Academic Conflict of Interest and Conflict of Commitment."

Undisclosed or inappropriate conflicts of interest can compromise the integrity of the research, can reflect negatively on faculty and investigators, and can result in financial and other sanctions on the University. It is therefore the policy of NYU Shanghai that conflicts of interest, including both actual and potential conflicts, be disclosed and permitted only in appropriate cases, after being evaluated in accordance with this policy and managed to the extent determined advisable. Faculty or investigators who are unclear as to whether a matter must be disclosed should err on the side of disclosure.

Research activities are subject to the University's broad policies regarding conflicts of interest. Human subjects research is the most sensitive area of research. Accordingly, the disclosures and review in this area include additional requirements and determinations as to whether to proceed and under what conditions are held to an even higher standard. For that reason, the scientific objectivity of an investigator maybe reasonably questioned in those cases where the investigator has *any* personal interests which could be affected by the research – no matter what positions or financial amounts are involved.

A "conflict of interest" means any circumstance in which the personal, professional, financial or other interests of an individual (including the immediate family members of the individual) may potentially or actually diverge from, or may be reasonably perceived as potentially or actually diverging from, his or

her professional obligations. A conflict of interest may exist whenever an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise.

NYU Shanghai has broad power to require disclosures of conflicts of interest to determine whether a conflict exists, to manage or eliminate conflicts of interest, to impose appropriate sanctions on faculty and investigators who violate this policy, to release information about conflicts of interest and to require faculty and investigators to take conflict of interest training.

Investigators carrying out research involving human subjects or applying for IRB approval of research protocols must disclose conflicts of interest to the IRB, and must promptly disclose any changes in circumstances regarding conflicts of interest.

11.8. Subject Recruitment

Investigators are responsible for recruiting research subjects in a manner that is fair, ethical and equitable. IRB approval is required for all recruitment procedures and materials. Recruitment materials must be consistent with the approved IRB protocol, accurate, and not coercive.

11.8.1. Recruitment Incentives

Payment arrangements among sponsors, organizations, investigators, and those referring research participants may place participants at risk of coercion or undue influence or cause inequitable selection. Payment in exchange for referrals of prospective participants from researchers (“finder’s fees”) is not permitted. Similarly, payments designed to accelerate recruitment that are tied to the rate or timing of enrollment (“bonus payments”) are also not permitted.

11.8.2. Payment to Subjects

Payment to research subjects may be an incentive for participation or a way to reimburse a subject for travel and other experiences incurred due to participation. However, payment for participation is not considered a research benefit. Regardless of the form of remuneration, investigators must take care to avoid coercion of subjects. 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 subjects must indicate in their research project application the justification for such payment. Such justification should:

- Substantiate that proposed payments are reasonable and commensurate with the expected contributions of the subject
- State the terms of the subject participation agreement and the amount of payment in the informed consent form,and
- Substantiate that subject payments are fair and appropriate, and that they do not constitute (or appear to constitute) undue pressure on the subject 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 entails problems of coercion or undue influence. Any amount paid as bonus for completion of the entire study should not be so great that it becomes coercive.

The consent form must describe the terms of payment and the conditions under which subjects would receive partial payment or no payment (e.g., if they withdraw from the study before their participation is completed).

11.9. Investigator Concerns

Investigators who have concerns or suggestions regarding NYU Shanghai's human research protection program should convey them to the Institutional Official or other responsible parties regarding the issue, when appropriate. The Institutional Official will research the issue, and when deemed necessary, convene the parties involved to form a response for the investigator or make necessary procedural or policy modifications, as warranted. In addition, the Chair of the IRB or the Research Compliance Manager will be available to address investigators' questions, concerns and suggestions.

12. Special Topics

12.1. NYU Shanghai Students and Employees as Subjects

When NYU Shanghai students and/or employees are being recruited as potential subjects, researchers must ensure that there are additional safeguards for these subjects. The voluntary nature of their participation must be primary and without undue influence on their decision. Researchers must emphasize to subjects that neither their academic status or grades, or their employment, will be affected by their participation decision. Record of the participation cannot be linked to an academic record. The IRB also ensures when necessary a certificate of confidentiality is sought in sensitive research topics such as mental health, drug/alcohol abuse, sexual behavior, or others that fall into this category.

To minimize coercion, investigators should avoid, whenever possible, the use of their students and employees in procedures which are neither therapeutic nor diagnostic. In these latter situations, investigators should solicit subjects through means such as bulletin board notices, flyers, advertisements in newspapers, and announcements in classes other than their own.

12.1.1. Recruitment and Enrollment of NYU Shanghai Students in Research Conducted by NYU Shanghai Faculty

As a university with a small student population, NYU Shanghai has specifically developed this policy for the recruitment and enrollment of NYU Shanghai students in research. NYU Shanghai faculty may recruit and enroll NYU Shanghai students in research so long as the research is approved (or determined exempt as the case might be) by the IRB. The following outlines some of the ethical concerns that arise when students are recruited or enrolled as subjects in research, and guidelines to help manage these concerns.

12.1.2. Definition

NYU Shanghai defines a student as an individual who has registered within any academic division of NYU Shanghai, regardless of whether he/she is enrolled in courses or studied away or on authorized leave; or an individual who has an advisee or mentee relationship with NYU Shanghai faculty, if he/she is not registered within any academic division of NYU Shanghai.

12.1.3. Ethical Concerns

Power Relationships

As it relates to participation as subjects in research conducted by faculty, it is important to recognize that students may feel an obligation to participate, that refusal to participate may reflect negatively on their academic performance, or, conversely, that participation may reflect positively on their academic performance. This effect is compounded when the research is being conducted by faculty from whom they are or will be taking courses or with whom they have an advisee or mentee relationship. These perceptions may exist regardless of faculty intent.

Peer Influence

When students are recruited in group settings, such as classrooms or meetings, or are recruited by fellow students, they may agree to participate in research simply because their peers agree to participate and they do not want to stand out, or because they feel an obligation to help a fellow student. Conversely, if friends of a student, influential students, or a majority of students in a group

setting decline participation in a research study, a student who would actually like to participate in a research study may refuse.

Inducements

Students may agree to participate in research when an inducement such as course credit or extra credit is offered. The incentive of securing academic credit or improving academic performance is powerful for many students and may cause them to accept risks or agree to procedures or use of their data that they would otherwise find objectionable.

Privacy & Confidentiality

When students agree to participate in research conducted by faculty, they may presume that their research data is subject to the same protections as their academic records and not fully appreciate how their information may be used and who may have access in the research context. Faculty must be cognizant of this and be certain to fully inform student participants about what information will be used, who will have access, and how their information will be protected.

12.1.4. Guidelines

The following guidelines apply to the recruitment and enrollment of NYU Shanghai students in research conducted by NYU Shanghai faculty. The IRB may grant exceptions to these guidelines when appropriate justification has been provided by the faculty and circumstances warrant.

Justification for Targeting Students

An investigator who plans to limit the subject population to NYU Shanghai students must be able to provide a rationale, other than convenience, for restricting the study population to NYU Shanghai students. The investigator should propose adequate methods and guidelines for recruitment and participation to minimize the ethical concerns outlined above.

Recruitment

An investigator may not directly solicit any NYU Shanghai student whom the investigator currently teaches, mentors, advises or academically supervises for participation in his/her research project. This guideline applies even if the student has previously indicated willingness to be contacted about the possibility of participating in research; for instance, by allowing her name to be posted within a research pool.

One exception to the above rule is that faculty may direct recruit their own students as subjects in their research **only** after grades have been posted. If a sequence class is offered, the recruitment may start **only** after grades for the sequence class have been posted.

NYU Shanghai students may be recruited through indirect methods such as the posting of IRB-stamped approved flyers and/or the placement of IRB-stamped approved advertisements. Acceptable methods include:

- Posting flyers to bulletin boards (analog or digital), or
- Posting advertisements to departmental and/or academic unit's website that contains a section labeled research participation opportunities

Investigators should avoid sending bulk email to mailing lists that are held by the university and/or departmental and/or academic units for research recruitment and advertisement.

Students who submit their names to a research subject pool may be directly contacted by phone or email if neither the recruiter nor the investigator teaches, mentors, advises, or academically supervises the student.

Recruitment in group settings is only permissible when the investigator has provided justification and a plan to promote voluntariness and to minimize the issues identified above to the IRB and the IRB has reviewed and approved the recruitment plan.

Recruitment of Students under the Age of Eighteen

In addition, research involving NYU Shanghai students under the age of eighteen is subject to the same regulations and guidance as all research involving minors. Prior to enrolling minors in research, investigators have the responsibility of ensuring that the IRB has approved the inclusion of minors in the research, that any potential student participants who are minors are identified as such, and that the students enrollment and participation complies with the regulations (45 CFR 46 Subpart D) for such research.

Incentives

The use of monetary incentives for soliciting NYU Shanghai student participation in research is permissible if the incentive is not of such magnitude that it may unduly influence a student's decision whether or not to participate in the research. All incentives must be reviewed and approved by the IRB prior to being offered or communicated to potential participants.

The use of extra credit or academic credit as an incentive for participation is not allowed at NYU Shanghai. The only exception is if participation in research is an integral part of an approved course curriculum. To submit a request to offer academic credit in exchange for participation, the investigator must:

- obtain support from the appropriate academic dean for the use of course credit as an incentive in courses where participation in research is part of the learning experience for the students;
- offer non-research alternatives by which students may earn an equivalent amount of course credit (appropriate non-research alternatives may include activities such as attending a departmental seminar or event, watching an educational film, reviewing some research articles and providing abstracts, attending or viewing research presentations, or reviewing literature and submitting an abstract or written summary of the event or materials; and alternatives must be easily accessible and must not entail more time and effort on the part of the student than the research activity); and
- any credit must be small in proportion to a student's overall grade; and a student's final grade should still reflect his/her mastery of course material, not his/her participation as a research subject.

The IRB has discretion to place other restrictions on the use of course credit as an incentive to participation. As above, all incentives must be reviewed and approved by the IRB prior to being offered or communicated to potential participants.

Minimal Risk and Greater than Minimal Risk Research

Enrollment in research activities that have been designated as "minimal risk" by the IRB are open to all students who satisfy the inclusion criteria for the research. While investigators may not directly recruit their own students, mentees, or advisees, they may enroll their students as research participants in minimal risk research should the students respond to non-direct recruitment methods such as IRB-approved flyers or advertisements posted outside of the investigator's classroom.

When research has been determined to be "greater than minimal risk" by the IRB, the IRB may place additional restrictions on how students may be recruited, and on which students may be recruited or included in the research. For example, the IRB may not permit inclusion of undergraduates in a particular research study.

Informed Consent

Unless the requirement has been waived by the IRB, students must be provided with informed consent for participation in research conducted by the faculty. The consent, whether verbal or written, must clearly describe the proposed activity as research, the purposes of the research, the fact that participation is purely voluntary and that student's academic performance and academic relationships will not be impacted, positively or negatively, describe any incentives and alternatives to achieve the same incentive, and describe what information about the student will be accessed and used for the research, who will have access, and how the information will be used and protected. When the research is not eligible for exempt status, the consent must also include all additional elements of consent required by regulations (45 CFR 46.116).

Privacy and Confidentiality

Whenever NYU Shanghai students participate in research, or their academic records or private information is used for research, investigators must provide the IRB with specific plans for ensuring that the privacy and confidentiality of students will be respected. These plans must take into account and adequately address concerns specific to conducting research in an educational environment, such as ensuring the study does not compromise the privacy of the students/families or disrupt the work of the students and teachers, and specifically address how and by whom students or their records will be identified, the recruitment plan, the circumstances under which informed consent will be sought, and how research records will be used, shared, and protected.

12.2. Oral History

The following is based on guidance received from OHRP:

> A decision whether oral history or other activities solely consisting of open ended qualitative type interviews are subject to the policies and regulations outlined in an institution's FWA and HHS regulations for the protection of human research subjects (45 CFR 46) is based on the prospective intent of the investigator and the definition of "research" under HHS regulations at 45 CFR 46.102(l): "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Specifically, for the purposes of this policy, the evaluation of such activities hinges upon whether:

- The activity involves a prospective research plan which incorporates data collection, including qualitative data, and data analysis to answer a research question; and
- The activity is designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings.

In order to be subject to the NYU Shanghai's human research protections policies, the activity must meet both of the above standards. This determination will be made according to the procedures described in Section 6.1.

General Principles for evaluating Oral History type activities:

- Oral history activities, such as open ended interviews, that only document a specific historical event or the experiences of individuals without intent to draw conclusions or generalize findings would not constitute "research" as defined by HHS regulations 45 CFR part 46.

> Example: An oral history video recording of interviews with holocaust survivors is created for viewing in the Holocaust Museum. The creation of the videotape does NOT intend to draw conclusions, inform policy, or generalize findings. The sole purpose is to create a historical record of specific personal events and experiences

related to the Holocaust and provide a venue for Holocaust survivors to tell their stories.

- Systematic investigations involving open-ended interviews that are designed to develop or contribute to generalizable knowledge (e.g., designed to draw conclusions, inform policy, or generalize findings) would constitute "research" as defined by HHS regulations at 45 CFR part 46.

  Example: An open ended interview of surviving Gulf War veterans to document their experiences and to draw conclusions about their experiences, inform policy, or generalize findings.

- Oral historians and qualitative investigators may want to create archives for the purpose of providing a resource for others to do research. Since the intent of the archive is to create a repository of information for other investigators to conduct research as defined by 45 CFR part 46, the creation of such an archive would constitute research under 45 CFR part 46.

  Example: Open ended interviews are conducted with surviving Negro League Baseball players in order to create an archive for future research. The creation of such an archive would constitute research under 45 CFR part 46 since the intent is to collect data for future research.

Investigators are advised to consult with the Research Compliance Office regarding whether their oral history project requires IRB review.

12.3. International Research

International research projects (those conducted outside of the United States or China) must be approved by the local equivalent of an IRB before they are presented to the NYU Shanghai IRB. If you plan to conduct your research at a site located outside of the United States or China, you should first obtain approval for your research from a local IRB or Research Ethics Committee (REC) before submitting your application to the NYU Shanghai IRB. Where there is no equivalent board or group, investigators must rely on local experts or community leaders to provide approval. The NYU Shanghai IRB requires written documentation of this "local context approval" before granting NYU Shanghai approval.

While we cannot impose our standards for written documentation on other cultures, we do not relax our standards for ethical conduct of research or for a meaningful consent process. Special attention should be given to local customs and to local cultural and religious norms in drafting written consent documents or proposing alternative consent formats.

In some instances it may be appropriate for the IRB to waive some or all requirements for written consent. Research proposals for which this may be reasonable should include explanations of cultural norms or conditions requiring such a waiver, e.g., societies where no written language is used, societies where signatures represent the surrender of spirit or soul to the researcher, or where a signed consent could place the subject at risk for retribution.

12.4. Student Research

12.4.1. Human Subject Research and Course Projects

Learning how to conduct ethical human subjects research is an important part of a student's educational experience. Research exercises that are designed as part of a course requirement for purposes of learning experience only and are **not** "designed to develop or contribute to generalizable knowledge" **do not require** IRB review and approval if all of the following conditions are true:

- Results of the research exercises are viewed only by the course instructor for teaching purposes and discussed within the classroom for teaching and learning purposes;
- Results of the research are not made public through presentation (outside of the classroom) and are not published in paper or electronic format (e.g., cannot be made available on the internet, cannot be published in a journal, publicly accessible blog, etc.);
- Research procedures present no more than minimal risk defined in Section 1;
- Vulnerable populations are not targeted (e.g., c e.g., children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons; please refer to Section 7.4. and Section 8 for definitions) and sensitive topics where the welfare of the individual requires special consideration (e.g., domestic violence) are not the focus;
- Data collected are recorded in such a manner that the subjects are not identifiable. When audio or video recordings are instrumental to the research exercise, the storage and cataloging of these materials does not contain identifying information. Video recordings and/or audio recordings are to be shared only in the context of classroom learning. If they are used or shown outside of the classroom, they then qualify as research and will require IRB approval;
- When appropriate, an informed consent process is in place.

In the event that a classroom research exercise yields results that a) warrants further study or b) the student would like to use the data for research purposes, the student must first contact the IRB before proceeding. The IRB will review the research to determine if the student might have some additional requirements in order to use the data or to continue the research for purposes other than classroom education; for example, possibly consenting or re-consenting subjects informing them of the new use.

Please note: If an individual conducts research without the appropriate IRB approval, it is possible that there would be a sanction in which the data could not be used. The IRB has the authority to determine whether the data collected without IRB approval can be used.

12.4.2. Responsibilities of the Course Instructor

The course instructor is responsible for communicating to the students the ethics of human subjects research, for ensuring the protection of human subjects (including a process is in place for obtaining voluntary informed consent from research subjects when appropriate), and for monitoring the students' progress.

When designing a project, students should be instructed on the ethical conduct of research and on the preparation of the IRB application when such is required. In particular, instructors and students should:

- Understand the elements of informed consent;
- Develop appropriate consent documents;
- Plan appropriate strategies for recruiting subjects;
- Identify and minimize potential risks to subjects;

- Assess the risk-benefit ratio for the project;
- Establish and maintain strict guidelines for protecting privacy and confidentiality; and
- In the case of research activities that go beyond classroom instruction, allow sufficient time for IRB review (if necessary) and completion of the project.

In making a determination of whether or not a class research project requires IRB review, the instructor is encouraged to visit the IRB website for more information or contact the Research Compliance Office (RCOinfo@nyu.edu) for assistance.

12.4.3. Individual Research Projects Conducted by Students

Independent study projects, senior theses, undergraduate research projects, and advanced degree research, and similar exercises involving human subjects research must be independently submitted for IRB review. It is important to keep in mind that any human subjects research activity that will ultimately contribute to part or all of a thesis, dissertation, or other type of publication or presentation must go through the IRB review process prior to enrolling subjects and collecting data. IRB review/approval cannot occur after a study has begun.

Students and advisors should contact the Research Compliance Office (RCOinfo@nyu.edu) with any questions.

12.4.4. Independent Study, Theses and Dissertations

Those research activities that are considered to meet the federal definition of human subjects research must be independently submitted to the IRB by the student-investigator. When students conduct research as part of a course of study, the faculty member is still ultimately responsible for the protection of the subjects, even if the student is the investigator and actually conducts the project. Faculty advisors assume the responsibility for students engaged in independent research, and instructors are responsible for research that is conducted as part of a course.

At NYU Shanghai, students may not serve as principal investigators. They must have a faculty sponsor who fulfills the Principal Investigator eligibility criteria (see: Section 11.1 *Investigator Classifications*), and who will serve as Principal Investigator and faculty advisor on the study.

12.4.5. Roles and Responsibilities of the Faculty advisor

What is the faculty advisor's role in student-conducted research?

The faculty advisor shares with the student the responsibility for the ethical conduct of the research. The advisor is responsible for ensuring that research activities involving human subjects are reviewed and approved by the NYU Shanghai IRB before they are initiated. The faculty advisor is expected to take an active role in student research activities and provide supervision for the duration of the project. The faculty advisor is responsible for all research activities and must review, approve and sign the submission to the IRB.

What are the responsibilities of the faculty advisor in student-conducted research?

1. **Be informed**. Contact the Research Compliance Office to discuss policies and procedures for obtaining IRB review before the initiation of research activities. Faculty advisors are expected to be familiar with institutional requirements for the conduct of human subjects research. Familiarize yourself with the IRB website.
2. **Complete the CITI training** for human subjects research. Faculty advisors are expected to be familiar with ethical and regulatory requirements.

3. **Know what must be reviewed**. Determine when an undergraduate or graduate student project constitutes research with human subjects and requires review by the IRB Office and/or the IRB. If you are unsure about whether or not a planned activity constitutes research with human subjects it is your responsibility to contact the Research Compliance Office for guidance.
4. **Assist students with protocol submission.** When proposed activities constitute research with human subjects, it is the responsibility of the faculty advisor to assist students in preparing and reviewing materials to be submitted to the NYU Shanghai IRB. Faculty advisors are responsible for reviewing the scientific integrity of the project, including evaluating the scientific rigor and merit of the study.
5. **Educate students** on the role of the NYU Shanghai IRB and the importance of research review. Students must complete the CITI training for human subjects research before submitting an application to the IRB.
6. **Maintain ethical standards.** Faculty advisors ensure that projects are conducted to the highest ethical standards and that students understand and implement these ethical standards in the conduct of their research.
7. **Help students navigate the IRB process.** Faculty advisors contact the Research Compliance Office to determine what the requirements are for submission to the IRB and help students understand the NYU Shanghai IRB process.
8. **Take an active role** in the IRB review process and assist students when presented with questions and comments from the IRB and/or IRB staff.
9. **Meet regularly with the student** to review project, progress and any issues.
10. **Ensure data security and retention** as described in the approved IRB protocol.
11. **Oversee changes.** Ensure that before a change is implemented to an approved protocol, the change is approved by the IRB. All changes must be reviewed by the faculty advisor before submission to the IRB.
12. **Report any unanticipated problems** or other research-related problems to the IRB as soon as possible.
13. **Ensure that continuing review requirements** are satisfied when applicable.
14. **Ensure that the study is closed** at the conclusion of the study.