

The City University of New York  
Human Research Protections Program  
Policies and Procedures  
2009

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# 1 INTRODUCTION

These Policies and Procedures describe the rules and regulations governing research with human subjects conducted under the auspices of The City University of New York (“CUNY” or the “University”) and the requirements for submitting research proposals for review by the CUNY Institutional Review Boards.

CUNY strives to foster a research environment that promotes respect for the rights and welfare of individuals recruited for, or participating in, research conducted at, by, or otherwise under the auspices of the University. In the review and conduct of human subjects research, CUNY is guided by the principles set forth in the [Belmont Report](#) (see Section 1.2) and shall act in accordance with the U.S. Department of Health and Human Services policy and regulations at [45 CFR 46](#) (the “Common Rule”) and, where applicable, the U.S. Food and Drug Administration policy and regulations at [21 CFR 50](#) and [21 CFR 56](#). CUNY will also conform to all other applicable federal, state, and local laws and regulations, and these Policies and Procedures.

At the time of publication, these Policies and Procedures present the most current information for reference by potential investigators and their staff. However, these Policies and Procedures are subject to change. Contact the CUNY Office of Research Conduct for information regarding any new developments. Copies of these Policies and Procedures are available on the CUNY and CUNY Research Foundation websites, and from the Office of Research Conduct upon request.

## 1.1 Applicability

These Policies and Procedures apply to all research involving human subjects, regardless of funding or performance site, conducted under the auspices of CUNY. This includes research:

- conducted at any CUNY facility;
- conducted by or under the direction of any student, faculty member, staff member, or agent of CUNY in connection with his or her institutional responsibilities;
- involving the use of CUNY nonpublic information to identify or contact human subjects.

Research conducted at performance sites outside the jurisdiction of U.S. laws must be conducted in a manner that conforms to ethical principles which are at least equivalent to those of CUNY, as described in Section 1.2 or as may be determined by the DHHS Secretary.

It is anticipated that the Research Foundation of CUNY (RFCUNY) will adopt these Policies and Procedures and that they will also apply to all research conducted by its employees.

## 1.2 Ethical Principles: The Belmont Report

In 1979 the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued its Ethical Principles and Guidelines for the Protection of Human Subjects of Research, commonly known as the Belmont Report. The Belmont Report is a statement of basic ethical principles and guidelines intended to assist in resolving the ethical problems that surround the conduct of research with human subjects. CUNY is guided by these principles, stated below, which are the touchstones of ethical research:

- that voluntary participation by the research subjects, indicated by free and informed consent, is assured;
- that an appropriate balance exists between the potential benefits of the research to the subject or to society and the risks assumed by the subject; and
- that there be fair procedures and outcomes in the selection of research subjects.

These principles are summarized as respect for persons, beneficence, and justice.

**1.2.1 Respect for Persons: Voluntary Participation and Informed Consent.** One of the most important elements in any research involving human subjects is the assurance of voluntary informed consent. Any person who is to be a research subject, whether designed for his or her own direct benefit or for the advancement of scientific knowledge in general, must understand as completely as possible what is to be done and what the potential risks and benefits are. The person must give his or her consent freely, without pressure or inappropriate inducement. CUNY strives to ensure voluntary informed consent of research subjects through careful review by its Institutional Review Boards (IRBs) of the recruitment and consent process, and of the consent form or information sheet to be used with subjects.

The informed consent concept is extended to those studies in which the subjects are not able to give personal consent for themselves. Here the consent document is addressed to those who have been designated responsible for the research subject's well being (for example, parents of children). An IRB's role is to verify that the consent process and document are likely to assist these persons to make an informed decision that is in the best interest of the research subject. The capacity for truly informed and voluntary participation in research varies widely among study populations. At one extreme, there may be ample understanding and manifest freedom from coercion; at the other, there may be degrees of understanding and freedom that affect the consent of potential subjects. The IRB must exercise special care when considering subjects whose ability to give free and informed consent may be compromised in any way.

**1.2.2** Beneficence: The Risk/Benefit Relationship. An IRB is charged with deciding, for any proposed activity that falls under its jurisdiction, whether the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept those risks.

The assessment of the risk/benefit relationship is a complex task. There are risks of injury or discomfort to the individual that can be physical, psychological, and/or social. There can be potential benefits to the individual, to a group to which the individual belongs, and/or to society. When reviewing protocols, the IRB must carefully assess the types and degrees of both risks and benefits for a given subject population, as well as the investigator's communication of these risks and benefits in the consent process and form. While the IRB is not charged with reviewing scientific design per se, it must sometimes do so in order to assess the risk/benefit relationship. If a study design does not seem adequate to attain the stated aim of the investigation, then no benefit can be anticipated from conducting the study, and there is no justification for placing any research subject at risk, however minimal. Thus the design of the study must be sound, and the nature and likelihood of all risks and benefits must be made clear in any application to the IRB.

**1.2.3** Justice: The Fair Selection of Research Subjects. Both the risks and the potential benefits of research should be spread fairly among potential individual research subjects and research subject groups. Study design and selection of subjects should avoid bias for or against particular social, racial, sexual, or ethnic groups.

**1.2.3.1** Sharing Research Risks. The guiding principle in the ethical selection of research subject groups is that any risks of the research should fall upon the groups who might benefit from the research. If the results of a risky protocol might benefit the general population, it would be unethical to focus subject recruitment on vulnerable or disadvantaged groups (for example, institutionalized people or prisoners, or patients at free clinics primarily patronized by people unable to afford other medical care) simply because they are easily accessible or can be persuaded to participate. An undue share of research risks should not burden groups already burdened by other factors. Rather, attempts should be made to include a fair sampling of the populations that might benefit from the study. When research involves persons whose autonomy is compromised, it is expected that the research bear some direct relationship to the conditions or circumstances of the research subject population. In addition, groups fully able to consider research risks and informed consent should be asked to face research risks before more vulnerable populations. Investigational drugs are usually tested in adults before they are tested in children. Certain

investigational drugs and procedures may be tested in healthy volunteers before being tested in patients.

**1.2.3.2** Sharing Research Benefits. In recent years, increasing attention has been paid to the rights of various groups to be included in research. As individuals and through advocacy groups, many patients have come to insist on having access to experimental treatments as these experimental treatments may potentially provide the best medical care available. In addition, investigators, ethicists, and public officials have recognized that because many clinical trials focus primarily on white, middle-class research subject groups, the results of some trials were of questionable value for members of other social, racial, sexual, and ethnic groups. As a result, both the National Institutes of Health and the Food and Drug Administration now require that study design include as broad a range of research subjects as feasible and the data be analyzed to uncover responses that differ between groups. Where women of childbearing potential and pregnant and nursing women previously were routinely excluded from new drug trials, it is now required that whenever possible these women be asked to make their own choices after being fully informed of the risks of the research.

## 2 DEFINITIONS

The following definitions apply to these Policies and Procedures.

See Section 18 for additional definitions relating to human subjects research covered by FDA regulations.

“**Common Rule**” means the Federal Policy for Protection of Human Subjects administered by DHHS and codified at 45 CFR 46, Subpart A.

“**CUNY**” or the “**University**” means The City University of New York.

“**DHHS**” means the U.S. Department of Health and Human Services.

“**FDA**” means the United States Food and Drug Administration.

“**Federal Regulations**” means the Common Rule and Subparts B, C, and D of the DHHS regulations at 45 CFR 46.

“**Human subject**” means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. “**Obtain**” means receive or access identifiable private information or identifiable specimens for research purposes. This includes an investigator’s use, study, or analysis for research purposes of identifiable private information or identifiable specimens already in the possession of the investigator. “**Intervention**” includes both physical procedures by which data are



gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. **"Interaction"** includes communication or interpersonal contact between investigator and subject. This includes surveys and questionnaires, even if there is no direct contact between the investigator and subject. **"Private information"** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, medical records, driver's license records, birth records, or student records). Private information must be individually identifiable (that is, the identity of the subject is or may readily be ascertained by the investigator or anyone associated with the information) in order for obtaining the information to constitute research involving human subjects.

**"Human Subjects Research"** means "research" involving a "human subject," as those terms are defined in this Section 2.

In addition, student research (that is, a student project involving the gathering of data from living individuals outside the classroom), if it involves obtaining data in a "systematic investigation" (as defined below) through intervention or interaction with the individual, or identifiable private information, is considered human subjects research, if the activity is designed to develop or contribute to generalizable knowledge. Such research must meet all of the requirements of these Policies and Procedures. See Section 19.5 for details on the procedures for IRB review of student research.

**"IRB"** means an Institutional Review Board established in accordance with and for the purposes expressed in these Policies and Procedures.

**"IRB approval"** means the determination of the IRB that the research has been reviewed and may be conducted under the auspices of an institution within the constraints set forth by the IRB and by other applicable institutional, federal, state, and local requirements.

**"Minimal risk"** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For research involving prisoners, "minimal risk" is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

**"OHRP"** means the Office for Human Research Protections, or any successor office, at DHHS.

**"ORC"** means the CUNY Office of Research Conduct.

“**PI**” means Principal Investigator.

“**Research**” means a “**systematic investigation**” (as defined in this Section 2), including research development, testing, and evaluation, designed to develop or contribute to “**generalizable knowledge**” (as defined in this Section 2). Research covered by these Policies and Procedures may be funded or unfunded, or may be conducted as a component of another program not usually considered research. For example, a demonstration or service program not intended to be, or designed as, a research project may later include a research component intended to address questions encountered in the process of administering the program, or may include evaluation components that constitute “research” under this definition.

“**RFCUNY**” means The Research Foundation of The City University of New York.

“**Systematic investigation**” means an activity that involves a retrospective or prospective research plan that incorporates data collection, both quantitative and qualitative, and/or data analysis to answer a research question. Investigations designed to develop or contribute to “**generalizable knowledge**” are those designed to draw general conclusions (that is, knowledge gained from the study may be applied to populations outside of the specific study population).

### **3 INSTITUTIONAL AUTHORITY**

#### **3.1 Assurance of Compliance**

CUNY and RFCUNY jointly hold FederalWide Assurance (FWA) for the Protection of Human Subjects for Institutions within the United States, Number FWA00003623. As part of the FWA, CUNY and RFCUNY have agreed to apply the Common Rule to all human subjects research that CUNY becomes engaged in that is conducted or supported by any federal department or agency that has adopted the Common Rule, unless the research is otherwise exempt from the requirements of the Common Rule or the federal agency or department determines otherwise.

#### **3.2 Vice Chancellor for Research**

The Chancellor of CUNY has designated the Vice Chancellor for Research as the responsible official for carrying out the University’s human research protections program. The Vice Chancellor for Research and the President of RFCUNY serve as the Signatory Officials on the FWA. The Vice Chancellor for Research, after consultation with the Office of the General Counsel, is authorized to amend these Policies and Procedures as needed to reflect changes in the law, including the Federal Regulations and CUNY policy.

### **3.3 CUNY Office of Research Conduct**

The CUNY Office of Research Conduct (ORC) has day-to-day responsibility for oversight of the University's human research protections program including oversight of all CUNY IRBs. The ORC is located within CUNY's Office of Academic Affairs, reports to the Vice Chancellor for Research, and works in concert with the President of RFCUNY. The ORC is supervised by an Executive Director with expert knowledge in regulatory issues regarding human subjects. The ORC Executive Director serves as the Human Research Protections Administrator, the principal point of contact at CUNY with the Office for Human Research Protections at DHHS.

The ORC's responsibilities include:

- oversight of all CUNY IRBs, including reviewing composition and evaluating performance of the IRBs and their members. The ORC may make recommendations as needed to the Vice Chancellor for Research to provide assistance to IRBs or members to improve performance, to suspend or terminate IRBs, or to remove members. The ORC may review IRB minutes, files, correspondence, and deliberations and may take other steps to evaluate IRB competency and actual or potential conflicts of interest of IRB members and staff, investigators, and key personnel.
- monitoring compliance by IRBs, investigators, and CUNY with applicable law and these Policies and Procedures;
- training IRB members and staff, CUNY investigators and key personnel, and CUNY officials;
- acting as a resource for IRBs, CUNY investigators, CUNY, and for information regarding human subjects research; and
- updating and maintaining these Policies and Procedures.

The ORC will review the membership and activity of the IRBs on an annual basis, or as needed, and make a determination as to the appropriate number of IRBs for CUNY, the effectiveness of the IRBs, and the compliance of the IRBs with applicable law and these Policies and Procedures.

In addition, the ORC has the authority to:

- determine whether specific projects constitute human subjects research;
- suspend, place restrictions on, or terminate approval of research activities that are not being conducted in accordance with applicable law and these Policies

and Procedures or that have been associated with unexpected adverse events;  
and

- observe or have a third party observe the consent process and the research if the ORC determines it to be appropriate.

The ORC may not approve IRB applications.

### **3.4 State and Local Law**

CUNY and its IRBs rely on the CUNY Office of the General Counsel for interpretations and applications of New York State and New York City law as it applies to human subjects research.

### **3.5 Institutional Review Boards**

The CUNY IRBs have jurisdiction over all human subject research conducted under the auspices of CUNY. See Section 4 for a full description of the CUNY IRBs.

### **3.6 Changes in Titles and Vacancies in Positions**

Officials with responsibilities under these Policies and Procedures are identified by titles that are current as of the effective date of these Policies and Procedures. If the title for a particular position changes at any time, the responsibilities under these Policies and Procedures will be performed by the individual having responsibilities similar to the individual who held the former title. If there is a vacancy at any time in the position, the responsibilities will be assumed by the individual to whom such position reports or to his or her designee.

## **4 CUNY INSTITUTIONAL REVIEW BOARDS**

The CUNY IRBs are administrative bodies established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of CUNY. These IRBs have been established in accordance with the requirements of current law.

### **4.1 IRB Program Structure**

Local IRBs are composed to give representation to each of the CUNY colleges. CUNY also has one “CUNY-Wide” IRB composed of all of the local IRB Chairs, as well as RFCUNY and community representation.

## 4.2 Authority of the IRBs

- 4.2.1** The IRBs at CUNY review and have authority to approve, require modifications in, or disapprove all human subject research activities conducted under the auspices of CUNY. In carrying out these activities, each local IRB has the authority to (i) suspend, place restrictions on, 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 unexpected adverse events, and (ii) observe or have a third party observe the consent process and the research if the IRB determines it to be appropriate.
- 4.2.2** The IRBs are required to ensure that appropriate safeguards exist to protect the rights and welfare of research subjects. In fulfilling these responsibilities, the IRBs shall review all the research documents and activities that bear directly on the rights and welfare of the subjects of proposed research. The protocol, consent documents, research materials (surveys, standardized instruments, etc.), applications for funding and the investigator's brochure for studies conducted under the Investigational New Drug (IND) regulations are examples of documents that the IRBs are authorized and obligated to review. The IRBs shall also review the methods and materials that investigators propose to use to recruit subjects.
- 4.2.3** Before any human subject is involved in research under the auspices of CUNY, an IRB shall give proper consideration to:
1. the risks to the subjects;
  2. the anticipated benefits to the subjects and others;
  3. the importance of the knowledge that may reasonably be expected to result; and
  4. the informed consent process to be employed.

## 4.3 Jurisdiction of the IRBs

- 4.3.1** Local IRBs. A local IRB's jurisdiction extends to **all** research (funded and not funded) involving human subjects conducted at the campus or campuses it serves, as well as **all** such research conducted elsewhere by the faculty, staff, and students of such campus or campuses.
- 4.3.2** CUNY-Wide IRB.
- 4.3.2.1** The CUNY-Wide IRB reviews:
1. multi-campus protocols (see Section 7.6.8);

2. CUNY Central Office protocols;
3. RFCUNY Central Office protocols;
4. protocols of College administrators, including presidents and provosts; and
5. appeals of disapproved protocols (see Section 7.11).

**4.3.2.2** The CUNY-Wide IRB also has authority to conduct an initial review of any protocol in the following situations:

1. the appropriate local IRB is not able to do so because of inability to obtain a quorum or other failure to meet the requirements of these Policies and Procedures;
2. the appropriate local IRB has an unmanageable conflict of interest. For purposes of these Policies and Procedures, a local IRB is always deemed to have an unmanageable conflict of interest with respect to protocols of administrators serving the College(s) associated with such local IRB;
3. at the request of a PI, subject to the approval of the ORC Executive Director, because of a local IRB's failure to review the protocol in a timely manner; or
4. any other reason deemed appropriate by the ORC Executive Director.

**4.3.2.3** The CUNY-Wide IRB may make recommendations to the Vice Chancellor for Research for updates and changes to these Policies and Procedures, and shall consider such other matters as may be referred to it by the Vice Chancellor or the ORC Executive Director.

#### **4.4 Relationship of IRBs to CUNY and Other Institutions**

**4.4.1** Relationship to CUNY. Each IRB functions independently of, but in coordination with, other parts of CUNY. An IRB makes its independent determination whether to approve or disapprove a protocol based upon whether or not human subjects are adequately protected. Research that has been reviewed and approved by the IRB may be subject to further review and approval or disapproval by CUNY officials, such as the Chancellor, the Office of General Counsel, and college presidents. However, no institutional official may approve research that has been disapproved by the IRB. [45 CFR 46.112]

**4.4.2** Relationships with Other Institutions

- 4.4.2.1** CUNY may choose, on a case-by-case basis, to provide human research protection oversight for another institution. In order for the University to provide this oversight, a formal relationship must be established between the University and the other institution through either a cooperative agreement or a memorandum of understanding. This relationship must be formalized before the University will accept any human research proposals from the other institution.
- 4.4.2.2** In the conduct of cooperative research projects, CUNY acknowledges that each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with applicable law. When a cooperative agreement exists, CUNY may enter into a joint review arrangement, rely on the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort. When doing so, CUNY shall ensure that the review arrangement is approved, in writing, by OHRP and by the appropriate officials of the institutions involved, and that the particular characteristics of its local research context are considered, either (i) through knowledge of its local research context by the CUNY IRB reviewing the project, or (ii) through subsequent review by appropriate designated institutional officials, such as the IRB Chair and/or other IRB members.
- 4.4.2.3** When CUNY is the coordinating center for a multi-center protocol, the IRB will require the CUNY Principal Investigator to ensure that IRB approval has been obtained at each participating site prior to initiation of the research at that site. At the time of initial review, the IRB will assess the procedures for dissemination of protocol information (for example, unanticipated problems involving risks to subjects or others, protocol modifications, or interim findings) to all participating sites.

## **4.5 IRB Officers**

- 4.5.1** Appointment of IRB Officers. Each IRB shall have at least two officers: a Chair and a Vice Chair. The IRB Chair and the Vice Chair shall be individuals with management skills and substantive experience in conducting or reviewing human subjects research and shall have a thorough knowledge of these Policies and Procedures.
- 4.5.1.1** Local IRBs. The President or his or her designee, such as a Chief Academic Officer at the campus(es) served by an IRB, shall recommend to the Vice Chancellor for Research individuals to serve as Chair and Vice Chair for the IRB. After consultation with the ORC Executive Director and the Vice Chancellor for Research, the President or his or her designee shall make the appointments. The IRB Chair and Vice Chair shall each serve a three-year term, which may be renewed no more than twice.

- 4.5.1.2** CUNY-Wide IRB. The Vice Chancellor for Research and the ORC Executive Director shall solicit nominations from the CUNY-Wide IRB and other CUNY officials for the position of CUNY-Wide IRB Chair. The nominees must meet the requirements for voting membership on the CUNY-Wide IRB. The final selection shall be made by the Vice Chancellor for Research after consultation with the ORC Executive Director and the Chair of the University Faculty Senate.
- 4.5.2** Resignation. An IRB Chair or Vice Chair may resign by written notice to the President or his or her designee, such as a Chief Academic Officer at the campus(es) served by an IRB. In addition, the Vice Chancellor for Research may remove any IRB officer he or she has appointed.
- 4.5.3** Notification to the ORC. The Vice Chancellor for Research shall give the ORC written notification of each appointment and any changes, including reappointment or removal, so that it may in turn notify OHRP.
- 4.5.4** Duties of the IRB Chair. The IRB Chair shall manage the IRB and any matters brought before it. The IRB Chair is responsible for conducting the meetings of the IRB and is a signatory on correspondence generated by the IRB. The IRB Chair may designate signatory authority to the IRB staff for correspondence related to requests for revisions, requests for additional information, requests for final reports, and renewal reminders. The IRB Chair may create subcommittees of the IRB to perform specific duties, such as expedited review of protocols. The IRB Chair shall advise the Vice Chancellor for Research and the ORC Executive Director about IRB member performance and competence.
- 4.5.5** Duties of the Vice Chair of the IRB. The Vice Chair shall serve as the Chair of the IRB in the absence of the IRB Chair and shall have the same authority and duties as the IRB Chair.

#### **4.6 Subcommittees of the IRBs**

- 4.6.1** Composition and Appointment. Subcommittees of an IRB shall consist of one or more individuals appointed by the IRB Chair to perform specific duties of the IRB. With the exception of an evaluation subcommittee, as described below, subcommittees shall consist of IRB members.
- 4.6.2** Duties. Duties of a subcommittee may include the following:
1. Conducting expedited review of new or continuing protocols, and/or modifications of continuing protocols. Individuals on this type of subcommittee must have served on an IRB for at least one year and should be matched as closely as possible with protocols involving research within their field of expertise.



2. Reviewing and approving nonsubstantive revisions submitted by investigators for protocols previously reviewed by the convened IRB.
3. Evaluating the inquiry process. The IRB Chair may appoint a subcommittee consisting of IRB members, and nonmembers if appropriate, to ensure fairness and expertise of an inquiry process. The subcommittee would be given a charge by the IRB, which can include any or all of the following:
  - a. Review of protocol(s) in question;
  - b. Review of any relevant documentation, including consent documents, case report forms, subject's investigational and/or medical files, etc., as it relates to the investigator's execution of her/his study involving human subjects;
  - c. Review of the FDA audit report of the investigator;
  - d. Interview of appropriate personnel;
  - e. Preparation of either a written or oral report of the findings, which would be presented to the full IRB at its next meeting; and
  - f. Recommendation of actions.
4. Conducting on-site reviews.

#### **4.7 Resources for IRBs**

It is the responsibility of the Chief Academic Officers to provide sufficient resources to the local IRBs, 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, shall be made available to the IRB and staff. The ORC will review the resources provided for the IRBs and local IRB offices during the annual budget review process.

#### **4.8 Conduct of Quality Assurance/Quality Improvement Activities for IRB Operation**

- 4.8.1** The ORC shall monitor and review the processes and procedures of each local IRB to ensure effectiveness, efficiency, and compliance with applicable law and these Policies and Procedures.
- 4.8.2** The local IRB office staff shall conduct investigations and audits of ongoing research when the IRB directs an audit be conducted, or a complaint or allegation of noncompliance is received. In addition, the staff shall conduct “not for cause” audits of research. (See Section 15.2 for a discussion of investigations and audits.)

## 4.9 Report of Undue Influence

If an IRB Chair, member, or staff person feels that an IRB has been unduly influenced by any party, he or she make a confidential report to the Vice Chancellor for Research, who shall thereafter conduct a thorough investigation and, if the findings warrant it, take appropriate corrective action to remedy that occurrence and/or to prevent additional occurrences.

## 5 IRB MEMBERSHIP [45 CFR § 46.107]

### 5.1 Composition of the IRBs

- 5.1.1 Minimum Number of Members.** Each CUNY IRB shall have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the University.
- 5.1.2 Qualifications.** Each IRB will be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
- 5.1.3 Knowledge of Policies, Laws, and Standards.** In addition to possessing the professional competence necessary to review specific research activities, each IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRBs shall, therefore, include persons knowledgeable in these areas.
- 5.1.4 Scientist and Nonscientist Members.** Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. Individuals qualify as “nonscientific” if their training and/or degree is in a nonscientific area (for example, law, business, or humanities) or if their primary occupation is nonscientific (for example, clergy, business, arts, or social service).
- 5.1.5 Nonaffiliated Member.** Each IRB shall include at least one member who is not otherwise affiliated with CUNY and who is not part of the immediate family of a person who is affiliated with the institution. “Affiliated with CUNY” includes individuals taking credit or noncredit courses at CUNY.
- 5.1.6 Experience with Vulnerable Populations.** If any of the IRBs regularly reviews research that involves a vulnerable category of subjects (for example, children, prisoners, pregnant women, or handicapped or mentally disabled persons),

consideration shall be given to the inclusion of one or more individuals on the IRB knowledgeable about and experienced in working with these subjects.

- 5.1.7 Biomedical Expertise.** If any of the IRBs regularly reviews research that involves biomedical procedures (such as physical therapy, blood draw, X-ray, or administration of drugs), consideration shall be given to the inclusion of one or more individuals on the IRB knowledgeable about and experienced in working with these procedures.
- 5.1.8 Nondiscrimination.** Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including CUNY's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB shall consist entirely of members of one profession.
- 5.1.9 Multiple Categories.** One member may satisfy more than one membership category.
- 5.1.10 Student Members.** A CUNY student may serve as a voting member of a local IRB. A prospective student member must provide written approval from his or her advisor to serve as an IRB member.

## **5.2 Appointment of Members to the IRB**

### **5.2.1 Local IRBs**

- 5.2.1.1** The President or his or her designee, such as a Chief Academic Officer at the campus(es) served by an IRB, is responsible for appointing members and alternates to that IRB, filing vacancies, and, with the assistance of the ORC Executive Director, ensuring that the IRB's composition meets the requirements of Section 5.1 above. The President or his or her designee, such as a Chief Academic Officer shall solicit nominations from Department Chairs, Program Directors, and others, including seeking advice regarding potential candidates from the IRB Chair and the ORC Executive Director. Except where necessary to achieve a diverse and experienced IRB, membership by untenured faculty is discouraged.
- 5.2.1.2** The IRB Chair, Vice Chair, and the ORC Executive Director shall promptly alert the President or his or her designee, such as a Chief Academic Officer, whenever they become aware of the need for a new, replacement, or alternate member.
- 5.2.1.3** IRB Members shall serve a three-year term, except that student members shall serve two-year terms. Members may be re-appointed. Members may resign by written notification to the IRB Chair. In addition, a President or his or her designee, such as a Chief Academic

Officer at the campus(es) served by an IRB, may remove for cause any IRB Member he or she has appointed, with the consent of the Vice Chancellor for Research.

- 5.2.1.4** The President or his or her designee, such as a Chief Academic Officer at the campus(es) served by an IRB, shall give the ORC prompt written notice of all appointments, re-appointments, and changes in appointment of IRB members.

## **5.2.2 CUNY-Wide IRB**

- 5.2.2.1** All campuses shall be represented on the CUNY-Wide Board as either voting members, alternates, or nonvoting members. There shall be at least five and no more than nine voting members, including representatives from both senior and community colleges, a member from RFCUNY, and a community member. Voting members must have two years or more experience as a local IRB Chair and/or member.
- 5.2.2.2** At the beginning of each academic year, the ORC Executive Director will solicit volunteers for the voting member positions from among the eligible CUNY-Wide Board members. In the event that there are an insufficient number of volunteers, the Executive Director shall appoint voting members from the Board. In doing so, the Executive Director shall comply with the composition requirements described in the previous paragraph.
- 5.2.2.3** All CUNY-Wide IRB members with more than one year but less than two years of experience as a local IRB Chair and/or member are designated alternate voting members of the CUNY-Wide Board. CUNY-Wide IRB members with less than one year of experience serve on the CUNY-Wide Board as nonvoting members. The CUNY-Wide IRB may also have community member alternate(s) in addition to the required voting member, and medical and prisoner advocate representative alternates rather than voting members.
- 5.2.2.4** Each CUNY-Wide IRB Board member is encouraged to contribute to the discussion of issues not requiring his or her recusal.

## **5.3 Alternate Members**

The appointment and function of alternate members is the same as that for primary IRB members, and the alternate's expertise and perspective shall be comparable to those of the primary member. The IRB roster shall identify the primary member(s) for whom each alternate member may substitute. Alternates may attend any IRB meeting and are encouraged to attend as many meetings as possible. An alternate member shall not be counted as a voting member unless the primary member is absent. However, the

alternate member may freely participate in the discussion. When an alternate member substitutes for a primary member, the alternate member shall receive and review the same materials prior to the IRB meeting that the primary member received or would have received. The IRB minutes shall document when an alternate member replaces a primary member.

#### **5.4 Use of Consultants (Outside Reviewers)**

- 5.4.1** An IRB may, at its discretion, invite individuals consultants with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals consultants may not vote with the IRB.
- 5.4.2** Prior to committing to any consultant's assistance, the IRB shall ask the consultant whether he or she has any of the roles described in Section 5.5.1.1 or any actual or potential conflict of interest described in Section 7.6.5 with respect to the protocol in question. Consultants who have any such role or conflict of interest, or whose household or family members have any such role or conflict of interest, may not provide consultation to the IRB.
- 5.4.3** The consultant's findings shall be presented either in person or in writing to the full IRB for consideration. If the consultant presents in person, he or she may provide advice or answer questions, but shall not participate in or observe the vote.
- 5.4.4** Ad hoc or informal consultations requested by individual IRB members (rather than the full board) shall be requested in a manner that protects the investigators' confidentiality and is in compliance with Section 5.4.2.

#### **5.5 Conflict of Interest – IRB Members/IRB Staff Members**

##### **5.5.1 Definition**

- 5.5.1.1** An IRB member will have a conflict of interest if he or she has one or more of the following roles with respect to the study in question:
1. Principal Investigator;
  2. Co-investigator;

3. Investigator or key personnel receiving funding from the study, as listed in the study budget;
4. Supervisor over the investigators of the study;
5. Faculty advisor to the investigator(s); or
6. Family member of PI.

**5.5.2** Rule. No IRB member or IRB staff member with a conflict of interest may participate in the IRB's initial or continuing review of a protocol, except to provide information requested by the IRB [45 CFR 46.107(e)], or vote on an IRB action for a protocol. See Section 7.5.7.2 regarding recusal.

### **5.5.3** Disclosure

**5.5.3.1** Each IRB member or IRB staff member is responsible for disclosing to the IRB Chair and/or the local IRB office any conflict of interest described in Section 5.5.1.1 that he or she may have concerning a protocol to be reviewed by the IRB. See Section 7.5.7

**5.5.3.2** If the conflict of interest status of an IRB member or IRB staff member changes during the course of the research, he or she shall disclose the change to the IRB Chair and/or the local IRB office within ten working days of his or her knowledge of the change.

## **5.6 Duty of Care**

The agenda, submission materials, protocols, proposed informed consent forms, continuing review forms and other appropriate documents (including research materials) regarding a research project shall be distributed to IRB members prior to the convened meeting at which the research is scheduled to be discussed. Each member shall review these materials at least one week before the meeting in order to participate fully in the review of the proposed project.

## **5.7 Confidentiality of Review Materials**

Each IRB member shall treat confidentially the research proposals, protocols, supporting data, and other documents and information he or she receives and reviews. Each member shall return all copies of these documents and information to the IRB staff at the conclusion of the review. The IRB staff shall shred or otherwise destroy these documents and information.

## **5.8 Attendance Requirements**

If an IRB member is unable to attend a scheduled meeting, he or she shall inform the IRB Chair or the local IRB office. If an IRB member is to be absent for an extended period of time, such as for a sabbatical, he or she shall notify the IRB Chair and the ORC Executive Director at least 30 days in advance, if possible, 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 (see Section 5.3), the alternate can serve during the primary member's absence, provided the IRB Chair and the ORC Executive Director have been notified in advance. The ORC shall amend the IRB roster to reflect the replacement.

## **5.9 Training and Ongoing Education**

A vital component of a comprehensive human research protection program is an education program for IRB Chairs, members, and staff. CUNY is committed to providing training and ongoing education for IRB Chairs, members, and staff of the local IRB offices related to the ethical conduct of research with human subjects. This training may be provided by the ORC, local IRB offices, and/or outside experts.

### **5.9.1 Orientation**

**5.9.1.1** Each new IRB member, including alternate members, shall meet with the IRB Chair and the ORC Executive Director for an informal orientation session prior to starting his or her service on an IRB. At the session, the new member will be given educational materials that include the Belmont Report, these Policies and Procedures, and the Federal Regulations relevant to their IRB.

**5.9.1.2** Each new member is also required to complete the Initial Education (see Section 5.9.2) for IRB members before he or she may serve as a primary reviewer.

**5.9.2 Initial Education.** CUNY maintains a subscription to the web-based "CITI Course in the Protection of Human Research Subjects" sponsored by the Collaborative Institutional Training Initiative (CITI). All IRB Chairs, members, and staff must complete the "IRB Members and Staff" Learner's Group modules of the CITI program with an overall competency level of at least 80% before they begin their IRB service.

**5.9.3 Continuing Education.** To ensure that CUNY's oversight of human subjects research under its auspices is ethically grounded and the decisions made by its IRBs are consistent with current regulatory and policy requirements, IRB members shall receive continuing education throughout their service on the IRBs. Educational activities shall include, but are not limited to:

- In-service training at IRB meetings;
- In-service training for IRB Chairs at CUNY-Wide IRB meetings;
- Annual training symposium or other workshops;
- Dissemination by the ORC of publications relevant to human research protection, including current news articles, and books such as “Institutional Review Board Management and Function” by Bankert and Amdur and “Institutional Review Board: Member Handbook”; and
- CITI refresher modules every three years.

### **5.10 Liability Coverage for IRB Members**

CUNY is indemnified by New York State (in the case of the senior colleges) and New York City (in the case of community colleges) pursuant to § 6205 of the NYS Education Law. CUNY employees and community representatives who are members of a CUNY IRB will be indemnified against claims or judgments arising out of their service as IRB members pursuant to this statute. RFCUNY employees who are members of a CUNY IRB will be indemnified pursuant to the RFCUNY’s general liability policies.

### **5.11 Review of IRB Member Performance**

Each IRB member’s performance will be reviewed on an annual basis by the local IRB Chair and Vice Chair, who are authorized to recommend to the Chief Academic Officer that a member be removed for cause, such as failure to comply with these Policies and Procedures or having an undue number of absences. The IRB Chair and the Vice Chair must report all removals to the ORC. In addition, the ORC will monitor and evaluate IRB members’ performance on a regular basis and is also authorized to recommend removal of a member for cause.

## **6 IRB RECORDS**

### **6.1 General – Documentation of Activities**

**6.1.1 Items Reviewed.** Each IRB must prepare and maintain adequate documentation of its activities. This includes receiving, maintaining and retaining copies of all items reviewed in accordance with Section 6.5, such as:

- research proposals;
- recruitment materials;
- scientific evaluations that accompany the proposals;
- approved consent documents;



- approved HIPAA Authorization documents;
- funding applications; and
- investigators' brochures.

**6.1.2** Statements of Significant Findings. The IRB shall maintain with the related research proposal any statements of significant new findings provided to subjects. When presented at an IRB meeting, these statements must be documented in the minutes. These statements must be retained in accordance with Section 6.5.1.

**6.1.3** Other Documentation. In addition, each IRB must record, maintain and retain copies of the following documents in accordance with Section 6.5.1:

1. action on each amendment to a proposal;
2. progress reports submitted by investigators;
3. reports of injuries to subjects and serious and unexpected adverse events;
4. documentation of protocol violations;
5. documentation of noncompliance with applicable regulations;
6. continuing review activities; and
7. all correspondence between the IRB and investigators.

## **6.2 Minutes of an IRB Meeting**

**6.2.1** The staff of each IRB shall prepare written minutes of the IRB's proceedings and retain them in accordance with Section 6.5.1. The staff shall make the minutes available for review by the next regularly scheduled IRB meeting. Once approved by the IRB members, the minutes shall not be altered.

**6.2.2** Minutes of an IRB meeting shall contain sufficient detail to show:

1. The presence of a quorum throughout the meeting, including the presence of one member whose primary concern is in a nonscientific area;
2. All individuals in attendance at the meeting, including IRB members (whether attending in person or via videoconference or teleconference), IRB staff, consultants, investigators, and guests, and identifying any representatives of vulnerable populations;

3. Documentation that those attending through videoconferencing or teleconferencing received all pertinent material prior to the meeting and were able to actively and equally participate in all discussions;
4. Alternate members attending the meeting and, if voting, for whom they were substituting;
5. Actions taken by the IRB, including those involving full review. The IRB shall use the minutes, via the Chair's Report, to notify IRB members of actions taken through expedited or exempt review;
6. Separate deliberations, actions, and votes for each protocol undergoing continuing review by the convened IRB;
7. Protocol-specific documentation that the research meets the required criteria (see Section 9.3.1), if approving a consent procedure that does not include or that alters some or all of the required elements of informed consent, or if waiving the requirement to obtain an informed consent;
8. Protocol-specific documentation that the research meets the required criteria (see Section 9.3.2), if the requirements for documentation of consent are being waived;
9. When approving research that involves vulnerable populations covered by Subparts B, C, or D of 45 CFR 46, documentation of 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;
10. The vote on actions, including the number of members voting for, against, and abstaining;
11. That, when an IRB member or IRB staff member has a conflict of interest relative to the protocol under consideration (see Section 5.5.1.1), he or she was not present during the deliberations or voting on the protocol and that the quorum was maintained;
12. The basis for requiring changes in or disapproving research, and documentation of resolution of these issues when resolution occurs;
13. A written summary of the discussion of controverted issues and their resolution;
14. Review of additional safeguards to protect vulnerable populations when enrolled as study subjects, if this is not otherwise documented in IRB records;

15. The determination of the level of risk, if not recorded elsewhere in IRB records;
16. The frequency of continuing review of each proposal, as determined by the IRB, if not recorded elsewhere in IRB records;
17. Documentation, as required by 45 CFR 164(i)(2), indicating the approval of a waiver or alteration of the HIPAA Authorization.

### **6.3 Membership Rosters**

- 6.3.1** Each local IRB office shall maintain and keep current a list of its members and copies of their resumes and retain these documents in accordance with Section 6.5.1. . This list shall identify members sufficiently to describe each member's chief anticipated contributions to IRB deliberations. The list shall contain the following information for each member: name, earned degrees and other indications of experience, affiliated or nonaffiliated status with CUNY, status as scientist (physician-scientist, other scientist, nonscientist, or social behavioral scientist), voting status, alternate status, and status as IRB Chair.
- 6.3.2** The local IRB office shall promptly report changes in IRB membership to the ORC, which will submit the changes to OHRP.

### **6.4 Security of IRB Records**

- 6.4.1** Each IRB shall maintain its records in a secure manner. Written records of local IRBs shall be kept in locked file cabinets at the IRB office or otherwise in a secure place that is accessible only by IRB members (including the IRB Chair) and IRB office staff. Electronic records shall be password protected with similar access limitations. The IRB office staff shall keep file access logs, indicating who accessed the files other than the IRB members and IRB office staff; what files were accessed; when files were accessed; and for what purpose the files were accessed.
- 6.4.2** All IRB records shall be accessible for inspection and copying by authorized representatives of CUNY, OHRP, the FDA, and other authorized entities at reasonable times and in a reasonable manner.

### **6.5 Records Retention Requirements**

- 6.5.1** IRB Records. The CUNY Records Retention and Disposition Schedule (available at <http://policy.cuny.edu/text/toc/rrs>) prescribes the following retention requirements for records to be retained by CUNY IRBs:
  1. Minutes of IRB meetings, and agendas, handouts, and other items prepared for the IRB meetings that are included as part of the minutes, must be retained permanently.

2. Records not included in the minutes of IRB meetings that relate to individual research protocols must be retained for at least three years after the research is concluded or otherwise terminated; provided, however, that for research protocols involving identifiable minors as human subjects and more than minimal risk to the subjects, such records must be retained at least until the youngest of these minors reaches the age of 21.
3. Records not included in the minutes of IRB meetings that do not relate to individual research protocols must be retained for at least three years.

6.5.2 Investigator Records. There are certain records that investigators must retain in connection with individual research protocols, such as informed consents and HIPAA Authorization forms signed by the subjects. These records must be retained for at least three years after the research is concluded or otherwise terminated; provided, however, that for research protocols involving identifiable minors as human subjects and more than minimal risk to the subjects, such records must be retained at least until the youngest of these minors reaches the age of 21.

## **7 IRB REVIEW**

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

### **7.1 Initiation of Research Projects**

All research involving human subjects must be reviewed and approved by the IRB prior to initiation of the research project. Approved research is subject to continuing review by the IRB at least yearly, or more frequently if specified by the IRB [45 CFR 46.109(e)]. The date of continuing review will be based on the date of IRB approval. [see Continuing Review for further details.]

The approval date and the termination (expiration) date are clearly noted on all IRB certifications sent to the PI and must be strictly adhered to. Sufficient time must be allowed for development and review of renewal submissions. By federal regulation, no extension to that date can be granted.

If a protocol has expired, it must be resubmitted for appropriate IRB review.

Research activities are subject to internal audit and verification from sources other than the investigator that no material changes have occurred since the last IRB review.

The IRB and the CUNY ORC reserve the right to observe the consent process conducted under any research protocol and to inspect the records of investigators to ensure the protection of the human research subjects.

## **7.2 Human Subjects Research Determination**

The responsibility and authority for determining whether an activity constitutes human subjects research rests with the IRB and the ORC. Since the University will hold the investigator responsible for obtaining appropriate review of research involving human subjects, investigators are urged to request a determination of whether an activity constitutes human subjects research—and therefore requires review—from the local IRB office or the ORC. Requests may be made verbally (by phone or in person) or in writing, including by e-mail or on the ORC's research determination form. Investigators should include sufficient information regarding the activity to allow a determination to be made. The IRB or the ORC may require that a verbal request be re-submitted in writing or supported with documentation, if necessary for the determination. If the request and determination are verbal, it is the investigator's responsibility to retain his or her own documentation of the request and the IRB's or the ORC's decision in accordance with Section 6.5.2. If the request is in writing, the local IRB or the ORC will also respond in writing. The local IRB office must retain a copy of all submitted materials and determination notices, and a record of determinations made, in accordance with Section 6.5.1.

CUNY must review all research conducted under its auspices that uses human subjects. Certain categories of research, such as "exempt research" and "expedited research," do not require convened IRB review and approval and are described further below.

## **7.3 Exempt Research [45 CFR 46.101]**

Certain categories of human subjects research (see below) are exempt from the Federal Regulations. Such research is nevertheless subject to CUNY review and any determination of exemption shall be made by the IRB Chair or Vice Chair, or by another reviewer designated by the IRB Chair from among members of the IRB.

A student may assume the role of principal investigator conducting exempt research so long as he or she has a faculty advisor who will serve as co-investigator and faculty advisor on the study. See Section 19.5.2.1.

**7.3.1** Categories of Research Permissible for Exemption. Subject to the limitations in Section 7.3.2, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from continuing IRB review, as determined by the IRB Chair or Vice Chair:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on

regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. [NOTE: See Section 7.3.2.1 for limitations on this exemption for research involving children.]
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2), if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. [NOTE: In order to be eligible for this exemption, all of the materials have to exist at the time the research is proposed.]
5. Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed; or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

## **7.3.2 Limitations on Exemptions**

- 7.3.2.1 Children.** Research involving survey or interview procedures or observations of public behavior with children does not qualify for exemption, except for research involving observations of public behavior when the investigator does not participate in the activities being observed. (See Section 11.1.1 for the definition of “children.”)
- 7.3.2.2 Prisoners.** Research involving prisoners does not qualify for exemption. (See Section 13.2.1 for the definition of “prisoner.”)
- 7.3.2.3 Nonrenewable.** Approval of exempt research is nonrenewable. The duration of study for exempt research is limited to that specified on the approved application, not to exceed three years. Investigators wishing to continue exempt research beyond the period specified on the approved application must submit a new application to the IRB for approval at the conclusion of the original period.
- 7.3.2.4 Belmont Report Applies.** Although exempt research is not covered by the Federal Regulations, this research is not exempt from the ethical guidelines of the Belmont Report. The individual making the determination of exemption has the authority to require additional protections for subjects in keeping with the guidelines of the Belmont Report, even though the research falls within an exempt category.

## **7.4 Expedited Review of Research [45 CFR 46.110]**

All nonexempt human subjects research must be reviewed by either the convened IRB or a subcommittee of the IRB. Research eligible for “expedited” review may be reviewed by a subcommittee of the IRB, subject to the following information.

- 7.4.1 Research Subject to Expedited Review.** An IRB may use the expedited review procedure to review either or both of the following:
1. some or all of the research appearing on the list in Section 7.4.5 below and found by the reviewer(s) to involve no more than minimal risk
  2. minor changes in previously approved research during the period for which approval is authorized. A “minor change” is one which, in the judgment of the IRB reviewer, makes no substantial alteration in:
    - a. the level of risks to subjects;
    - b. the research design or methodology;
    - c. the number of subjects enrolled in the research (no greater than 10% of the total requested);

- d. the qualifications of the key personnel;
- e. the facilities available to support safe conduct of the research; or
- f. any other part of the research that would otherwise warrant review of the proposed changes by the convened IRB.

#### **7.4.2** Limitations.

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

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

**7.4.2.3** The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

**7.4.3** Procedure. Under an expedited review procedure, the review may be carried out by the IRB Chair or by one or more reviewers (for example, a subcommittee of the IRB) designated by the IRB Chair from among members of the IRB.

**7.4.3.1** Experience. IRB members serving as designees to the IRB Chair for expedited review shall be experienced in terms of seniority on the IRB, and shall be matched as closely as possible with their field of expertise to the study.

**7.4.3.2** Alternate Members. Alternate members are eligible to serve as expedited reviewers if they meet the above criteria.

**7.4.3.3** Documents Reviewed. When reviewing research under an expedited review procedure, the IRB Chair, or designated IRB member(s), shall receive and review all documentation that would normally be submitted for a convened review, including the complete protocol and funding applications.

**7.4.4** Authority of Reviewer(s). In reviewing the research, the reviewer(s) may exercise all of the authorities of the IRB except that the reviewer(s) may not disapprove the research. A research activity may be disapproved only after



review in accordance with the non-expedited procedure set forth in Section 7.5 below.

**7.4.5** Categories of Research Eligible for Expedited Review [63 FR 60364-60367, November 9, 1998]. The activities listed below should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects. The categories in this list apply regardless of the age of subjects, except as noted.

Research Categories 1 through 7 pertain to both initial and continuing IRB review:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met:
  - (a) Research on drugs for which an investigational new drug application [21 CFR Part 312] is not required. [NOTE: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.]
  - (b) Research on medical devices for which (i) an investigational device exemption application [21 CFR Part 812] is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
  - (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
  - (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week. [NOTE: See Section 11.1.1 below for the DHHS definition of "children."]
3. Prospective collection of biological specimens for research purposes by noninvasive means.

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

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

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

[NOTE: Some research in this category may be exempt from the Federal Regulations. See Exempt Categories and 45 CFR 46 101(b)(4). This listing refers only to research that is not exempt.]

6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language,

communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

[NOTE: Some research in this category may be exempt from the Federal Regulations. See Exempt Categories and 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.]

8. Continuing review of research previously approved by the convened IRB as follows:
  - (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
  - (b) where no subjects have been enrolled and no additional risks have been identified; or
  - (c) where the remaining research activities are limited to data analysis.

[NOTE: Category 8 identifies three situations in which research that is greater than minimal risk and has been initially reviewed by a convened IRB may undergo subsequent continuing review by the expedited review procedure. For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever the conditions of category 8 (a), (b), or (c) are satisfied for that site. However, with respect to category 8(b), while the criterion that "no subjects have been enrolled" is interpreted to mean that no subjects have ever been enrolled at a particular site, the criterion that "no additional risks have been identified" is interpreted to mean that neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source.]

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

[NOTE: The determination that "no additional risks have been identified" does not need to be made by the convened IRB.]

**7.4.6** Informing the IRB of Expedited Review Approvals. All members of an IRB shall be apprised of all expedited review approvals and exemptions by means of the Chair's Report. The local IRB, in consultation with the ORC, shall determine the appropriate mechanism and frequency for distributing the Chair's Report to the

IRB. The local IRB office shall make copies of expedited review approvals and exemptions available for review at the request of any IRB member.

**7.4.7** Full Review of Minimal Risk Research. If a protocol eligible for expedited review is instead reviewed at a convened meeting, the IRB may complete the review and may approve the protocol at the meeting. The IRB shall determine that the protocol meets the criteria for expedited review, determine the appropriate category of expedited review, and document this in the minutes. All subsequent reviews, including continuing reviews and modifications may be conducted under expedited review, provided the risk level does not change and the protocol continues to meet the eligibility criteria for expedited review.

## **7.5 Convened IRB Meetings**

Except when an expedited review procedure is used (see Section 7.4), the IRB must review all nonexempt research at “convened” meetings (also known as full-board meetings) at which a quorum (see below) is present.

### **7.5.1** Schedule of IRB Meetings

**7.5.1.1** Each local IRB shall set its own meeting schedule as appropriate for the amount of research reviewed, although each IRB shall meet at least twice during the academic year. If there is no research to be reviewed at the semi-annual meeting, then the meeting shall be used for educational purposes.

**7.5.1.2** Each campus served by a local IRB shall make available the IRB’s meeting schedule in advance to all faculty and students. The local IRB office shall submit the IRB’s meeting schedule to the ORC at the beginning of each academic year, and shall promptly inform the ORC of any changes in the schedule.

### **7.5.2** Quorum and Voting

**7.5.2.1** Simple Majority. Quorum for the conduct of business at an IRB meeting shall be a simple majority of the voting membership.

**7.5.2.2** Nonscientific Member. Quorum requires the presence of at least one member whose primary concern is in a nonscientific area.

**7.5.2.3** Tele- and video-conferencing. IRB members shall make every attempt to be physically present at a meeting. If a member cannot be physically present, the member may be considered present if he or she participates through teleconferencing or videoconferencing. In this case the member must have received all pertinent material prior to the meeting and must be able to participate actively and equally in all discussions. The ORC must be consulted in advance of utilizing

teleconferencing or videoconferencing, except under emergency circumstances, in which case the ORC must be notified immediately following the meeting.

- 7.5.2.4** Confirmation of Quorum. The IRB Chair, with the assistance of the IRB staff, shall confirm that an appropriate quorum is present before calling the meeting to order. A quorum must also be present at the time of any vote. If a quorum is not present, the proposal must be deferred or the meeting must be terminated.
- 7.5.2.5** Majority Vote. In order for a proposal to be approved, it must receive the approval of a majority of those voting members present at the meeting at which there is a quorum.
- 7.5.2.6** Absent Members. IRB members present at a meeting may consider the opinions of absent members that have been transmitted by mail, telephone, facsimile or e-mail, but these opinions may not be counted as votes or used to satisfy the quorum for convened meetings.
- 7.5.2.7** Alternates. As noted in Section 5.3, alternates may attend any IRB meeting and are encouraged to attend as many meetings as possible. An alternate member shall not be counted as a voting member unless the primary member is absent. However, the alternate member may freely participate in the discussion.
- 7.5.3** New Research Applications. New applications shall be screened by the local IRB office staff for completeness and regulatory compliance prior to their placement on the IRB agenda.
- 7.5.3.1** The research application must include or address:
1. Title of the study
  2. Purpose of the study
  3. Sponsor of the study
  4. Results of previous related research
  5. Subject inclusion/exclusion criteria
  6. Recruitment procedures
  7. Justification for use of any special/vulnerable subject populations

8. The importance of the knowledge that might reasonably be expected, that is, the scientific or scholarly validity.
9. Study design (including, as needed, a discussion of the appropriateness of research methods)
10. Description of procedures to be performed
11. The possible/potential risks to the subjects
12. Provisions for minimizing risks/managing adverse reactions
13. The anticipated benefits of the research
14. An assessment of the risk/benefit relationship
15. Circumstances surrounding the consent procedure and copies of any consent, permission or assent forms to be used
  - a. Setting
  - b. Subject autonomy concerns
  - c. Language difficulties
  - d. Vulnerable populations
  - e. Procedures for documenting informed consent
  - f. Obtaining parental permission and assent from minors
  - g. Using witnesses and/or translators
16. Document storage
17. Compensation to subjects for their participation
18. Compensation for injured research subjects
19. Costs to subjects for their participation in the study
20. Costs to third-party payers because of subject's participation
21. Provisions for protection of subject's privacy
22. Description of the resources available to protect research subjects, including: supervision, number and training of staff, appropriate support services.
23. Study-specific conflict of interest information
24. Whether the research requires review by other University research compliance committees.

25. Assurances. The PI must certify that:

- a. The study has been designed to protect the human subjects;
- b. The PI is responsible for the scientific conduct of the research and for providing all reports and information to the IRB as required;
- c. All members of the research team are appropriately credentialed to perform the work undertaken in the study; and
- d. The PI and other investigators and key personnel, and their household or family members, do not have any actual or potential conflict of interest described in Section 7.6.5 in connection with the study and do not anticipate having such a conflict of interest while participating in the research.

**7.5.3.2** In addition to the research application, the investigator must submit any external or internal grant application or contract, including PSC CUNY programs.

**7.5.3.3** Investigators who have other individuals write their research protocols and application responses to the IRB should recognize that the ultimate responsibility of any study lies with the PI. It is incumbent upon the PI to check all material that is submitted to the IRB for review before signing the application.

**7.5.4** Primary Reviewers. Each IRB shall have a primary reviewer for each protocol requiring full IRB review. At some local IRBs the IRB Chair will serve as the primary reviewer. At others the local IRB office will assign a primary reviewer from the members of the IRB. To the extent possible, reviewers shall be assigned protocols based on their related expertise. When making reviewer assignments, the local IRB office staff shall take into consideration the vulnerable populations involved in the research and shall assign the protocol to at least one individual who has experience with this population.

**7.5.5** Pre-Meeting Document Distribution and Review

**7.5.5.1** Approximately one week prior to each meeting, the IRB office shall provide an agenda, with review assignments, and copies of all protocols and supporting documentation to be reviewed, to all IRB members.

**7.5.5.2** The place and time of the IRB meeting shall be set forth on the cover page of the agenda.

**7.5.5.3** All IRB Members shall receive a copy of the research application, including without limitation:

- the description of the study
- proposed consent, parental permission, and/or assent form(s)
- recruitment materials and subject information (including all surveys and questionnaires)

In addition, if the research is sponsored, the primary reviewer shall receive copies of any grant applications, sponsorship contracts and budgets. Other IRB members may also receive this information upon request to the IRB office.

**7.5.5.4** Before the meeting the primary reviewers shall carefully review each research application.

### **7.5.6** Activities at the Meeting

**7.5.6.1** Presentation and Consideration. At the meeting, the primary reviewer shall present an overview of the research goals, design, study procedures, and safety procedures, and the qualifications of the investigators. The IRB members should pay particular attention to the risk/benefit relationship of the research and the adequacy of the consent form in conveying human subjects concerns. The IRB should discuss problems identified by the primary reviewer or other IRB members, and should decide on any changes needed to the protocol. The members shall consider these issues when voting to decide IRB action.

**7.5.6.2** Role of PI. At the discretion of the IRB, the PI may be invited to the IRB meeting to answer questions about the proposed or ongoing research. The PI may not be present during the discussion and vote by the IRB.

**7.5.6.3** Experts and Consultants. When necessary, the IRB may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. See Section 5.4 regarding Consultants.

**7.5.7** Conflicts of Interest. No IRB member shall participate in the initial or continuing review of any research in which he or she has a conflict of interest described in Section 5.5.1.1, except to provide information requested by the IRB.

**7.5.7.1** Disclosure. IRB members and IRB staff members are expected to identify their own conflicts of interest. A primary reviewer or expedited reviewer with a conflict of interest must notify the IRB Chair and/or the local IRB office prior to the IRB meeting or review so that the protocol can be re-assigned. Other IRB members and IRB staff members with a conflict of interest must disclose the conflict to the IRB Chair and/or



the local IRB office prior to the beginning of the IRB's discussion of the relevant protocol.

- 7.5.7.2** Recusal. Except when requested by the IRB to be present to provide information, an IRB member or IRB staff member with a conflict of interest shall leave the meeting room when the IRB reviews the protocol in which that individual has a conflict. The IRB Chair shall allow for committee discussion and vote only after the conflicted individual has recused himself or herself. The recused individual shall not be counted toward a quorum, and his or her absence during the discussion and vote on the protocol shall be noted in the IRB meeting minutes. If a quorum is lost as a result of an IRB member's recusal (either due to the number of IRB members or the absence of a nonscientist), then the review of the protocol shall be deferred.

## **7.6 IRB Review Process**

Except where noted, the following applies to exempt and expedited review and review at a convened meeting:

### **7.6.1 Possible IRB Actions Taken by Vote**

- 7.6.1.1** Approval. The study is approved as submitted.

- 7.6.1.2** Deferred for Nonsubstantive Issues (with Directed Changes). The protocol and/or consent form require minor revisions, such as wording changes. The IRB agrees at the meeting on the specific revisions the PI must make and conditionally approves the research subject to verification that the revisions have been made. No further action by the full IRB is required; the revisions may be verified by the IRB Chair, Vice Chair, or a subcommittee of the IRB. For convened review, the date of approval is the date the fully convened IRB reviewed the protocol and granted conditional approval rather than the date that the revisions were verified by the IRB Chair, Vice Chair or subcommittee. For exempt and expedited review, the date of approval is the date the revisions were verified by the IRB Chair, Vice Chair or subcommittee.

- 7.6.1.3** Deferred for Substantive Issues (Convened review only). Substantive modification or clarification regarding the protocol or informed consent process/form is required or materials (such as questionnaires) are missing. The IRB shall not approve the proposed research until the modifications or other responsive materials submitted by the PI are reviewed at a convened IRB meeting.

If the application is deferred for substantive issues, the following shall occur:

1. The local IRB office shall inform the PI in writing of the IRB's decision, questions and concerns.
2. The PI shall send his or her response to the local IRB office.
3. In order for a deferred protocol to be approved, it must be submitted for full IRB review at a subsequent, convened meeting. The local IRB office shall place the item on the agenda for the following meeting and shall provide the IRB with the PI's response, the revised protocol and the previously submitted protocol.
4. The full IRB shall again review the research application. Whenever possible, the deferred protocol shall be reassigned to the original reviewer(s).
5. The local IRB office shall again inform the PI in writing of the IRB's deliberations.
6. The IRB documents its determination concerning the subsequent amended submission in the minutes of that meeting.

The date of approval for a protocol deferred for substantive issues is the date of the last fully convened IRB meeting at which the protocol and revisions were reviewed, rather than the date that any subsequent minor, nonsubstantive changes were approved by the IRB Chair, Vice Chair or subcommittee.

- 7.6.1.4** Deferred for Additional Information. The protocol or consent form contains insufficient information for the IRB to judge the research application adequately (for example, the risks and benefits cannot be assessed with the information provided). If the protocol was reviewed at a convened meeting, the protocol must be resubmitted with the necessary information and reviewed at a subsequent convened IRB meeting.

The date of approval for a protocol deferred for additional information is the date of the last fully convened IRB meeting at which the protocol and the additional information were reviewed, rather than the date that any subsequent minor, nonsubstantive changes were approved by the IRB Chair, Vice Chair or subcommittee. For exempt and expedited review, date of approval is the date the revisions were verified by the IRB Chair, Vice Chair or subcommittee.

- 7.6.1.5** Disapproved. The IRB has questions of such significance regarding the protocol that it feels approval of the study is unwarranted.

Approval of a previously disapproved protocol requires full IRB review. An exempt or expedited review subcommittee may not disapprove a study. The exempt or expedited review committee shall forward the protocol for convened review.

- 7.6.1.6** 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. One is if study procedures are to be developed during the course of the research, but human subjects approval is required by the sponsoring agency. The other is if the involvement of human subjects depends on the outcomes of work with animal subjects. Under either circumstance, the IRB may then grant approval without having reviewed the as yet undeveloped recruitment, consent, and intervention materials. However, if the proposal is funded, the PI must submit such materials to the IRB for approval at least 60 days before recruiting human subjects into the study, or into any pilot studies or pre-tests. Approval in principle is granted to satisfy sponsoring agency requirements or to allow investigators to have access to funding to begin aspects of the project that do not involve human subjects. Approval letters must clearly state that approval to engage human subjects in the research has not yet been granted.
- 7.6.2** Determination of Risk. At the time of initial review, the IRB shall make a determination regarding the risks associated with the research protocol. Risks associated with the research shall be classified as either “minimal” or “greater than minimal.” The meeting minutes shall reflect the IRB’s determination regarding risk levels.
- 7.6.3** Period of Approval. At the time of initial review and at continuing review, the IRB shall make a determination regarding the frequency of review of the research protocol. Each protocol shall be reviewed by the IRB at intervals appropriate to the degree of risk, but no less than once per year. In some circumstances, a shorter review interval (for example, semiannually, quarterly, or after accrual of a specific number of subjects) may be required. The meeting minutes shall reflect the IRB’s determination regarding review frequency.
- 7.6.3.1** Research Requiring More than Annual Review. Unless specifically waived by the IRB, research that meets any of the following criteria will require review more often than annually:
1. Significant risk to research subjects (for example, death or serious physical injury, permanent or long lasting psychological disability, significant negative social consequences) without the possibility of direct benefit to the subjects;

2. The involvement of especially vulnerable populations likely to be subject to coercion (for example, institutionalized psychiatric patients, incarcerated minors); or
3. A history of serious or continuing noncompliance on the part of the PI.

**7.6.3.2** Additional Factors in Review. The following factors shall also be considered when determining which studies require review more frequently than on an annual basis:

1. The probability and magnitude of anticipated risks to subjects;
2. The likely medical condition of the proposed subjects;
3. The overall qualifications of the PI and other key personnel;
4. The specific experience of the PI and other key personnel in conducting similar research;
5. The nature and frequency of adverse events observed in similar research at this and other institutions;
6. The novelty of the research making unanticipated adverse events more likely; and
7. 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 subjects to be either studied or enrolled. If a maximum number of subjects to be studied or enrolled is used to define the approval period, the approval period cannot exceed 365 days, and the number of subjects studied or enrolled shall determine the approval period only when that number of subjects is studied or enrolled in less than 365 days.

**7.6.4** Independent Verification Regarding Material Changes. Protecting the rights and welfare of subjects sometimes requires that the IRB verify independently, using sources other than the investigator(s), information about various aspects of the study. This information might include, but is not limited to, adverse event reporting, information in the scientific literature, reports of drug toxicity, drug approval status, and that no material changes occurred during the IRB-designated approval period.

**7.6.4.1** Criteria. The IRB shall determine the need for verification from outside sources on a case-by-case basis and according to the following criteria:

1. Protocols where concern about possible material changes occurring without IRB approval have been raised based on information provided in continuing review reports or from other sources.
2. Protocols conducted by PIs who have previously failed to comply with the Federal Regulations and/or the requirements or determinations of the IRB.
3. Protocols randomly selected for internal audit.
4. Whenever else the IRB deems verification from outside sources is relevant.

**7.6.4.2** Other Factors to Consider. The following factors shall also be considered when determining which studies require independent verification:

1. The probability and magnitude of anticipated risks to subjects.
2. The likely condition of the proposed subjects.
3. The probable nature and frequency of changes that may ordinarily be expected in the type of research proposed.

In making determinations about independent verification, 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 or may require such verification at any time during the approval period in the light of new information.

**7.6.5** Conflict of Interest – Investigators. The IRB application asks protocol-specific questions regarding actual or potential conflicts of interest of the investigators and key personnel, including whether any of the investigators or key personnel, or any of their household or family members, has:

1. A current or anticipated financial interest in the research, regardless of amount, including without limitation:
  - a. salary (except from the University);
  - b. other payments for services (except for income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities, or in

- connection with service on advisory committees or review panels for public or nonprofit entities);
- c. equity interests (e.g., stocks, stock options, or other ownership interests); and
  - d. intellectual property rights (e.g., patents, copyrights, and royalties from such rights).
2. A current or anticipated appointment as an executive or director of the agency or company sponsoring the research; or
  3. Any other current or anticipated non-financial interest that the investigator or key personnel reasonably believes may interfere with his or her ability to protect the subjects of the research.

As part of its review process, the IRB shall make a determination as to whether the conflict of interest adversely affects the protection of human subjects. If the answer is “yes”, the IRB shall work with the PI and the conflicted individual to develop a plan to manage, reduce, or eliminate the conflict of interest so that the human subjects in the protocol are adequately protected. As part of such a plan, the IRB may require, at its discretion, that the consent form provided to potential research subjects include an appropriate description of the actual or potential conflict of interest. The IRB may consult with the ORC in reviewing any conflicts of interest of investigators or key personnel.

The IRB shall document its plan to manage, reduce, or eliminate the conflict of interest in the IRB minutes, or in the protocol file if the research is expedited or exempt. If an actual or potential conflict of interest exists, the IRB cannot give final approval to the protocol until an approved plan that adequately protects the human subjects in the protocol is in place. The IRB’s decisions regarding conflicts of interest may be appealed in accordance with Section 7.11.

The PI is responsible for being informed of the conflict of interest status of all of the investigators and key personnel, and their household of family members, throughout the course of the research. If the conflict of interest status of any of the investigators or key personnel, or any of their household of family members, changes during the course of the research, the PI is required to notify the local IRB office within ten working days of his or her knowledge of the change. The IRB shall review the change as a modification to the protocol.

At the time of continuing review, the PI shall inform the IRB whether there has been any change in the conflict of interest status of any of the investigators or key personnel, or any of their household of family members, relating to the research, and the IRB shall review any such conflict of interest as part of its continuing review.

**7.6.6 Consent Monitoring.** In reviewing the adequacy of informed consent procedures for proposed research, an IRB may on occasion determine that special monitoring of the consent process by an impartial observer (consent monitor) is required in order to reduce the possibility of coercion and undue influence. Such monitoring may be particularly warranted where the research presents significant risks to subjects, or if subjects are likely to have difficulty understanding the information to be provided. Monitoring may also be appropriate as a corrective action where the IRB has identified problems associated with a particular investigator or a research project.

**7.6.7 Reporting IRB Actions** [45 CFR 46.109(e), 46.113].

**7.6.7.1 Reporting to the PI.** The IRB Chair or designee shall communicate each IRB action to the PI, or designated primary contact person for the protocol, in writing within ten working days of the action. The IRB shall notify investigators in writing of its decision to approve the proposed research activity, of modifications required to secure IRB approval of the research activity, or of a decision to disapprove the proposed research activity. The IRB shall use CUNY's standard templates when communicating IRB actions to the PI. Only an IRB Chair, Vice Chair, or designated IRB Member who serves on the IRB that reviewed the protocol may sign the approval and disapproval letters/memos.

For approved research, the IRB shall inform the PI of the following rules:

1. **Continuing Review:** It is the investigator's responsibility to insure that an application for continuing review approval has been submitted before the expiration date of the current approval. If the investigator does not receive approval before the expiration date, all study activities shall stop until a new approval letter is received.
2. **Consent Form:** Investigators shall use an approved and stamped consent form for all research subjects, and investigators are responsible for retaining signed consent forms and required HIPAA Authorization forms for each research subject in accordance with Section 6.5.2.
3. **Mandatory Reporting to the IRB:** The PI shall report any adverse events that are Unanticipated Problems (see Section 7.9) or protocol deviations.
4. **Modifications:** All modifications of protocols involving human subjects must have prior IRB approval except those involving the prevention of immediate harm to a subject. The PI shall report to

the IRB any modification for the prevention of immediate harm to a subject within 24 hours of the modification.

In order to maintain active approval status of approved research, a PI shall sign and return a verification statement acknowledging that he or she has received the approval letter and is aware of, and agrees to abide by, all of its stipulations, including prompt reporting of adverse events and serious problems, proposed protocol modifications, and annual continuing review. Each PI shall also acknowledge that he or she is aware that it is his or her responsibility to be knowledgeable of all federal, state and university regulations regarding human subjects research, including those incorporated in CUNY's FWA.

If the IRB decides to disapprove a research activity or require modifications of the protocol before approving the activity, it shall include in its written notification to the PI a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

**7.6.7.2** Reporting to CUNY. The IRB shall report its findings and actions to CUNY in the form of its minutes and Chair's Reports, which shall be available to CUNY institutional officials upon request. The IRB shall submit all minutes and Chair's Reports to the ORC upon approval.

**7.6.8** CUNY Multi-Campus Review. A multi-campus protocol is defined as a protocol that involves the conduct of human subjects research at more than one CUNY campus. Since CUNY has one FWA, it is only necessary for one IRB within the CUNY system to review and approve a multi-campus protocol. In order to avoid unnecessary duplication of the review process and unnecessary delays for the investigators, only the CUNY-Wide IRB will review multi-campus protocols. The processes for submitting and reviewing multi-campus protocols are described below. Each local IRB Chair will have the opportunity to participate in the review of all research proposed on his or her campus. All local IRBs shall accept the decision of the CUNY-Wide IRB without further review.

It is incumbent upon the PI to indicate on the IRB application that it is a multi-campus project, and indicate which CUNY campuses will be involved.

**7.6.8.1** Multi-Campus Expedited Review Process

1. The PI shall submit the application to the CUNY-Wide IRB, indicating all campuses to be involved. Any local IRB receiving a multi-campus application directly shall instruct the PI to submit the application to the CUNY-Wide IRB, and shall alert the CUNY-Wide IRB to expect the submission.



2. The CUNY-Wide IRB Chair or Administrator shall invite each local IRB Chair as a reviewer for every protocol involving his or her campus.
3. The CUNY-Wide IRB Chair shall coordinate the review process.
4. The CUNY-Wide IRB Chair shall include the approval in his or her Report to the CUNY-Wide IRB.

#### **7.6.8.2 Multi-Campus Full-Committee Review Process**

1. The PI shall submit the application to the CUNY-Wide IRB, indicating all campuses to be involved. Any local IRB receiving a multi-campus application directly shall instruct the PI to submit the application to the CUNY-Wide IRB, and shall alert the CUNY-Wide IRB to expect the submission.
2. The CUNY-Wide IRB Chair or Administrator shall invite each IRB Chair to participate in the full-committee review of every protocol involving his or her campus(es).
3. The CUNY-Wide IRB Chair shall coordinate the review process.
4. The CUNY-Wide IRB Chair shall include the approval in the Chair's Report to the CUNY-Wide IRB.

#### **7.6.8.3 Process for Reviewing an Amendment to a Protocol**

1. The PI shall submit the amendment application to the CUNY-Wide IRB. If this is an amendment to add new campuses, the application must indicate all new campuses to be involved.
2. The CUNY-Wide IRB Chair or Administrator shall invite each IRB Chair as a reviewer for every protocol involving his or her campus (including each IRB Chair of any of the new campuses to be added) under the expedited or full-committee review processes described above.

### **7.7 Continuing Review of Active Protocols (Renewals)**

Approved research is subject to continuing IRB review at least yearly, or more frequently if specified by the IRB [45 CFR 46.109(e)]. This review must take place before the approval expiration date; any lapse in approval will result in suspension of subject recruitment/enrollment and, if the research is DHHS-sponsored, notification of the funding agency. The approval date and the termination (expiration) date shall be clearly noted on all IRB communications sent to the PI and shall be strictly adhered to.

Investigators should allow sufficient time for development and review of renewal submissions.

Continuing IRB review occurs as long as the research remains active only for long-term follow-up of subjects, even when the research is permanently closed to the enrollment of new subjects and all subjects have completed all research-related interventions. Continuing IRB review of research also occurs even when the remaining research activities are limited to the analysis of identifiable data. However, the analysis of de-identified data does not require continuing review.

To assist investigators the local IRB office staff will send out renewal notices to investigators at least two months in advance of the expiration date of the approved research. However, 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.

Research activities are subject to internal audit and verification from sources other than the investigator that no material changes have occurred since the last IRB review.

**7.7.1** Continuing Review Process. In accordance with DHHS regulations at 45 CFR 46.108(b) and at 46.115(a)(2), continuing review by the convened IRB, with recorded vote on each study, is required unless the research is otherwise appropriate for expedited review under Section 46.110 (see Section 7.7.2 below). Furthermore, DHHS regulations at 45 CFR 46.111 set forth the criteria that must be satisfied in order for the IRB to approve research. These criteria include, among other things, determinations by the IRB regarding risks, potential benefits, informed consent, and safeguards for human subjects. The IRB shall ensure that these criteria are satisfied at the time of both initial and continuing review. The procedures for continuing review by the convened IRB may include a primary reviewer system.

**7.7.1.1** Information to be Provided to IRB Members. In conducting continuing review of research not eligible for expedited review, all IRB members shall at a minimum receive from the IRB office and review a status report on the progress of the research, including the following information from the past year (cumulative data shall also be included after the first renewal):

1. the number of subjects enrolled;
2. number of subjects who withdrew prematurely and reason(s) for their withdrawal;
3. a current copy of the description of the study;

4. a summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review;
5. summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review;
6. any other relevant information, especially information about risks associated with the research;
7. a copy of the current informed consent document and any newly proposed consent document;
8. a copy of the current HIPAA Authorization document, if applicable;
9. a copy of any relevant grant or funding application; and
10. any relevant multi-center trial reports.

At least one member of the IRB (that is, a primary reviewer) shall also receive from the IRB office a copy of the complete protocol including any modifications previously approved by the IRB. Furthermore, upon request, each IRB member shall also have access to the complete IRB protocol file and relevant IRB minutes prior to or during the convened IRB meeting.

**7.7.1.2** IRB Considerations. When reviewing the current informed consent document(s), the IRB shall ensure the following:

1. the currently approved or proposed consent document is still accurate and complete;
2. any significant new findings that may relate to the subject's willingness to continue participation are provided to the subject in accordance with DHHS regulations at 45 CFR 46.116(b)(5).

When conducting continuing review, the IRB shall make and document a determination as to whether the risks to subjects have changed.

**7.7.1.3** Frequency of Informed Consent Reviews. The IRB shall review currently approved or newly proposed consent documents during its scheduled continuing review of research, but the IRB shall also review informed consent documents whenever new information becomes available that would require modification of information in the informed consent document.

**7.7.2 Expedited Review of Continuing Review.** Generally, if research did not qualify for expedited review at the time of initial review, it will not qualify for expedited review at the time of continuing review, except in limited circumstances described by expedited review categories (8) and (9) at 63 FR 60364-60367 (see Expedited Review Categories at Section 7.4.5). It is also possible that research activities that previously qualified for expedited review in accordance with 45 CFR 46.110, have changed or will change, such that expedited IRB review would no longer be permitted for continuing review.

**7.7.3 Determination of Continuing Review Date.** Department of Health and Human Services regulations at 45 CFR 46.108(b) and 109(e) require, respectively, that:

- (1) except when an expedited review procedure is used, the IRB shall review proposed research at convened meetings at which a majority of the members of the IRB is present, including at least one member whose primary concerns are in nonscientific areas; and
- (2) an IRB shall conduct continuing review of research at intervals appropriate to the degree of risk, but not less frequently than once per year. The IRB should decide the frequency of continuing review for each study protocol necessary to ensure the continued protection of the rights and welfare of research subjects.

At CUNY, determination of the review interval and the need for additional supervision and/or participation is made by the IRB on a protocol-by-protocol 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.

**7.7.3.1 Scenarios.** Several scenarios for determining the date of continuing review apply for protocols reviewed by the IRB at a convened meeting. The date by which continuing review must occur depends on the date of the convened meeting at which IRB approval occurs. (These examples presume the IRB has determined that it will conduct continuing review no sooner than within one year.)

- Scenario 1: The IRB reviews and approves a protocol without any conditions at a convened meeting on October 1, 2008. Continuing review must occur within one year of the date of the meeting, that is, by October 1, 2009.
- Scenario 2: The IRB reviews a protocol at a convened meeting on October 1, 2008, and approves the protocol contingent on specific minor conditions that the IRB Chair or his or her designee can verify. On October 31, 2008, the IRB Chair or designee confirms

that the required minor changes were made. Continuing review must occur within one year of the date of the convened IRB meeting at which the IRB reviewed and approved the protocol, that is, by October 1, 2009.

- Scenario 3: The IRB reviews a study at a convened meeting on October 1, 2008, and has serious concerns or lacks significant information. The IRB conducts additional review of the study at subsequent convened meetings on October 15 and October 29, 2008. At their October 29, 2008 meeting, the IRB completes its review and approves the study. Continuing review shall occur within one year of the date of the convened meeting at which the IRB reviewed and approved the protocol, that is, by October 29, 2009.

**7.7.3.2** Study Approved under Expedited Review. For a study approved under expedited review, continuing review shall occur within one year of the date the expedited reviewer gave final approval to the protocol.

**7.7.3.3** Effect of Change in Protocol. Review of a change in a protocol ordinarily does not alter the date by which continuing review shall occur. This is because continuing review is review of the full protocol, not simply a change to it.

**7.7.3.4** No Grace Period. The regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. Therefore, continuing review and re-approval of research must occur on or before the date when IRB approval expires. When continuing review occurs annually and the IRB performs continuing review within 30 days before the IRB approval period expires, the IRB may retain the anniversary date as the date by which the continuing review must occur. This would be, for example, October 1, 2009, in the above Scenarios 1 and 2, and October 29, 2009, in Scenario 3, even if the continuing reviews took place up to 30 days prior to these dates.

**7.7.4** Lapse in Continuing Review. The IRB and investigators must plan ahead to meet required continuing review dates. If an investigator has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the continuing review date specified by the IRB, the research must stop. Enrollment of new subjects cannot occur after the expiration of IRB approval. The IRB will consider, on a case-by-case basis whether there is an overriding safety concern or ethical issue involved such that it is in the best interests of individual subjects to continue participating in the research interventions or interactions prior to reapproval.

- 7.7.4.1** Continuing Research without Approval is a Violation. The continuation of research after expiration of IRB approval is a violation of the regulations governing research with human subjects and these Policies and Procedures.
- 7.7.4.2** Renewal Notices. As a courtesy, the local IRB office will send out renewal notices a minimum of 60 and 30 days before the studies expire. However, it is ultimately the investigator's responsibility to initiate a renewal application, allowing sufficient time for the review and re-approval process to be completed before the current approval expires. Retrospective approval for work done after the expiration date cannot be granted.
- 7.7.4.3** Renewal Process. If the investigator has not submitted the continuing review materials by the expiration date, the study “expires” and the research must stop. To renew the study, the investigator must submit a new application for review. If the investigator submitted the continuing review materials in time for review, but the IRB does not complete the review and approve the study before the expiration date, the study “lapses” and research must stop until the IRB completes the review and approves the continuing review.
- 7.7.5** Studies that are Approved but Never Started. When an IRB approves a study, continuing review should be performed at least annually. For the purposes of continuing review, the review date is determined by the date of initial IRB approval. The PI shall provide the IRB with written progress reports for all studies that are in approved status prior to the date of expiration of IRB approval. If subjects were never enrolled, the investigator's progress report would be brief. Such studies may receive continuing IRB review using expedited procedures. If the study is finally canceled without subject enrollment, records shall be retained by the IRB in accordance with Section 6.5.1 and the PI in accordance with Section 6.5.2.

## **7.8 Amendment to or Modification of an Approved Protocol**

Investigators may wish to modify or amend their approved applications. Investigators must seek IRB approval before making any changes in approved research - even if the changes are planned for the period for which IRB approval has already been given - unless the change is necessary to eliminate an immediate hazard to the subject (in which case the PI shall promptly notify the IRB; see Section 7.8.1.3).

- 7.8.1** Changes Within the Scope of Original Protocol. The IRB may approve modifications if they are within the scope of what the IRB originally authorized. For example, if an investigator 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. The IRB's decision with respect to a proposed change shall be communicated to the PI in writing.

**7.8.1.1** Expedited Review of Minor Changes. An IRB may use expedited review procedures to review minor changes (that is, changes that do not involve increased risk or discomfort to subjects) in ongoing previously-approved research during the period for which approval is authorized [45 CFR 46.110; 63 FR 60364-60367, November 9, 1998]. An expedited review may be carried out by the IRB Chair or by one or more experienced reviewers designated by the IRB Chair from among members of the IRB.

**7.8.1.2** Significant Changes – No Immediate Hazard. When a proposed change in a research study is not minor (for example, procedures involving increased risk or discomfort are to be added) and there is no apparent immediate hazard to the research subjects, then the IRB must review and approve the proposed change at a convened meeting before the change can be implemented.

**7.8.1.3** Significant Changes – Immediate Hazard. If a change is necessary to eliminate apparent immediate hazards to the research subjects, the PI may implement the change as necessary to protect the subjects, and shall promptly thereafter notify the IRB of the change. The IRB shall review the change to determine that it is consistent with ensuring the subjects' continued welfare.

**7.8.2** Changes to the Scope of the Original Protocol. If the investigator wishes to add a population and/or revise study procedures, he or she shall submit a new application for human subjects approval.

## **7.9 Unanticipated Problems and Adverse Events**

**7.9.1** Unanticipated Problems. The Federal Regulations require that CUNY have in place procedures for the prompt reporting to the IRB, institutional officials, sponsors, and OHRP of unanticipated problems involving risks to subjects or others ("Unanticipated Problems"). Unanticipated Problems include those events that:

- are not expected given the nature of the research procedures and the subject population being studied;
- are related or possibly related to the research; AND
- suggest that the research places subjects or others at a greater risk of harm or discomfort than was previously known or recognized.

Not all Unanticipated Problems involve direct harm to subjects. An event can occur which is unexpected and results in new circumstances that increase the risk of harm to subjects without directly harming them. In addition, the event may have presented unanticipated risks to others (such as, 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, the event nevertheless represents an Unanticipated Problem and shall be promptly reported as described in Section 7.9.3. Unanticipated Problems could include:

- Any change to the protocol taken without prior IRB review to eliminate apparent immediate hazard to a research subject;
- Any deviation from the protocol (protocol violation) that are related to participant safety, significant new findings, a defined subset of adverse events and IND safety reports;
- Any publication in the literature, safety monitoring report, interim result, or other finding that indicates an unexpected change to the risks or potential benefits of the research;
- Any complaint from a subject that indicates an unanticipated risk or which cannot be resolved by the research staff;
- Breach of confidentiality of research data;
- Breach of privacy, confidentiality or data security; loss of study data; or destruction of study data due to noncompliance;
- Incorrect labeling/dosing of study medication or test article;
- Any event that requires prompt reporting according to the sponsor

**7.9.2** Adverse Events. An adverse event is any untoward physical, psychological or social occurrence affecting one or more subjects during the course of research. Adverse events occur most commonly in the context of biomedical research, although on occasion, adverse events can occur in the context of social and behavioral research. Any assessment of the significance and expectedness of a particular adverse event or group of adverse events needs to take into account the level of severity and frequency of the adverse events occurring in the subject population.

**7.9.2.1** Significance. Adverse events may be serious or not serious. A serious adverse event is one that is fatal or life-threatening, requires or prolongs hospitalization, produces a disability, or results in a congenital



anomaly/birth defect. In social and behavioral research, a serious adverse event is one that results in severe emotional trauma, results in loss of employment or income, or requires counseling or therapy.

**7.9.2.2** Expectedness. Adverse events may be expected or unexpected. An unexpected adverse event is an adverse event not previously known or anticipated to result from:

1. the interventions and interactions used in the research;
2. the collection of identifiable private information under the research;
3. an underlying disease, disorder, or condition of the human subject; and/or
4. other circumstances related to the research or an underlying disease, disorder, or condition of the subject.

**7.9.2.3** Internal v. External. Adverse events may be internal or external. Internal adverse events are those experienced by subjects enrolled at the site(s) under the IRB's jurisdiction for either multi-center or single-center research projects. External adverse events are those experienced by subjects enrolled in multi-center clinical trials at sites other than the site(s) over which the IRB has jurisdiction.

**7.9.3** Relationship Between Adverse Events and Unanticipated Problems. Not all adverse events are Unanticipated Problems. Only those adverse events that are Unanticipated Problems are required to be reported.

**7.9.3.1** Adverse Events that Are not Unanticipated Problems – NO NEED TO REPORT. Many adverse events, both serious and nonserious, occurring in the context of research are expected in light of the known untoward effects of the research procedures or are due to the natural history of subjects' underlying diseases and conditions. Therefore, these adverse events do not represent Unanticipated Problems, and do not need to be reported.

**7.9.3.2** Adverse Events that Are Unanticipated Problems – MUST REPORT. The following three categories of adverse events are considered Unanticipated Problems that shall be reported:

1. Adverse events that are serious, unexpected, and related or possibly related to participation in the research.

2. Serious adverse events that are expected in some subjects, but are determined to be occurring at a significantly higher frequency or severity than expected.
3. Other unexpected adverse events, regardless of severity, that may alter the IRB's analysis of the risk versus potential benefit of the research and, as a result, warrant consideration of substantive changes in the research protocol or informed consent process/document.

**7.9.4** PI Reporting of Unanticipated Problems. The PI shall report all Unanticipated Problems to the IRB on the ORC report form. Only those adverse events that are considered Unanticipated Problems must be reported. See Section 7.9.3.2 above for the categories of adverse events that would be considered Unanticipated Problems. In addition, investigators shall retain a record of all adverse events occurring during the course of their research that are not considered Unanticipated Problems in accordance with Section 6.5.2 and shall submit a summary to the IRB at the time of continuing review.

**7.9.4.1** Internal Adverse Events. The PI shall assess whether the adverse event may be considered an Unanticipated Problem based on the criteria presented above.

*If the PI determines that the adverse event may be considered an Unanticipated Problem, the PI shall report it to the IRB office using the ORC report form. The PI shall report unexpected, serious, adverse events, including those that are fatal or life-threatening, to the IRB office within 48 hours of the PI becoming aware of the event. Other adverse events that are Unanticipated Problems should be reported within 10 working days of the PI becoming aware of the event. In either case, the report shall include the following information:*

1. Appropriate identifying information, such as (i) the title of the research protocol; (ii) the investigator's name; (iii) the IRB protocol number; (iv) the name of the supporting agency and the relevant award number; and (v) any relevant investigational new drug (IND) or investigational device exemption (IDE) number;
2. A complete, detailed description of the internal adverse event and the basis for determining that it may be considered an Unanticipated Problem; and
3. A description of any actions that have been taken or proposed by the study sponsor, the study coordinating site, any other monitoring entity (such as a Data Safety Monitoring Board [DSMB] or Data Monitoring Committee [DMC]), and/or the local PI in response to

the Unanticipated Problem (for example, suspension of new subject enrollment, modification of the research protocol, and/or modification of the informed consent information and/or process).

For multi-center research, the local PI should consult with the study sponsor or coordinating center regarding any changes to the protocol and/or informed consent documents being proposed by the local investigator. The PI also must ensure that the adverse event is reported to a central or independent monitoring entity (for example, a DSMB/DMC, independent medical monitor, coordinating site, and/or sponsor) if required under a monitoring plan described in the IRB-approved protocol.

*If the PI determines that the adverse event is not considered an Unanticipated Problem, the PI must still ensure that the adverse event is reported to a central or independent monitoring entity (for example, a DSMB/DMC, independent medical monitor, coordinating or statistical center, and/or study sponsor) if required under the monitoring plan described in the IRB-approved protocol. If the monitoring entity subsequently determines, in contrast to the PI's determination, that the adverse event does represent an Unanticipated Problem, procedures should be in place for the monitoring entity to communicate this determination to the PI, who then shall report the Unanticipated Problem to the IRB, following the procedures outlined below for external adverse events.*

**7.9.4.2** External Adverse Events. If the PI receives a report of an external adverse event from the study sponsor, a study coordinating or statistical center, a DSMB/DMC, or other central monitoring entity, the PI shall submit to the IRB reports of only those adverse events that have been determined, preferably by the central monitoring entity, to represent an Unanticipated Problem based on the criteria presented above.

*If the PI determines that the adverse event may be considered an Unanticipated Problem, the PI shall report it to the IRB within 30 working days of the PI's receipt of the report using the ORC report form as described above for reporting internal adverse events that are Unanticipated Problems. The report to the IRB shall present the adverse event in the context of the entire multi-center study, if possible. In addition, the local PI should consult with the study sponsor or coordinating center regarding any changes to the protocol and/or informed consent documents independently proposed by the local PI.*

*If the PI determines that the external adverse event should not to be considered an Unanticipated Problem, the PI shall retain a copy of the external adverse event report and documentation of the basis for this determination in accordance with Section 6.5.2. The PI shall make this record available to the IRB or other authorized entities on request and at continuing review.*

**7.9.4.3** Other Unanticipated Problems (not related to adverse events). The PI shall report Unanticipated Problems not related to adverse events to the IRB office within 10 working days of the event using the ORC report form.

### **7.9.5** IRB Review of Unanticipated Problems

**7.9.5.1** The IRB Chair and/or other experienced member(s) designated by the IRB Chair shall receive from the PI and review the report of the adverse event(s) considered to be an Unanticipated Problem.

**7.9.5.2** The IRB Chair (or designee) shall make a determination as to whether the event is to be regarded as an Unanticipated Problem, and if so, whether it involves more than minimal risk to subjects or others. The IRB Chair shall promptly notify the ORC of any events determined to be an Unanticipated Problem by submitting to the ORC the original signed copy of the ORC report form from the PI. All of the actions of the IRB Chair (or designee) and IRB described in this Section 7.9.5 are subject to the ORC's final approval.

**7.9.5.3** If the IRB Chair (or designee) determines that the Unanticipated Problem involves more than minimal risk to subjects or others, the IRB Chair (or designee) shall report the matter to the convened IRB for consideration. The IRB Chair (or designee) may directly handle Unanticipated Problems involving no more than minimal risk to subjects or others.

**7.9.5.4** All individuals reviewing the event shall receive the report of the event as well as a copy of the current consent form and the research application. In addition, the reviewers shall have access to the full protocol. The IRB and the IRB Chair (or designee) also have authority to require submission of more detailed contextual information by the PI, the sponsor, the study coordinating center, or DSMB/DMC about any adverse event occurring in a research protocol as a condition of the continuation of the IRB's approval of the research.

**7.9.5.5** Unanticipated Problems that may be addressed without modification to the protocol or the informed consent process or documents, as determined by the IRB or the IRB Chair (or designee), may be:

1. filed in the IRB records without further review by the convened IRB or,
2. at the discretion of the IRB Chair (or designee) referred to the rest of the IRB members for review and further action, as appropriate, at a convened meeting.

**7.9.5.6** Unanticipated Problems for which modifications to the protocol or informed consent process/documents are needed, either as requested by the PI or determined by the IRB or the IRB Chair (or designee), shall be handled as follows:

1. If all proposed modifications represent minor changes, the IRB Chair (or designee) may review and, if appropriate, approve the modifications under an expedited review procedure. The related report of the Unanticipated Problem may be: (i) filed in the IRB records without further review by the convened IRB or, (ii) at the discretion of the IRB Chair (or designee), referred to the rest of the IRB members for review and further action, as appropriate, at a convened meeting.
2. If any of the proposed modifications represent more than a minor change, or if the IRB Chair (or designee) determines for any reason that he or she should not approve the proposed modifications under an expedited review procedure, the proposed modifications shall be forwarded to IRB for review at a convened meeting.
3. For multi-center research, if the IRB or the IRB Chair (or designee) determines that modifications in addition to those proposed by the PI are needed in response to an Unanticipated Problem, the IRB will request in writing that the PI discuss the proposed additional modifications with the study sponsor or coordinating center and submit a response or the necessary additional modifications for review by the IRB.

**7.9.5.7** The IRB submits the recommended actions to the ORC for final approval. The ORC will report to the relevant regulatory agencies and institutional officials according to the procedures in Section 15.5.

## **7.10 Further Review/Approval of IRB Actions by Others within the Institution**

Research that has been reviewed and approved by the IRB may be subject to further review and approval or disapproval by CUNY officials, such as the Chancellor, the Office of General Counsel, and college presidents. However, no institutional official may approve research that has been disapproved by the IRB. [45 CFR 46.112]

## **7.11 Appeal of IRB Decisions**

**7.11.1 Subcommittee Decisions.** If a subcommittee of an IRB makes a decision that the investigator believes to be unduly restrictive on the proposed research, the investigator may appeal, in writing, for review by the convened appropriate IRB.

**7.11.2 Convened Local IRB Decisions.**

**7.11.2.1** If the convened IRB disapproves a protocol, the PI may appeal the decision of the IRB, in writing. The IRB will reconsider the appeal based upon the new information provided and will re-review the protocol.

**7.11.2.2** If the IRB disapproves a protocol a second time, the PI has the right to appeal the disapproval, in writing, to the CUNY-Wide IRB. The decision of the CUNY-Wide IRB is final and cannot be appealed.

**7.11.3 CUNY-Wide IRB Decisions.** If a protocol originates with the CUNY-Wide IRB for review rather than with a local IRB and it is first disapproved by CUNY-Wide, the PI may appeal the disapproval only once to CUNY-Wide.

**7.11.4 Notice to the ORC.** The IRB must notify the ORC regarding any disapprovals and appeals.

## **8 CRITERIA FOR IRB APPROVAL OF RESEARCH**

In accordance with 45 CFR 46.111, in order to approve research, an IRB shall determine that all of the following requirements are satisfied:

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

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. 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 interventions 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.

(3) 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, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

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

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

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

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

(8) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

## **8.1 Risk/Benefit Assessment**

**8.1.1 Goal.** The goal of the assessment is to ensure that the risks to research subjects posed by participation in the research are justified by the anticipated benefits to the subjects or society. Toward that end, the IRB shall:

1. judge whether the anticipated benefit, either of new knowledge or of improved health or welfare of the research subjects, justifies asking any person to undertake the risks;
2. disapprove research in which the risks are judged unreasonable in relation to the anticipated benefits.

**8.1.2 Assessment Steps.** In carrying out the assessment, the IRB shall take the following steps:

1. identify the risks associated with the research, as distinguished from the risks of interventions the subjects would receive even if not participating in research;
2. determine whether the risks will be minimized to the extent possible:
  - A) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; and

- B) whenever appropriate, by using procedures already being performed on the subjects for nonresearch purposes;
- 3. identify probable benefits to be derived from the research;
- 4. determine whether the risks are reasonable in relation to the benefits to subjects, if any, and assess the importance of the knowledge to be gained;
  - A) 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 interventions subjects would receive even if not participating in the research.
  - B) 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.
- 5. ensure that potential subjects will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits.

**8.1.3 Scientific Merit.** In order to assess the risks and benefits of the proposed research, the IRB must determine that:

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

In making this determination, the IRB may draw on its own knowledge and disciplinary expertise, or the IRB may draw on the knowledge and disciplinary expertise of others, such as reviews by a funding agency, or departmental review. If departmental scientific review is used, it must be documented by the signature of the administrative official responsible for the investigator's research unit on new research applications.

## **8.2 Selection of Subjects is Equitable**

Justice requires equitable distribution of both the burdens and benefits of research. In other words, individuals and groups that bear the burden should share in the benefits and individuals and groups that benefit from research should share in the burden.

**8.2.1 IRB Review of Selection Criteria.** The IRB shall review the inclusion and exclusion criteria for the research to ensure equitable selection of subjects.



**8.2.1.1** In making this assessment the IRB shall take into account the purposes of the research and the setting in which the research will be conducted and shall be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, fetuses, pregnant women, human in vitro fertilization, persons who are cognitively impaired, or persons who are economically or educationally disadvantaged (see Section 10 - Vulnerable Populations).

**8.2.1.2** The IRB shall ensure that the selection of subjects is justified by the science. Subjects shall not be included simply because they are available or because they cannot say no or do not know that they can say no. The IRB must be particularly sensitive to the recruitment of subjects who are vulnerable to coercion or undue influence such as students, employees or the poor.

**8.2.2** IRB Review of Subject Recruitment Methodologies. The IRB shall review all recruitment procedures, materials and advertisements to ensure that they are consistent with the protocol, accurate, and noncoercive. When subjects are being paid, the IRB shall review both the amount of payment and the proposed method and timing of disbursement to assure that neither are coercive or present undue influence. The IRB shall not consider payment made to subjects as a benefit to participation.

### **8.3 Informed Consent**

The IRB shall ensure that 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. In addition, the IRB shall ensure that informed consent will be appropriately documented in accordance with, and to the extent required by 45 CFR 46.117. See Section 9 for detailed policies on informed consent.

### **8.4 Data Safety Monitoring**

Data safety monitoring refers to the oversight and monitoring of the research to ensure the safety of subjects and the validity and integrity of the data. This can be done by the investigator, an independent monitor, or an independent committee (sometimes referred to as a Data Safety Monitoring Board) depending on the nature of the research. All research, even research that appears to be innocuous, should have a data safety monitoring plan. The IRB shall review the data safety monitoring plan for protocols involving more than minimal risk during initial review and at continuing review.

### **8.5 Privacy and Confidentiality**

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

**8.5.2** “Privacy” means having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

**8.5.3** “Confidentiality” refers to methods used to ensure that information obtained by investigators about their subjects is not improperly divulged. Confidentiality and anonymity are not the same. Anonymous means no one, anywhere, ever can identify individual subjects through names or other identifiers. The fact of subjects’ participation in the research may need to be kept confidential as well as their data. See Section 18.1 for detailed information regarding certificates of confidentiality.

## **8.6 Vulnerable Populations**

The IRB shall 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 (for example, persons with diminished autonomy). See Sections 10 through 14 for detailed policies on vulnerable populations.

## **9 INFORMED CONSENT [45 CFR 46.116 & 45.117]**

### **9.1 Informed Consent Process**

**9.1.1** Consent Required. 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 unless a waiver of consent has been approved by the IRB in accordance with Section 9.3 of these Policies and Procedures.

**9.1.1.1** In general, the IRB shall consider individuals who are unable to consent for their own clinical care or other interventions to be unable to consent for research participation. Tools or instruments such as the Mini Mental Exam can also be used to determine capability to consent.

**9.1.1.2** Investigators shall obtain consent prior to entering a subject into a study and/or conducting any procedures required by the protocol, unless consent is waived by the IRB. The IRB may grant a waiver of obtaining consent to gather information preparatory to research, while requiring consent to enroll subjects in the study.

### **9.1.2 Circumstances Surrounding Consent**

**9.1.2.1** Consent must always be sought under circumstances that:

1. provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate; and

2. minimize the possibility of coercion or undue influence.

**9.1.2.2** The IRB shall consider where the consent process will take place and the individual who will be obtaining consent (for example, the investigator, collaborator, or qualified designee) in its determination regarding the appropriateness of the consent process. When the prospective subject's understanding of the research or his or her ability to voluntarily consent may be impaired due to the timing, location, or individuals participating in the proposed consent process, the IRB shall require an alternative process.

### **9.1.3 Language of Consent**

**9.1.3.1** The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.

**9.1.3.2** 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, or releases or appears to release the investigator, the sponsor, CUNY or its agents from liability for negligence.

### **9.1.4 Individual Obtaining Consent**

**9.1.4.1** A person knowledgeable about the consenting process and the research to be conducted (that is, the PI or key personnel) shall obtain the informed consent.

**9.1.4.2** If someone other than the investigator is to conduct the interview and obtain consent, the investigator shall first formally delegate this responsibility. Prior to seeking consent from the prospective subject, the person so delegated shall have received appropriate training in the protocol and the consent process, as well as in the protection of human subjects in general (see Section 16.9 for additional information).

## **9.2 Basic Elements of Informed Consent**

**9.2.1** Informed consent must be sought from each potential subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.

**9.2.2** The basic elements of informed consent are:

1. a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a

- description of the procedures to be followed, and identification of any procedures which are experimental;
2. a description of any reasonably foreseeable risks or discomforts to the subject;
  3. a description of any benefits to the subject or to others which may reasonably be expected from the research;
  4. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
  5. a statement describing the extent, if any, to which confidentiality of records identifying the subject must be maintained;
  6. for research involving more than minimal risk, an explanation as to the availability of medical treatment in the case of research-related injury, including who will pay for the treatment and whether other financial compensation is available;
  7. an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
  8. a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

**9.2.3** Additional elements of informed consent to be applied, as appropriate:

1. a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. any additional costs to the subject that may result from participation in the research;
4. the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

5. a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation must be provided to the subject; and
6. the approximate number of subjects involved in the study.

### **9.3 Waiver or Alteration of Informed Consent**

**9.3.1** The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement for informed consent provided the IRB finds and documents that:

1. the research involves no more than minimal risk to the subjects;
2. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. the research could not practicably be carried out without the waiver or alteration; and
4. whenever appropriate, the subjects must be provided with additional pertinent information after participation.

**9.3.2** In addition, informed consent may be waived or altered if:

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:
  - (i) public benefit or service programs;
  - (ii) procedures for obtaining benefits or services under those programs;
  - (iii) possible changes in or alternatives to those programs or procedures; or
  - (iv) 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.

### **9.4 Documentation of Informed Consent**

**9.4.1** Informed consent shall be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.

**9.4.2** Informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. The consent form may be read to the subject or the subject's legally authorized representative, but the subject or representative must be given adequate opportunity to read it before it is signed. A copy of the consent form shall be given to the person signing the form.

**9.4.3** The consent form shall include all of the required elements of informed consent detailed in Section 9.2 (unless the IRB approved the waiver or alteration of some or all of the elements) and shall be in language understandable to the subject. The consent form should be written at no more than the 8th grade reading level and all technical terms or jargon should be explained in ordinary language.

**9.4.4** For subjects who do not read or understand English, 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 may be used. See Section 9.8.3. When this method is used:

1. There shall be a witness to the oral presentation;
2. The IRB shall approve a written summary of what is presented to be signed by the subject or representative;
3. The witness shall sign both the short form and a copy of the summary;
4. The person actually obtaining consent shall sign a copy of the summary; and
5. A copy of the summary shall be given to the subject or representative, in addition to a copy of the short form.

**9.4.5** IRB approval of the wording of the consent form shall be documented through the use of a certification stamp on each page that indicates the date of the most recent IRB approval of the document and the expiration date. If the consent form is amended during the protocol approval period, the form shall bear the approval date of the amendment rather than the date of the approved protocol. The expiration date, however, does not change.

## **9.5 Waiver of Documentation of Informed Consent**

**9.5.1** Written informed consent is not necessarily appropriate for all research, especially research in the social and behavioral sciences. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds and documents that the:

1. the research presents no more than minimal risk of harm to subjects; and

2. the research involves no procedures for which written consent is normally required outside of the research context.

**9.5.2** The IRB may also waive the documentation of consent if the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. In these cases subjects shall be asked whether they want documentation linking them with the research, and their wishes shall govern.

**9.5.3** In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

## **9.6 Parental Permission and Assent**

See Section 11.4 for policies on parental permission and assent in research involving children.

## **9.7 Surrogate Consent**

The regulations generally require that the investigator obtain informed consent from subjects. However, under appropriate conditions, investigators also may obtain informed consent from a legally authorized representative of a subject ("surrogate consent"). "Legally authorized representative" is defined in 45 CFR 26.102(c) as 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. See Section 14.5 for the policies and procedures regarding surrogate consent.

## **9.8 Consent and Language Barriers**

**9.8.1** Investigators shall provide the IRB with both English language and translated consent forms for proposals that include non-English-speaking subjects. The investigator should include an explanation of the translations and evidence of the comparability of the English and non-English consent forms. The IRB may consult with language experts or require a "back-translation" into English. The translation should provide documentation to verify the accuracy of the translation and back-translation.

**9.8.2** If a non-English-speaking subject is enrolled unexpectedly, investigators may rely on an oral translation of the English 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 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. If the subject is a patient, a note about the translation should be made in the patient's research records as well.

Investigators should try to provide a written translation of the vital emergency contact information. The IRB shall be notified each time this procedure is used.

- 9.8.3** If a subject understands, but does not read or write English, an impartial witness should document that the subject understands the research and the consent process, and has consented to participate.

## **10 VULNERABLE POPULATIONS - GENERAL**

When some or all of the subjects in a protocol are likely to be vulnerable to coercion or undue influence, the IRB shall include additional safeguards to protect the rights and welfare of these subjects. Some of the vulnerable populations that might be involved in research include children, pregnant women, fetuses, neonates, prisoners, students, employees, homeless persons, or adults who lack the ability to consent.

If the IRB regularly reviews research that involves categories of subjects vulnerable to coercion or undue influence, when reviewing such research the IRB should include one or more individuals who are knowledgeable about or experienced in working with those vulnerable populations. The IRB shall also examine its local context for other vulnerable populations that should be represented on the IRB.

45 CFR 46 has additional subparts designed to provide extra protections for vulnerable populations that also have additional requirements for IRBs.

- 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

**All research conducted under the auspices of CUNY that involves any of these populations must comply with the requirements of the relevant Subparts.**

## **11 RESEARCH INVOLVING CHILDREN [45 CFR 46, Subpart D]**

### **11.1 Definitions**

**11.1.1** “Children” means 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.

**11.1.1.1** In New York State, a person under age 18 is deemed a minor. Once a person reaches age 18, he or she may give effective consent for medical, dental health and hospital services for himself or herself.

**11.1.1.2** Not all minors are Children. In New York State any person, regardless of age, who has been married or who has borne a child may give



effective consent for medical, dental, health, and hospital services for his or her child. Any person who is pregnant, regardless of age, may give effective consent for medical, dental, health, and hospital services relating to prenatal care.

**11.1.1.3** Under certain circumstances, New York State law also permits minors to consent to treatment for outpatient mental health services, treatment for substance abuse, and treatment for sexually transmitted disease. In addition, under certain circumstances minors over the age of 16 can consent to inpatient mental health treatment and to the administration of psychotropic medications. [NYS Public Health Law; NYS Mental Hygiene Law]

**11.1.2** “Assent” means a child's affirmative agreement to participate in research. Mere failure to object, absent affirmative agreement, should not be construed as assent.

**11.1.3** “Permission” means the agreement of parent(s) or legal guardian to the participation of their child or ward in research.

**11.1.4** “Parent” means a child's biological or adoptive parent.

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

## **11.2 Limitations on “Exempt Research” Involving Children**

The exemption at 45 CFR 46.101(b)(2) for research involving survey or interview procedures or observation of public behavior does not apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

## **11.3 Allowable Categories**

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

**11.3.1** 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 (that is, minimal risk).

- The IRB may find that the permission of one parent is sufficient.
- Requires assent of the child, if the child is capable of providing assent.

**11.3.2** Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subject.

- The risk is justified by the anticipated benefit to the subjects.
- The IRB may find that the permission of one parent is sufficient.

- Requires assent of the child, if the child is capable of providing assent.

**11.3.3** 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.

- The risk represents a minor increase over minimal risk.
- The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.
- Permission of either both parents, or legal guardian, is required, unless one parent is deceased, unknown, incompetent, or not reasonably available; or only one parent has legal responsibility for the care and custody of the child.
- Requires assent of the child, if the child is capable of providing assent.
- NOTE: In New York, if such research is not federally-funded, a parent or guardian may not consent to have a child submit to painful and/or potentially life-threatening research and may have the same result as a denial of necessary medical treatment.

**11.3.4** Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate serious problems affecting the health or welfare of children.

- The IRB shall notify the ORC as soon as the IRB is aware of research in this category.
- Federally-funded research in this category shall be approved by the Secretary of Health and Human Services, and requires consent of either both parents, or legal guardian.
- However, in New York, if such research is not federally-funded, a parent or guardian may not consent to have a child submit to painful and/or potentially life-threatening research and may have the same result as a denial of necessary medical treatment.

#### **11.4 Parental Permission and Assent**

**11.4.1** Parental Permission. In accordance with 45 CFR 46.408(b), the IRB shall determine that adequate provisions have been made for soliciting the permission of each minor's parent or guardian.

**11.4.1.1** Parents or guardians shall be provided with the basic elements of consent as stated in 45 CFR 46.116(a)(1-8) and any additional elements the IRB deems necessary.

**11.4.1.2** The IRB may find that the permission of one parent is sufficient for research to be conducted under 45 CFR 46.404 or 45 CFR 46.405. The IRB's determination of whether permission shall be obtained from one or both parents will be documented in the meeting minutes or the Chair's Report if the research is reviewed under expedited review.

**11.4.1.3** Permission from both parents is required for research to be conducted under Categories .3 and .4 of Section 11.3 (45 CFR 46.406 and 45 CFR 46.407) unless:

1. One parent is deceased, unknown, incompetent, or not reasonably available; or
2. When only one parent has legal responsibility for the care and custody of the child.

**11.4.1.4** The IRB may waive the requirement for obtaining permission from a parent or legal guardian if both the following requirements are met:

1. The research meets the provisions for waiver in 45 CFR 46.116(d)(1-4) and if the IRB determines that the research protocol is designed for conditions or a subject population for which parental or guardian permission is not a reasonable requirements to protect the subjects (for example, neglected or abused children).
2. An appropriate mechanism for protecting the minors 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, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

**11.4.1.5** Permission from parents or legal guardians shall be documented in accordance with and to the extent required by 45 CFR 46.117. (See Section 9 of these Policies and Procedures.)

**11.4.2 Assent from Children.** Children, ages 7 and older, should be given an opportunity to provide assent. That means that they voluntarily agree to be in the research.

**11.4.2.1** Generally, verbal assent through the use of a script should be obtained from children 7 - 11 years of age. Written assent using a written document for the children to sign should be sought for older children. Children 12 years of age or older shall sign assent after the parent or legal guardian has given permission. The assent process should be tailored to the age, maturity, and psychological state of the children involved and should be easy for the children to understand. Therefore, a given research study may make use of multiple documents to obtain assent, for example:

- verbal script (ages 7 -11);
- written assent document (ages 12- 15); and

- a written assent matching the detail of an adult consent document (ages 16 -17).

**11.4.2.2** Assent from children must be obtained unless:

1. The research holds out the prospect of direct benefit to the subject and which is available only in the context of the research (for example, new intervention when none is available);
2. The subject is incapable, mentally or emotionally, of being reasonably consulted; or
3. The IRB specifically waives the requirement and documents protocol-specific justification.

**11.4.2.3** 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 grant permission to it.

**11.4.2.4** The Assent Form. Investigators should try to draft a form that is age-appropriate and study specific, taking into account the typical child's experience and level of understanding, and composing a document that treats the child respectfully and conveys the essential information about the study. The assent form should:

1. tell why the research is being conducted;
2. describe what will happen and for how long or how often;
3. say it is up to the child to participate and that it is okay to say no;
4. explain if it will hurt and, if so, for how long and how often;
5. say what the child's other choices are;
6. describe any good things that might happen;
7. say whether there is any compensation for participating; and
8. ask for questions.

For younger children, the document should be limited to one page if possible. Illustrations might be helpful, and larger type makes a form easier for young children to read. Studies involving older children or adolescents should include more information and may use more complex language.

## **11.5 Children Who are Wards**

**11.5.1** The special protections for children set forth in Subpart D include additional limitations on some research involving children who are wards of the state or any other agency, institution, or entity. Where the research involves greater than minimal risk and no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition (45 CFR 46.406), or requires DHHS Secretarial approval (45 CFR 46.607), children who are wards may be included only if such research is:

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

**11.5.2** In addition, if the research falls into one of the above categories, the IRB shall require, for each child who is a ward, that an advocate be appointed in addition to any other individual acting on behalf of the child as legal guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall 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. [45 CFR 46.409]

## **11.6 Institutionalized Children**

Whenever institutionalized children might be involved in research, the IRB shall take care to ensure that the children are not included as subjects simply because of their availability to the investigator.

# **12 RESEARCH INVOLVING PREGNANT WOMEN OR FETUSES**

## **12.1 Research Not Funded by DHHS**

**12.1.1 Minimal Risk.** For research that is not funded by DHHS where the risk to the fetus is no more than minimal, no additional safeguards are required and there are no restrictions on the involvement of pregnant women.

**12.1.2 More Than Minimal Risk.** Pregnant women or fetuses may be involved in research that is not funded by DHHS, involving more than minimal risk to a fetus, if all of the following conditions are met:

1. Where scientifically appropriate, pre-clinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
2. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus;
3. Any risk is the least possible for achieving the objectives of the research;
4. If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, then the consent of the pregnant woman is obtained in accordance with the provisions for informed consent;
5. If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accordance with the provisions for informed consent, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
6. Each individual providing consent under paragraph 4 or 5 of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
7. For children who are pregnant, assent and permission are obtained in accordance with the provisions of permission and assent;
8. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
9. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
10. Individuals engaged in the research will have no part in determining the viability of a neonate.

## **12.2 Research Funded by DHHS**

Subpart B of 45 CFR Part 46 applies to all DHHS-funded research involving pregnant women. Under 45 CFR Subpart B, pregnant women or fetuses may be involved in research funded by DHHS if all of the following conditions are met:

1. Where scientifically appropriate, pre-clinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risk to pregnant women and fetuses;
2. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
3. Any risk is the least possible for achieving the objectives of the research;
4. If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, then the consent of the pregnant woman is obtained in accordance with the provisions for informed consent;
5. If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accordance with the provisions for informed consent, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest;
6. Each individual providing consent under paragraph 4 or 5 of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
7. For children who are pregnant, assent and permission with respect to the pregnant child are obtained in accordance with the provisions of permission and assent in Section 11.4. However, the pregnant child has the right to give consent regarding the fetus ;
8. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
9. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
10. Individuals engaged in the research will have no part in determining the viability of a neonate.

## 12.3 Research Involving Neonates

Most social and behavioral research does not involve neonates. The following policies and procedures apply to all research involving neonates, regardless of funding source. A neonate is a newborn.

**12.3.1 Neonates of Uncertain Viability and Nonviable Neonates.** Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

1. Where scientifically appropriate, pre-clinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
2. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
3. Individuals engaged in the research will have no part in determining the viability of a neonate.
4. The requirements of Neonates of Uncertain Viability or Nonviable Neonates (see below in this section) have been met as applicable.

**12.3.1.1 Neonates of Uncertain Viability.** Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions have been met:

1. The IRB determines that:
  - a. The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or
  - b. The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and
2. The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accordance with the provisions of permission and assent, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.



**12.3.1.2** Nonviable Neonates. After delivery, nonviable neonates may not be involved in research covered by this subpart unless all of the following additional conditions are met:

1. Vital functions of the neonate will not be artificially maintained;
2. The research will not terminate the heartbeat or respiration of the neonate;
3. There will be no added risk to the neonate resulting from the research;
4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
5. The legally effective informed consent of both parents of the neonate is obtained in accordance with the provisions of permission and assent, except that the waiver and alteration of the provisions of permission and assent do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph.

**12.3.2** Viable Neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accordance with the requirements of IRB Review Process and Research Involving Children (See Section 11).

## **12.4 Research Involving, After Delivery, the Placenta, the Dead Fetus or Fetal Material**

**12.4.1** Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, must be conducted only in accordance with any applicable federal, state, or local laws and regulations regarding such activities.

**12.4.2** If information associated with material described above in this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent sections of this manual are applicable.

## **12.5 Research Not Otherwise Approvable**

If the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and the research is not approvable under the above provisions, then the IRB shall consult with a panel of experts in pertinent disciplines (for example, science, medicine, ethics, law) and provide the opportunity for public review and comment, including a public meeting. Based on the recommendation of the panel and public comment, the IRB may approve the research based on either:

1. That the research in fact satisfies the conditions of Research Involving Pregnant Women or Fetuses, as applicable; or
2. The following:
3. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;
4. The research will be conducted in accordance with sound ethical principles; and
5. Informed consent will be obtained in accordance with the provisions for informed consent and other applicable sections of these Policies and Procedures.

## **13 RESEARCH INVOLVING PRISONERS**

Prisoners are another of the three classes that are deemed so vulnerable to exploitation in research that there are special rules protecting them. In the past, prisoners were viewed as a convenient research population. They are housed in a single location, constitute a large and relatively stable population, and live a routine life. Unfortunately, all the things that make a prison and prisoners a convenient research population also make prisoners ripe for exploitation. The concern Subpart C and these policies and procedures based on Subpart C attempt to address is whether prisoners have any real choice in participation in research, or whether incarceration prohibits free choice.

### **13.1 Applicability**

This Section 13 applies to all human subjects research conducted under the auspices of CUNY involving prisoners as subjects. In addition, such research is subject to the Administrative Regulations of the New York State Department of Corrections and any other applicable State or local law.

## **13.2 Definitions**

**13.2.1** “Prisoner” means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. [45 CFR 46.303]

**13.2.1.1** The following are not prisoners:

- Persons court-ordered to nonresidential treatment programs as an alternative to incarceration;
- Persons released to halfway houses;
- Probationers and parolees.

**13.2.1.2** Persons under house arrest are prisoners.

**13.2.1.3** The definition of prisoner also includes research subjects who become prisoners during the course of research (see Section 13.7).

**13.2.1.4** Minors can be prisoners, in which case the requirements of Section 10.1 of this policy apply in addition to those set forth in this Section.

**13.2.2** “Minimal Risk” is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons [45 CFR 46.303]

This definition differs from the general Common Rule definition (see Section 2). For research involving prisoners, minimal risk relates to “physical and psychological harm,” as opposed to “harm and discomfort” as used in the general definition. Also, unlike the general definition, the Subpart C definition uses risk to healthy persons as the basis for comparison and includes dental examinations in the list of routine examinations.

## **13.3 Composition of the IRB**

**13.3.1** In addition to satisfying the general requirements detailed in the IRB section of these policies and procedures (see Section 5.1), when reviewing research involving prisoners, the IRB must also meet the following requirements:

1. A majority of the IRB (exclusive of prisoner members) must have no association with the prison(s) involved, apart from their membership on the IRB.

2. At least one member of the IRB must be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement.

The prisoner representative must have a close working knowledge, understanding and appreciation of prison conditions from the perspective of a prisoner, and should review the research with an eye toward protecting the best interests of the prisoner.

The prisoner representative may be a regular member of the IRB or an alternate member who participates in Subpart C reviews only.

CUNY shall notify OHRP of any changes in the IRB roster to include or replace a prisoner representative.

**13.3.2** These composition requirements apply to all types of IRB review of research involving prisoners: initial, continuing, review of protocol amendments, review of unanticipated problems involving risks to subjects, and review of applicability of a waiver for certain epidemiology research.

**13.3.3** If the local IRB does not meet these composition requirements, it shall contact the ORC to arrange for review of the research by another CUNY IRB.

#### **13.4 Protocol Review**

**13.4.1** The IRB should conduct full reviews of all initial protocols for research involving prisoners. Although the regulations do not prohibit expedited review of such research, it is CUNY's view that the concerns inherent in these protocols justify full review.

**13.4.2** In addition to meeting all other responsibilities prescribed for IRBs in the IRB Review Process sections of this manual (see Section 7), the IRB shall not approve research involving prisoners unless it makes and documents each of the following seven findings set forth in 45 CFR 46.305(a):

1. The research falls into one of the following permitted categories described in 45 CFR 46.306(a)(2):
  - a. study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
  - b. study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

- c. research on conditions particularly affecting prisoners as a class (for example, research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults);
- d. research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.

NOTE: Categories (a) and (b) apply only to minimal risk research.

- 2. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.

In other words, are the advantages of participating in the study coercive? Some questions an IRB might ask are: Will subjects be paid? If so, is the payment the same or less than that paid to nonprisoners?

If prisoners and nonprisoners receive the same payment, does this create a problem if the payment is higher than that for other prison jobs? In other words, is the higher payment encouraging prisoners to sign up for something that they might not otherwise do? On the other hand, if payment is less than that to nonprisoners, is the project exploiting the cheap labor of prisoners? Some ways to handle this issue might be to pay all research subjects the same fee, but only directly give the prisoner subjects an amount equal to the prison wage and put the rest in an escrow account until the prisoner is released.

Another question an IRB might ask when looking at the potentially coercive nature of a project is whether efforts will be made to ensure that prisoners understand that participation is voluntary.

- 3. The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers.

Among other things, the IRB should consider whether or not information about or collected from prisoners is kept confidential. In a prison setting, privacy of information is particularly important to ensure subject safety. A prisoner who discusses prison behaviors or activities may be seen as an informant – by prison staff or by his or her fellow prisoners. Information obtained from prisoners in a group setting could jeopardize the safety of individuals.

4. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.

One question an IRB might ask is whether the decision to participate in the research is made in a “public” setting. Prisoners may feel pressured to participate if a request for volunteers is done at a group meeting. This could be particularly true if it appears that prison authorities support the research.

5. The information is presented in language which is understandable to the subject population.

The IRB should ask whether investigators are using necessary measures to assure that incompletely educated or poor/non English speakers understand the nature of the research. In fact, IRBs should consider this issue with respect to every protocol they review, whether or not prisoners are involved.

6. Adequate assurance exists that a Parole Board will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.
7. Where the IRB finds there may be a need for follow-up examination or care of subjects after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing subjects of this fact.

### **13.5 Waiver for Epidemiology Research [68 Fed. Reg. 36,929 (2003)]**

**13.5.1** As noted above, the Subpart C limits research involving prisoners to research directly relevant to prisoners; that is, the regulations do not allow research that could be conducted in a nonprisoner population. The Secretary of DHHS has waived this restriction for certain research conducted or supported by DHHS that involves epidemiologic studies. This is not a waiver of IRB review, but a waiver from the restrictions in the allowable categories of research.

**13.5.2** The specific type of epidemiologic research subject to the waiver involves no more than minimal risk and no more than inconvenience to the human subject subjects. The waiver would allow the conduct of minimal risk research that does not now fall within the categories set out in 45 CFR 46.306(a)(2).

**13.5.3** The range of studies to which the waiver would apply includes epidemiologic research related to chronic diseases, injuries, and environmental health. This type of research uses epidemiologic methods (such as interviews and collection

of biologic specimens) that generally entail no more than minimal risk to the subjects. Specifically, this waiver only applies to research in which the sole purposes are:

- To describe the prevalence or incidence of a disease by identifying all cases, or
- To study potential risk factor associations for a disease.

**13.5.4** In reviewing research under this waiver, the IRB shall ensure that, among other things, there are adequate provisions to protect the privacy of subject and to maintain the confidentiality of data.

**13.5.5** If the IRB approves research under the waiver, it shall notify the ORC of the approval. The ORC shall then notify OHRP. In order to qualify for the waiver, CUNY must be able to certify to OHRP that the IRB has approved the research and fulfilled its duties under 45 CFR 46.305(a)(2)–(7) and determined and documented that the research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and prisoners are not a particular focus of the research.

## **13.6 Additional Requirements if Research is Conducted or Supported by DHHS**

### **13.6.1 CUNY Requirements**

**13.6.1.1** Before any DHHS-supported research involving prisoners may be conducted, CUNY must certify to the Secretary of DHHS (through OHRP) that the IRB has reviewed and approved the research including making the seven findings required under 45 CFR 46.305(a), including the finding that the proposed research represents one of the permissible categories of research under 45 CFR 46.306(a)(2). CUNY must send OHRP a certification letter, to that effect, which should include CUNY's name and address and specific identification of the research protocol, including the relevant grant number.

**13.6.1.2** Under its authority at 45 CFR 46.115(b), OHRP requires CUNY to also submit to OHRP a copy of the research proposal so OHRP can determine whether the proposed research involves one of the categories of research permissible under 45 CFR 46.306(a)(2), and if so, which one. The term "research proposal" includes:

- the IRB-approved protocol;
- any relevant DHHS grant application or proposal;
- any IRB application forms required by the IRB; and

- any other information requested or required by the IRB to be considered during initial IRB review

**13.6.1.3** OHRP also encourages institutions to include the following information in their prisoner research certification letters, to facilitate processing:

- OHRP Assurance #
- IRB # for Designated IRB
- Date(s) of IRB Meeting(s) in which protocol was considered, including a brief chronology that encompasses:
  - Date of initial IRB review
  - Date of Subpart C review

**13.6.1.4** The local IRB shall forward the required documentation to the ORC for submission to OHRP.

### **13.6.2 OHRP Requirements**

**13.6.2.1** The Secretary of DHHS (through OHRP) must determine that the proposed research falls within the categories of research permissible under 45 CFR 46.306(a)(2).

**13.6.2.2** The following types of research may not proceed until the Secretary (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Registers, of his or her intention to approve such research:

- Research under 45 CFR 46.306(a)(2)(iii) [involving conditions particularly affecting prisoners as a class] ; and
- Research under 45 CFR 46.306(a)(2)(iv) [involving practices having the intent and reasonable probability of improving the health or well-being of the subject], which requires the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit for the research.

### **13.7 Special Rules Regarding Subsequently Incarcerated Persons**

**13.7.1** The definition of “prisoner” includes a research subject who becomes a prisoner after the protocol is approved by the IRB. If this occurs, the PI shall immediately notify the IRB and all activities involving the prisoner must stop.



**13.7.2** The IRB shall then either:

1. remove the prisoner from the study; or
2. re-review the protocol to determine whether the Subpart C requirements are met. If the IRB does not meet the composition requirements in Section 13.3, then it shall contact the ORC to arrange review by another CUNY IRB. Research involving the prisoner shall not continue until this is done unless the PI and the IRB Chair determine that it is in the best interests of the subject to continue while Subpart C requirements are being met. This exception would most likely come into play during biomedical research when removing the prisoner from the protocol would be harmful.

### **13.8 Documentation of IRB Findings**

An IRB that reviews research involving prisoners needs written documentation that it has complied with this Section 13. This should include:

- Curriculum Vitae of the prisoner representative
- Documentation of protocol-specific information justifying each of the seven findings of 45 CFR 46.305(a). It is not sufficient for the minutes to simply state that the seven findings were made. The IRB must tie the findings into particular parts of the protocol.

## **14 RESEARCH INVOLVING PERSONS WITH MENTAL DISABILITIES OR PERSONS WITH IMPAIRED DECISION-MAKING CAPACITY**

Research involving subjects who are mentally ill or subjects with impaired decision-making capacity warrants special attention as these populations are considered to be vulnerable to coercion.

### **14.1 IRB composition**

**14.1.1** IRBs must have sufficient expertise to review research involving this population. IRBs that regularly review research involving the mentally disabled or those with questionable capacity should consider including among their members one or more individuals who are knowledgeable about and experienced in working with those subjects. Consideration shall be given to adding others who are a member of the population, a family member of such a person, or a representative of an advocacy group for that population.

**14.1.2** The IRB may utilize ad hoc members or consultants as necessary to ensure appropriate expertise.

### **14.2 Approval Criteria**

The IRB shall not approve research involving persons with impaired decision-making capability unless the following conditions are met:

#### **14.2.1 Selection of Subjects**

**14.2.1.1** The PI shall demonstrate to the IRB that the research bears some direct relationship to the condition or circumstances of the proposed subjects, making incompetent persons or persons with impaired decision-making capacity the only suitable research subjects.

**14.2.1.2** Incompetent persons or persons with impaired decision-making capacity shall not be chosen as subjects in the research simply because they are readily available.

**14.2.1.3** Subjects shall be recruited from among noninstitutionalized populations whenever possible. Institutionalized subjects shall not be used unless the research pertains to aspects of institutionalization.

**14.2.2 Degree of Risk.** The proposed research shall entail either:

1. no significant risks, tangible or intangible; or
2. minimal risk or a minor increase over minimal risk, but the research is intended to directly benefit the subject and the probability of the benefit is greater than the risk of harm to the subject.

**14.2.3 Informed Consent.** As with all human subjects research, in reviewing research involving individuals with diminished capacity the IRB shall determine that the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative (surrogate consent), unless otherwise exempt from consent. [45 CFR 46.116]

### **14.3 Assessing Capacity to Consent**

#### **14.3.1 Competency Assessment**

**14.3.1.1** The IRB shall require investigators to conduct a competency assessment whenever there is a possibility of either impaired mental status or decision-making capacity in prospective subjects.

**14.3.1.2** As a general rule, all adults, regardless of their diagnosis or condition, should be presumed competent to consent unless there is evidence of serious mental disability that would impair reasoning or judgment. Mental disability alone should not disqualify a person from consenting to participate in research; rather, there should be specific evidence of individuals' incapacity to understand and to make a choice before they are deemed unable to consent. A key factor in subjects' decision-

making is their appreciation of how the risks, benefits, and alternatives to participation in the study apply to them personally.

- 14.3.1.3** An individual's capacity to consent may fluctuate or change over the course of the research. Consequently, it may be necessary to assess capacity not only prior to beginning the study, but also periodically throughout the course of the research.

#### **14.3.2 Who may conduct the Assessment?**

- 14.3.2.1** If the research involves no more than minimal risk and the research team includes a physician or mental health professional qualified to analyze competency, the IRB may permit the assessment to be carried out by that team member.
- 14.3.2.2** If the research involves more than minimal risk, or it is no more than minimal risk but there are no competency experts on the research team, the IRB shall require the competency assessment to be carried out by an independent, qualified professional.

- 14.3.3 Notice to Potential Subject.** The potential subject must be notified that his or her capacity is being evaluated and be given the opportunity to contest to any resulting determination.

#### **14.4 Consent of Subject**

In those situations when an investigator expects to be able to obtain valid consent from subjects with diminished capacity, IRBs should consider whether the consent process, including consent documents, set forth in the research protocol adequately address the following:

1. Differences both between individualized treatment and research and between clinician and clinical investigator. Potential and actual research subjects, especially those with permanent or transient cognitive impairments, may find it difficult to understand the difference between research and treatment, and to understand investigators' multiple roles, making "therapeutic misconceptions" particularly problematic, and possibly creating confusion among subjects and their families.
2. Sufficient decision-making time. Individuals who are decisionally impaired may need more time to consider the information they are given about a research protocol. Information should be provided incrementally to facilitate understanding. Planning built-in waiting periods within the consent process also may be useful to allow potential subject time to consult with family members about whether or not to participate.

3. Fluctuations in decision-making capacity. For subjects with fluctuating decision making capacity or those with decreasing capacity to give consent, a re-consenting process may be necessary. It is the responsibility of investigators to monitor the decision-making capacity of subjects enrolled in research studies and to determine if individual or surrogate consent must be re-obtained. Procedures for this monitoring should be documented in the IRB-approved protocol or included in an amendment to the protocol. If a potential subject is able to provide initial consent, but may lose the capacity to decide whether to continue or withdraw consent during the research as a result of disease progression (for example, Alzheimer's disease), the IRB may require that the investigator discuss designation of a surrogate with the subject early in the research.

## **14.5 Surrogate Consent**

This policy regarding surrogate consent 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.

NOTE: This section addresses surrogate consent issues in adult subjects only. It is generally accepted that minors are incapable of consenting to research activities. This is due to immaturity in decision-making skills, rather than to impairment. See Section 11 for information regarding research involving minors, including parental/guardian consent.

**14.5.1 Legally Authorized Representative.** As stated above, the Federal Regulations provide that under appropriate conditions investigators may obtain informed consent from a legally authorized representative of a subject (surrogate consent). "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 [45 CFR 46.102(c)].

**14.5.2 Criteria for Determining Appropriateness of Surrogate Consent.** In those situations when an investigator expects to rely on surrogate consent, the IRB must use the following criteria to determine whether to permit the use of surrogate consent for participation in a research study:

1. Surrogate consent may be permitted by the IRB only when the prospective research subject is incompetent or has an impaired decision-making capacity.
2. The research study must relate to the cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of the research subjects.
3. The investigator must include in the protocol a rationale for the use of surrogate consent.

4. There must be a protocol-specific plan for the sequence of steps that will be employed by the investigator(s) to acquire and document surrogate consent provided by a legally authorized representative. The investigator must include a description of this plan in the protocol and provide details of how the decision-making capacity of subjects will be assessed and who will perform the assessment. Investigators are encouraged to use a decision-making capacity tool for assessing competency to consent.
5. The protocol must include procedures to guarantee that subject's representatives are well informed regarding their roles and obligations to protect the incompetent subject or person with impaired decision-making capacity. Health care agents designated by a valid health care proxy, guardians, and next-of-kin must be given descriptions of both proposed research studies and the obligations of the person's representatives. They must be told that their obligation is to try to determine what the subject would do if competent, or if the subject's wishes cannot be determined, what they think is in the incompetent person's best interest.

**14.5.3 Who May Provide Surrogate Consent?** The following individuals may provide surrogate consent on behalf of potential subjects, in order of priority:

1. A health care agent appointed under a health care proxy that specifies that the proxy has the authority to consent to the subject's participation in therapeutic research
2. Individuals granted legally documented authority (for example, guardian appointed under NYS Mental Hygiene Law Art. 81 or NYS Surrogate's Court Procedure Act Art. 17-A). Such authority must specifically include that to make decisions regarding participation in research activities.
3. A family member of the potential subject, in the following order of priority: spouse, adult son or daughter, parent, adult sibling

If the first available party on this list objects or no one from the list is available to give consent, application for consent may be made to a court of competent jurisdiction.

**14.5.4 Adding Surrogate Consent after the Start of Research.** Modification requests to add surrogate consent require full board review by a convened IRB committee because adding the use of surrogate consent to an existing protocol is a significant alteration.

**14.5.5 Assent of Subject**

- 14.5.5.1 The autonomy of individuals with impaired decision-making capacity should be respected. Despite the fact that consent may be obtained from a legally authorized representative, the feelings and expressed wishes of an incompetent person should still be respected.
- 14.5.5.2 When an IRB approves surrogate consent for a protocol, it is with the understanding that, whenever possible, investigators will attempt to obtain assent to participate directly from the subject and the subject's decision to withdraw from a study at any time will be honored.
- 14.5.5.3 Under no circumstances shall subjects be forced or coerced to participate or continue in a research protocol, even if approved by their legally authorized representatives.

## **15 COMPLAINTS, NONCOMPLIANCE, AND SUSPENSION OR TERMINATION OF IRB APPROVAL OF RESEARCH**

### **15.1 Complaints**

The IRB Chair must promptly handle (or delegate an IRB member to handle), and, if necessary, investigate all complaints, concerns, and appeals received by the IRB. This includes complaints, concerns, and appeals from investigators, research subjects and others. The IRB Chair must promptly notify the ORC of any complaints, concerns or appeals and the plan for handling them.

### **15.2 Noncompliance**

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

#### **15.2.1 Definitions**

- 15.2.1.1 “Noncompliance” means failure to comply with any of the regulations and policies described in these Policies and Procedures. Noncompliance may be minor or sporadic or it may be serious or continuing.
- 15.2.1.2 “Minor or sporadic noncompliance” means a failure to comply with one or more of the regulations and policies described in these Policies and Procedures that in the opinion of the IRB Chair (or designee) is administrative in nature. Examples of minor or sporadic noncompliance include turning in a report of an Unanticipated Problem a day late or failure to date a consent form.
- 15.2.1.3 “Serious noncompliance” means a failure to comply with one or more of the regulations and policies described in these Policies and

Procedures that, in the judgment of either the IRB Chair, the convened IRB, or the ORC increases risks to subjects, decreases potential benefits, or compromises the integrity of the human research protection program. Research being conducted without prior IRB approval is considered serious noncompliance.

- 15.2.1.4** “Continuing noncompliance” means a pattern of noncompliance that, in the judgment of the IRB Chair, the convened IRB, or the ORC suggests a likelihood that instances of noncompliance will continue without intervention. Continuing noncompliance also includes failure to respond to a directive to resolve an episode of noncompliance.
- 15.2.1.5** “Allegation of Noncompliance” means an unproved assertion of noncompliance.
- 15.2.1.6** “Finding of Noncompliance” means an allegation of noncompliance that is proven true or a report of noncompliance that is clearly true. For example, a finding on an audit of an unsigned consent document, or an admission of an investigator that the protocol was willfully not followed would represent reports of noncompliance that would require no further action to determine their truth and would therefore represent findings of noncompliance.

## **15.2.2** Review of Allegations of Noncompliance.

- 15.2.2.1** All allegations of noncompliance shall be reviewed by the IRB Chair and the ORC. They will review:
1. all documents relevant to the allegation;
  2. the last approval letter from the IRB;
  3. the last approved IRB application and protocol;
  4. the last approved consent document;
  5. the last approved investigator’s brochure, if applicable;
  6. the grant, if applicable; and
  7. any other information they deem pertinent.
- 15.2.2.2** Upon review of the allegation of noncompliance, the IRB Chair and the ORC shall make a determination as to the truthfulness of the allegation. They may request additional information or an audit of the research in question.

- 15.2.2.3** If in the judgment of the IRB Chair and the ORC, the reported allegation of noncompliance is not true, no further action will be taken. If in the judgment of the IRB Chair and the ORC Executive Director, the reported allegation of noncompliance is true, the noncompliance shall be processed according to Section 15.2.3.
- 15.2.2.4** If in the judgment of the IRB Chair and the ORC, any allegation or findings of noncompliance warrants suspension or termination of the research before completion of any review or investigation to ensure protection of the rights and welfare of subjects, the IRB Chair may terminate or suspend the research as described in below with subsequent review by the IRB. Such terminations must be reported to the ORC and OHRP according to the procedures in Section 15.5.
- 15.2.2.5** If, in the judgment of the IRB Chair and the ORC, the reported finding of noncompliance is not serious, not continuing, and the proposed corrective action plan is adequate, no further action is required and the IRB shall be informed at its next convened meeting.
- 15.2.2.6** If, in the judgment of the IRB Chair and the ORC, the reported finding of noncompliance is serious and/or continuing or the proposed corrective action plan is inadequate, the matter shall be presented to the IRB at a convened meeting with a recommendation that a formal inquiry (described below) be held.
- 15.2.2.7** Prior to the convened meeting to review the findings of noncompliance, all IRB members shall receive:
1. all documents relevant to the allegation;
  2. the last approval letter from the IRB;
  3. the last approved IRB application; and
  4. the last approved consent document.
- 15.2.2.8** At the convened meeting, the IRB may:
1. find that there is no issue of noncompliance;
  2. find that there is noncompliance that is neither serious nor continuing and an adequate corrective action plan is in place;
  3. find that there may be serious or continuing noncompliance and direct that a formal inquiry (described below) be held; or



4. request additional information.

### **15.2.3 Formal Inquiry**

**15.2.3.1** The convened IRB may determine that a formal inquiry into the noncompliance is necessary based on several issues that may include but are not limited to:

1. subjects' complaint(s) that rights were violated;
2. report(s) that investigator is not following the protocol as approved by the IRB;
3. unusual and/or unexplained adverse events in a study;
4. an external (for example, sponsor) audit;
5. repeated failure of investigator to report required information to the IRB.

**15.2.3.2** The IRB Chair or the ORC Executive Director shall appoint a subcommittee consisting of IRB members, and nonmembers if appropriate, to ensure fairness and expertise. The IRB shall give the subcommittee a written charge, which shall include the following:

1. review of the protocol(s) in question;
2. review of any relevant documentation, including consent documents, subject's research and/or medical files etc., as they relate to the investigator's execution of her/his study involving human subjects;
3. review of case report forms and sponsor audit reports of the investigator, if appropriate;
4. interview of appropriate personnel, if necessary;
5. preparation of either a written or oral report of the findings that shall be presented to the convened IRB;
6. recommendation of actions, if appropriate.

### **15.2.4 Final Review**

**15.2.4.1** The IRB subcommittee conducting the inquiry shall report its results at a convened IRB meeting. If the results of the inquiry substantiate the

finding of serious or continuing noncompliance, the IRB's possible actions could include, but are not limited to:

1. request a correction action plan from the investigator;
2. verification that subject selection is appropriate and observation of the actual informed consent;
3. an increase in data and safety monitoring of the research activity;
4. request a directed audit of targeted areas of concern;
5. request a status report after each subject receives intervention;
6. modify the continuing review cycle;
7. request additional investigator and staff education;
8. notify current subjects, if the information about the noncompliance might affect their willingness to continue participation;
9. suspend the study (see below); or
10. terminate the study (see below).

**15.2.4.2** The IRB shall consult with the ORC prior to taking any final action. The IRB shall inform the investigator in writing of its determination and the basis for the determination. The investigator shall be given an opportunity to respond. If the IRB determines that the noncompliance was serious and/or continuing, the results of the final review must be reported as described below in Section 15.5.

### **15.3 Suspension or Termination**

**15.3.1** An IRB is authorized, pursuant to 45 CFR 46.112, to suspend or terminate approval of research that is not being conducted in accordance with these Policies and Procedures or that has been associated with unexpected serious harm to subjects. The IRB's authority in this area takes precedence over any desire on the part of a college or the University to continue the research.

**15.3.2** As described above, the IRB must consult with the ORC prior to suspending or terminating approval of research. The IRB must prepare a written statement of the reasons for its action and written instructions to the investigator regarding the steps the investigator must take. The IRB must promptly provide copies of the statement and instructions to the investigator and the ORC. If appropriate, the ORC will report the suspension or termination to the sponsor, appropriate CUNY officials, and the DHHS or agency head.

**15.3.3** When an IRB terminates or suspends research approval, the investigator must stop all research activities and notify any subjects currently participating in the research that it has been terminated. The investigator must consider the rights and welfare of subjects when developing procedures for withdrawal of enrolled subjects. If the IRB determines to permit or require the investigator to follow-up subjects for safety reasons, the investigator must so inform the subjects and must report any adverse events or outcomes the IRB and the sponsor.

## **15.4 Additional Sanctions**

**15.4.1** In addition to suspension or termination of IRB approval as described above, failure to abide by these Policies and Procedures and the Federal Regulations may result in the following sanctions, among others:

1. Denial of Federal Sponsorship. When deciding whether to support or approve research covered by these Policies and Procedures, DHHS or the head of the sponsoring federal agency may take into account whether the applicant has been subject to a termination or suspension as described above, and whether the applicant or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the judgment of DHHS or the head of the sponsoring federal agency, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects.
2. Other Federal Sanctions. OHRP and/or the FDA may:
  - a. withhold approval of all new CUNY studies by the IRB;
  - b. direct that no new subjects be added to any ongoing studies;
  - c. terminate all ongoing studies, except when doing so would endanger the subjects; and/or
  - d. notify relevant federal, state, and other interested parties of the violations.
3. University Discipline. CUNY may pursue disciplinary action against the investigator or other personnel involved in the research, up to and including dismissal, pursuant to CUNY policies and procedures.

## **15.5 Reporting**

**15.5.1** The IRB shall promptly report to the ORC any Unanticipated Problems involving risks to subjects or others, any serious or continuing noncompliance with these Policies and Procedures, the Federal Regulations or the requirements, or determinations of the IRB, and any suspensions or terminations of IRB approval of research.

**15.5.2** The ORC shall promptly report these incidents to:

1. the Vice Chancellor for Research, the President of the RFCUNY, the General Counsel and Senior Vice Chancellor for Legal Affairs, and the appropriate college dean and/or provost; and
2. OHRP (including the Division of Oversight Compliance if an investigator is to be suspended), any sponsoring department or agency head, and the FDA if the research involves FDA-regulated products.

## **16 INVESTIGATOR RESPONSIBILITIES**

### **16.1 Categories of Investigators and other Research Personnel**

#### **16.1.1 Principal Investigators**

**16.1.1.1** Only CUNY faculty or staff members with University- or RFCUNY-paid appointments may serve as the PI or faculty advisor on a research project involving human subjects that is carried out under the auspices of CUNY and is not exempt from the Federal Regulations.

**16.1.1.2** Adjunct faculty of the University and any investigator whose status is considered to be “in training” (that is, undergraduate students) may serve as a PI for exempt research only, and may serve as a co-investigator for nonexempt research.

**16.1.1.3** The IRB shall recognize only one PI for each study. The PI is ultimately responsible for the conduct of research. Principal Investigators may delegate research activities. However, PIs retain ultimate responsibility for the conduct of those to whom they delegate responsibility. If a research protocol requires skills beyond those held by the PI, it is the PI’s responsibility to see that the protocol is modified to meet the PI’s skills or to include one or more additional qualified individuals as co-investigator(s).

**16.1.2 Undergraduate Student Investigators.** With the exception of exempt research, undergraduate students may not serve as PIs unless they have a faculty advisor who fulfills the PI eligibility criteria and will sign the application, and who will serve as co-investigator and faculty advisor on the study. Student investigators and faculty advisors must receive appropriate training in human research protections (See Section 16.9.)

**16.1.3 Key Personnel.** Key personnel are individuals, other than the PI, who contribute to the scientific development or execution of research in a substantive, measurable way, whether or not they receive salaries or compensation under the protocol. All key personnel shall receive appropriate training in human research

protections. Faculty advisors to undergraduate student investigators are considered key personnel.

## **16.2 General Investigator Requirements**

In order to satisfy the requirements of these Policies and Procedures, investigators (both PIs and co-investigators) who conduct research involving human subjects must:

1. receive appropriate training in human research protections as detailed in Section 16.9 and ensure that all key personnel associated with the research have received appropriate training;
2. develop and conduct research that is in accordance with the ethical principles in the Belmont Report;
3. develop a research protocol that is scientifically sound and minimizes risk to the subjects;
4. have sufficient resources necessary to protect human subjects, including: supervision, a sufficient number of appropriately trained staff, and appropriate support services;
5. protect the rights and welfare of prospective subjects;
6. have plans to monitor the data collected for the safety of research subjects;
7. have a procedure to receive complaints or requests for additional information from subjects and respond appropriately;
8. ensure that applicable laws, regulations, and CUNY procedures and guidelines are observed by key personnel;
9. obtain and document informed consent as required by these Policies and Procedures, the Federal Regulations and the IRB and ensure that no human subject is involved in the research prior to obtaining their consent;
10. ensure that all research involving human subjects receives IRB review and final approval in writing before commencement of the research;
11. comply with all IRB decisions, conditions, and requirements;
12. ensure that protocols receive timely continuing IRB review and approval;
13. report Unanticipated Problems affecting risk to subjects or others or serious adverse events to the IRB;

14. obtain IRB review and approval in writing before amending approved protocols or consent forms; and
15. seek IRB assistance when in doubt about whether proposed research requires IRB review.

### **16.3 Protocol Development**

**16.3.1** The PI shall develop a description of the study and consent form(s) using CUNY's IRB research application form. The PI shall ensure that consent form information is in agreement with the research plan.

**16.3.2** The description of the study shall include or address each of the following:

1. title of the study;
2. purpose of the study;
3. sponsor of the study;
4. results of previous related research;
5. subject inclusion and exclusion criteria;
6. recruitment procedures;
7. justification for use of any special/vulnerable subject populations;
8. study design (including, as needed, a discussion of the appropriateness of research methods);
9. description of procedures to be performed;
10. possible risks to subjects;
11. minimalization of risks and management of adverse reactions;
12. anticipated benefits of the research;
13. assessment of the risk/benefit relationship;
14. circumstances surrounding the consent procedure;
15. research setting;
16. subject autonomy concerns;

17. communication obstacles;
18. vulnerable populations to be involved;
19. procedures for documenting informed consent;
20. obtaining parental permission and assent from minors;
21. using witnesses and/or translators;
22. document storage;
23. compensation to subjects for their participation;
24. compensation for subjects injured as a result of the research;
25. costs to subjects for their participation in the study;
26. costs to third-party payers because of subject's participation;
27. protection of subject's privacy; and
28. resources available to protect subjects, including: supervision, number and training of staff, appropriate support services.

**16.3.3** The proposed consent, parental permission, and/or assent form shall include or address:

1. the general principles and basic elements of informed consent (see Section 9);
2. translated consent documents, as necessary, considering likely subject population(s);
3. CUNY IRB-approved formats for consent forms and assent forms, or waiver of consent conditions.

**16.3.4** If research is sponsored, the PI shall submit the entire grant application to the IRB. If there is a significant variation between the grant application and the IRB protocol, the PI shall identify and justify the variation.

**16.3.5** The PI shall submit the original and required copies of all materials to the local IRB office. Investigators should contact the local IRB office before submission of documents to determine the number of copies to be submitted.

## **16.4 Changes in Approved Research**

**16.4.1** A PI shall seek IRB approval before making any change in approved research unless the change is necessary to eliminate an immediate hazard to the subject. See Section 7.8.

**16.4.2** The PI shall submit an amendment form specifying the changes requested, a revised consent form (if applicable), and a copy of the approved protocol with the proposed changes highlighted, directly to local IRB office. The IRB Chair or Vice Chair shall advise the PI in writing of the IRB's decision regarding the proposed change.

**16.4.3** IRB-approved amendments to ongoing research do NOT extend the original approval expiration date.

## **16.5 Continuing Review after Protocol Approval**

**16.5.1** The IRB shall review ongoing research studies at least annually, or more often, if the IRB finds that the degree of risk to subjects warrants more frequent review. This review shall take place prior to the approval expiration date noted on the approved protocol. If review does not occur in a timely manner, the research must stop. See Section 7.7.4.

**16.5.2** The PI is responsible for submitting a timely continuing review application. As a courtesy, the local IRB office will send a reminder to the PI at least two months prior to the expiration of each approved protocol. The PI should allow sufficient time for development and review of renewal submissions. The "approval date" and the "approval expiration date" are listed on all IRB approval letters.

**16.5.3** The continuing review application shall include a status report on the progress of the research, including the following information for the past year (cumulative data shall also be included after the first renewal):

1. the number of subjects enrolled;
2. number of subjects who withdrew prematurely and reason(s) for their withdrawal;
3. a current copy of the description of the study;
4. a summary of Adverse Events and any Unanticipated Problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review;
5. summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review;
6. any other relevant information, especially information about risks associated with the research;
7. a copy of the current informed consent document and any newly proposed consent document,



8. a copy of the current HIPAA Authorization document, if applicable; and
9. any relevant multi-center trial reports.

## **16.6 Required Reports to the IRB**

- 16.6.1 Unanticipated Problems.** The PI shall report to the IRB Chair any adverse events that are Unanticipated Problems as required by Section 7.9 above.
- 16.6.2 Completion of Research.** The PI shall promptly notify the IRB when an approved research project is completed. The PI shall submit a final progress report to the IRB that includes, for the last year of the research, all of the information listed above to be submitted with applications for continuing review of protocols.

Once the approved research project is completed and the research is closed at the University, the PI is not required to submit any further reports of the research to the IRB.

## **16.7 Record-Keeping Requirements**

- 16.7.1** The PI shall retain copies of all correspondence with the IRB, including approvals and documents approved, and shall implement a system to comply with approval expiration dates.
- 16.7.2** The PI shall retain and store securely a copy of each signed and dated consent form and HIPAA Authorization form collected in connection with the research for a minimum of three years after completion of the research in accordance with Section 6.5.2.

## **16.8 Investigator's Conflict of Interest**

See Section 7.6.5 for policies and procedures regarding conflicts of interest of investigators and key personnel.

- 16.8.1** As part of the application process for IRB approval of research, the PI shall disclose any potential or actual conflict of interest he or she may have in connection with the research, including but not limited to conflicts related to any sponsor of the research. "Conflict of interest" for these purposes shall be as defined in CUNY's Conflict of Interest Policy, and any conflicts shall be resolved pursuant to the procedures in that Policy.
- 16.8.2** If the PI is permitted to proceed with the research following review under the CUNY Conflict of Interest Policy, the consent form provided to potential research subjects shall include an appropriate description of any relationship that might be perceived as a potential conflict of interest.
- 16.8.3** The PI shall report to the IRB Chair any change in his or her conflict of interest status that arises during the course of the research.

## **16.9 Training and Ongoing Education**

An important component of a comprehensive human research protection program is an education program for all individuals involved with research subjects. CUNY is committed to providing training and ongoing education for PIs and key personnel related to ethically conducting research with human subjects.

**16.9.1 Orientation.** Principal Investigators and key personnel shall re review core training documentation including the CUNY PI Manual, and the Belmont Report.

**16.9.2 Initial Education.** CUNY maintains a subscription to the web-based “CITI Course in the Protection of Human Research Subjects” sponsored by the Collaborative Institutional Training Initiative (CITI). Prior to beginning any human subjects research, the PI and key personnel shall complete those modules of the CITI program required by the ORC Executive Director, with an overall competency level of at least 80%.

**16.9.2.1** The PI shall include evidence that he or she has completed the initial education requirement (or the continuing education requirement once the initial education requirement has been satisfied) with any application to the IRB for review of new research or continuing review of research.

**16.9.2.2** Although the IRB will accept applications for review of new research or continuing review if the PI, but not all of the co-investigators or key personnel, holds a current certification of CITI training, the IRB will not grant final approval until all co-investigators and key personnel have completed the initial education requirement (or the continuing education requirement once the initial education requirement has been satisfied).

**16.9.3 Continuing Education and Recertification.** Principal Investigators and key personnel shall satisfy the CUNY continuing education requirement for human research protection by completing the CITI Refresher Course 101 every three years.

**16.9.4 Additional Resources.** CUNY makes human research protection information available on its website to ensure that the University research community is apprised of current regulatory and policy requirements and training opportunities. In addition, some local IRB offices maintain their own websites. The website for OHRP is also an excellent resource.

## **16.10 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.

### **16.11 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 shall be proportional to the risks and inconveniences posed by participation in the research. The amount of payment shall also be equitable with regard to the subjects' socio-economic status.

**16.11.1** The IRB shall review both the amount of payment and the proposed method of disbursement to assure that neither entails coercion or undue influence.

#### **16.11.2 Raffles as Incentives**

Raffles, drawings, and sweepstakes (referred to collectively in this section as "raffles") may be used as incentives to participate in a research protocol only if the requirements described below have been met.

New York Law. Raffles and other games of chance are highly regulated by New York (and most other states) and may be deemed to be illegal lotteries if not properly structured. In New York an illegal lottery is one that requires individuals to provide consideration in order to participate, and in which the winner(s) are determined by chance. Under New York law investigators who wish to use a raffle as an incentive to participation in a research protocol must abide by the following rules to avoid creating an illegal lottery:

1. No monetary or non-monetary consideration shall be required in order to take part in the raffle. This means that:
  - a. The raffle must be open to everyone, even if they were not solicited to participate in the research protocol, choose not to participate in it, or withdraw from it.
  - b. Individuals must not be required to pay anything in order to take part in the raffle.
2. The PI must provide the IRB with the following information, which must also be disclosed to potential research participants:

- a. A statement that the raffle is open to everyone who meets the eligibility requirements, whether or not they participate in the research protocol or withdraw from it;
  - b. Any permissible eligibility requirements. Permissible requirements include age and place of residence;
  - c. A statement that multiple entries are prohibited and that all entrants have an equal chance of winning;
  - d. A description of the prize(s) and the monetary value;
  - e. The approximate odds of winning each prize;
  - f. The date, location, or timing of the raffle;
  - g. How and when the winner(s) will be notified; and
  - h. The methods by which people can enter the raffle. For example, if the standard entry method is that an individual is automatically entered in the raffle after completing an on-line survey, the researcher must provide an alternative method for individuals who choose not to participate in the protocol.
3. The informed consent must state that it is not necessary to complete the research in order to participate in the raffle.

Research Conducted Outside of New York State or Over the Internet. If a raffle is done in conjunction with a survey or other research that will be conducted in one or more locations outside of New York State, or will be conducted over the internet and open to participants located outside of New York State, the raffle must comply with the games of chance laws of each of those locations. In these situations, in addition to complying with the requirements of New York law described above, the PI must also confirm in writing to the IRB that the raffle complies with the applicable laws of each of the non-New York research locations, including any foreign locations.

Other Inducement Programs. Inducement programs in which each research participant receives a prize and all prizes are of equal value (e.g., all participants receive a \$10 gift certificate to a bookstore) are also acceptable. These are not raffles nor illegal lotteries because they do not involve the element of chance.

- 16.11.3** The consent form shall describe the terms of payment and the conditions under which subjects would receive partial payment or no payment (for example, if they withdraw from the research before their participation is completed).

**16.11.4** If monies for payment are to be administered through the University or RFCUNY, the PI should contact the appropriate accounting office for guidance on taxes and recordkeeping.

## **16.12 Investigator Concerns**

Investigators who have concerns or suggestions regarding CUNY's human research protection program should convey them to the ORC, the Vice Chancellor for Research or other responsible parties regarding the issue, when appropriate. The Vice Chancellor for Research 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 IRB Chair will be available to address investigators' questions, concerns and suggestions.

## **17 HIPAA PRIVACY RULE**

### **17.1 History**

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a complex statute dealing with many different health care issues. DHHS issued privacy regulations under HIPAA to insure that concerns over privacy would not compromise one of the statute's most important goals -- the increased efficiency of health care delivery and payment through the electronic transmission of health information. These privacy regulations, commonly called the "Privacy Rule", became effective on October 15, 2002, and have been enforceable since April 14, 2003. They impose limits on the ways in which most health care providers and other entities covered by HIPAA may use or disclose health information for various purposes, including human subjects research.

### **17.2 Differences from the Common Rule**

The Privacy Rule applies to human subjects research separately from the Common Rule and in some ways has broader application. The Privacy Rule applies to all research uses and disclosures of Protected Health Information (PHI) by an entity covered by HIPAA, regardless of whether the research is funded by the Federal government. PHI is defined under the Privacy Rule as individually identifiable health information that is transmitted or maintained in any form or medium by a HIPAA-covered entity, with certain exceptions for education records covered by the Family Educational Rights and Privacy Act (FERPA) and employment records held by the entity in its role as an employer.

The forms and procedures under the Privacy Rule are different from those required by the Common Rule. For example, the written authorization required under the Privacy Rule for research uses and disclosures of PHI is not the same as the informed consent, and the waiver of authorization under the Privacy Rule is distinct from a waiver of informed consent.

Research involving PHI may qualify for exempt review from an IRB but may still require a HIPAA Authorization or waiver. “Exempt” research that is problematic under the Privacy Rule might involve PHI that is identifiable only to the investigator. Even though the investigator recorded data without any identifying information using existing medical or mental health records held by a hospital and may therefore have been approved by the IRB in the exempt category, such research is not exempt from HIPAA requirements, because the investigator had access to the PHI when the information was recorded.

### **17.3 CUNY’s Status under HIPAA**

CUNY is a “hybrid entity” under the Privacy Rule, since the Center for the Biology of Natural Systems at Queens College (CBNS) has been designated as a health care component under HIPAA, while other units and entities within CUNY are not so designated. As a result, investigators at CBNS are covered under the Privacy Rule. All other investigators at CUNY are not covered under the Privacy Rule unless, in order to conduct research, they are using or disclosing patient or client information that they (a) create or receive when acting as HIPAA-covered health care providers, (b) create or receive as members of the workforce of a HIPAA-covered entity, or (c) obtain from a HIPAA-covered entity. For example, CUNY faculty or students who conduct or assist with research may also be employees or trainees in hospital or social service settings that are covered by HIPAA and may be using data obtained from those settings in their research. Investigators at CUNY may also be collaborating with co-investigators who are covered by HIPAA. Consistent with the Privacy Rule, instead of establishing separate privacy boards to handle research-related HIPAA issues, CUNY has determined that its IRBs will deal with such issues.

### **17.4 HIPAA Authorizations**

The Privacy Rule generally requires HIPAA-covered entities to obtain signed permission before using or disclosing an individual’s PHI. This permission is known under the Privacy Rule as an Authorization. When a CUNY research study requires use or disclosure of PHI from a HIPAA-covered entity, the investigator should ordinarily prepare a HIPAA Authorization form and submit it to the IRB at CUNY for review prior to presenting the form to research subjects. (See section 17.5 regarding appropriate circumstances for a waiver of a HIPAA Authorization and sections 17.7 and 17.8 for uses of PHI without a HIPAA Authorization or waiver.)

**17.4.1 Types of HIPAA Authorizations.** There are three HIPAA Authorization forms that CUNY has made available at <http://www.cuny.edu> for certain types of research involving human subjects and for retrospective research involving existing medical records or identifiable biological specimens:

- HIPAA Research Authorization – General
- HIPAA Research Authorization – General HIV, and
- HIPAA Research Authorization – Psychotherapy Notes.

The General form should be used when the PHI from the HIPAA-covered entity does not include any HIV-related information. The General HIV form should be used if the PHI contains HIV-related information. Neither of these forms may be combined with the form for Psychotherapy Notes, which are notes recorded in any medium by a mental health professional that document or analyze the contents of conversation during a counseling session and are kept separate from the rest of the individual's medical record.

None of these three HIPAA Authorization forms is intended to be used in any clinical trial or research that involves a physical procedure or intervention with individual subjects. If a clinical trial or research involves a physical procedure or intervention with individual subjects, the investigator should consult the HIPAA-covered entity's privacy officer for more information and inform the staff of the IRB at CUNY as well, since such research will require additional elements in the HIPAA Authorization form.

**17.4.2 Preparation of HIPAA Authorizations.** Each of the HIPAA Authorization forms includes instructions on how it should be prepared in order to satisfy the requirements of the Privacy Rule, as set forth in 45 CFR 164.508(c). All necessary uses and disclosures of the PHI, and all persons and classes of persons who will disclose, receive, and/or use the PHI, must be described accurately and completely in the HIPAA Authorization form.

**17.4.3 Use of Separate Informed Consent and HIPAA Authorization Documents.** Under the Privacy Rule, a HIPAA Authorization may be separate from the informed consent form, or (except for Psychotherapy Notes, as described below in most cases) the two may be combined into a single document. Although many institutions use combined forms, investigators at CUNY should use separate documents when both an informed consent form and a HIPAA Authorization are required, for the following reason: If a subject stops participating in a research study, a withdrawal of informed consent may be implied even though the subject has not affirmatively withdrawn consent. Where a HIPAA Authorization has been combined with an informed consent form, this implied revocation of informed consent may unintentionally constitute a revocation of the HIPAA Authorization as well. While a subject may explicitly revoke his or her HIPAA Authorization at any time, the implied revocation of the HIPAA Authorization in the foregoing such circumstances could terminate the investigator's ability to use and disclose PHI obtained before the subject stopped participating in the research study. In addition, beyond regardless of any concern about implied revocation, the Privacy Rule provides that a HIPAA Authorization for the use or disclosure of Psychotherapy Notes may not be combined with an informed consent, just as

such a HIPAA Authorization may not be combined with any other HIPAA Authorization (see section 17.4.1). If a HIPAA-covered entity requires the use of a combined HIPAA Authorization and informed consent form, the investigator should consult with the IRB at CUNY regarding the possible risks of using the combined form.

**17.4.4 IRB and Investigator Review of HIPAA Authorizations.** The IRB must review the completed HIPAA Authorization form before it is presented to the research subjects. Prior to submitting the form to the IRB, the investigator should verify that each HIPAA-covered entity involved in the research will accept CUNY's HIPAA Authorization form. If a HIPAA-covered entity requires the use of its own form and the investigator is not a part of the HIPAA-covered entity, the investigator may use the HIPAA-covered entity's form unless the IRB at CUNY finds that it is clearly deficient. If the investigator is part of the HIPAA-covered entity (and thus potentially liable for HIPAA violations), he or she should thoroughly review the HIPAA-covered entity's form for the presence of all required elements and statements as set forth in 45 CFR 164.508(c).

## **17.5 Waiver of HIPAA Authorization**

An investigator may request that an IRB waive or alter the requirement for HIPAA Authorization for a research study that will use or disclose PHI. An IRB may not, however, waive the requirement of HIPAA Authorization for the use or disclosure of Psychotherapy Notes. A copy of the form for requesting a waiver is available at <http://www.cuny.edu>.

**17.5.1 Criteria for Waiver of HIPAA Authorization.** Under 45 CFR 164.512(i), a grant of waiver or alteration of HIPAA Authorization is based on the IRB's finding all three of the following: (a) the use and disclosure of PHI involves no more than a minimal risk to the privacy of the subjects, (b) the research could not practicably be conducted without the waiver or alteration, and (c) the research could not practicably be conducted without access to and use of the PHI. Before approving a request for waiver of HIPAA Authorization, the IRB must also agree that the PHI requested by the investigator is the minimum necessary for the purpose of the research.

**17.5.2 Partial Waiver of HIPAA Authorization.** Under the Privacy Rule, treating health care providers may talk to, or review the records of, their patients and clients without HIPAA Authorization in order to determine whether these individuals would be willing or eligible to enroll in a research study. An investigator who is not a treating health care provider must apply to the IRB for a partial waiver of HIPAA Authorization if he or she does not want to enlist a treating provider to contact potential subjects about enrolling in a research study or to have potential subjects sign a HIPAA Authorization. The partial waiver would allow the



investigator to review records containing PHI to identify potential research subjects and record their names and contact information. The partial waiver does not serve as a waiver of authorization for the conduct of the study. The investigator would either obtain HIPAA Authorization from the subjects or obtain a waiver of authorization from the IRB for the actual research.

A copy of any partial waiver of HIPAA Authorization granted by a HIPAA-covered entity's IRB must be submitted with the investigator's application to the IRB at CUNY. Alternatively, if the HIPAA-covered entity's IRB has indicated that it will respect the judgment of the IRB at CUNY to grant a partial waiver of HIPAA Authorization, the investigator should attach a letter to that effect from the HIPAA-covered entity and attach it to the application to the IRB at CUNY.

## **17.6 HIPAA Identifiers and De-Identification**

The Privacy Rule permits a HIPAA-covered entity or investigator to use and disclose information without restriction, and without a HIPAA Authorization or waiver, if the information has been "de-identified", and thus is no longer PHI. Information is not de-identified if there is any reasonable basis to believe that it could be used to identify an individual. Only an employee of the HIPAA-covered entity may de-identify the HIPAA-covered entity's information, unless the HIPAA-covered entity hires a "Business Associate" to perform this function and enters into an agreement with the Business Associate under the terms required by the Privacy Rule.

The Privacy Rule provides a "safe harbor" for the creation of De-Identified Information if all 18 "HIPAA Identifiers" set forth in 45 CFR 164.514(b)(2)(i) are removed. Even so, the HIPAA-covered entity may not release information with these 18 identifiers removed if its staff has knowledge that the remaining information could be used, alone or in combination with other available information, to re-identify the subject of the information. The Privacy Rule also provides that a HIPAA-covered entity may treat information as "de-identified" if a statistical expert, using generally accepted methods and analyses, concludes and documents that the risk of re-identification is very small.

## **17.7 Limited Data Sets**

The Privacy Rule recognizes the limited value of De-Identified Information to investigators and creates a category of information called a "Limited Data Set" as an alternative to the requirement of a HIPAA Authorization or waiver. While De-Identified Information must exclude all of the 18 HIPAA Identifiers, the Limited Data Set may include dates of treatment, addresses (but not specific street addresses), and birth dates of subjects from the PHI. As with De-Identified Information, only employees of the HIPAA-covered entity or its Business Associates may remove the necessary identifiers to create a Limited Data Set. Unlike De-Identified Information, a Limited Data Set is

considered PHI, and its use and disclosure are subject to the requirements of the Privacy Rule.

An investigator may request that a HIPAA-covered entity disclose a Limited Data Set to the investigator for research purposes, provided that the investigator enters into a “Data Use Agreement” with the HIPAA-covered entity. The Data Use Agreement specifies that the data will be used only for the research purpose for which it was received, and it requires the investigator to use appropriate safeguards to prevent the use or disclosure of the data other than as permitted by the Privacy Rule. An investigator who signs a Data Use Agreement must agree not to re-identify the data or contact the subjects of the data. The investigator’s application to the IRB must indicate that the investigator will be obtaining a Limited Data Set from the HIPAA-covered entity in connection with the research and attach a copy of the Data Use Agreement to the application.

## **17.8 Other Uses of PHI without HIPAA Authorization or Waiver**

Under the Privacy Rule, an investigator who is not part of a HIPAA-covered entity’s workforce may obtain PHI from the HIPAA-covered entity without a HIPAA Authorization or waiver in connection with reviews preparatory to research and research on decedent’s information.

**17.8.1 Reviews Preparatory to Research.** Recognizing that it may be necessary for an investigator who is not a member of a HIPAA-covered entity’s own workforce to review health records in order to assess the feasibility of research or formulate a research hypothesis, the Privacy Rule permits an investigator to conduct a review preparatory to research without a HIPAA Authorization from individuals whose PHI will be accessed. The investigator must give certain representations to the HIPAA-covered entity, including that no PHI will be removed from the HIPAA-covered entity’s premises by the investigator in the course of the review. DHHS has made clear that this prohibition against the removal of data applies to the electronic transfer of PHI from a HIPAA-covered entity to the investigator’s office. If the investigator would like to record the contact information of potential research subjects identified during a review preparatory to research, he or she should apply to the IRBs at CUNY and the HIPAA-covered entity for a partial waiver of HIPAA Authorization prior to conducting the review (see Section 17.5.2).

**17.8.2 Research on Decedent’s Information.** The Privacy Rule allows HIPAA-covered entities to disclose PHI of decedents to investigators for research purposes without a HIPAA Authorization or waiver, except in the case of Psychotherapy Notes, for which authorization from each decedent’s legally authorized representative is required. The investigator must give certain representations to the HIPAA-covered entity and provide documentation, at the request of the HIPAA-covered entity, of the death of the decedents involved.

**17.8.3 Procedures for Other Uses of PHI without HIPAA Authorization or Waiver.** In order to make use of the provisions regarding reviews preparatory to research and research on decedent's information, an investigator should complete the HIPAA-covered entity's form containing the investigator representations, submit the completed form to the HIPAA-covered entity's privacy officer for approval, and provide a copy of the completed form to the HIPAA-covered entity's data custodian (for example, the Medical Records Department). These provisions of the Privacy Rule give a HIPAA-covered entity the right to disclose the appropriate PHI at its own discretion, and they do not assure that the investigator will be given the right to receive such PHI.

## **17.9 Accounting Obligations**

Under the Privacy Rule, an individual is entitled to an accounting of all disclosures of his or her PHI that have not been authorized through a HIPAA Authorization. Thus, even though the IRB has approved a waiver of HIPAA Authorization or PHI is obtained in connection with a review preparatory to research or research on decedent's information, a HIPAA-covered entity (such as the Center for the Biology of Natural Systems at Queens College) that provides PHI for the research study will need to account for all disclosures made to persons other than the HIPAA-covered entity's own workforce if the individual asks for such an accounting. The accounting must include the name of the individual, the date of the disclosure, the name and (if known) the address of the recipients of the PHI, a brief description of the PHI disclosed, and a brief statement of the purpose of the disclosure. HIPAA-covered entities should have systems in place that will capture this information at the time of disclosure to the investigator. Investigators who are part of a HIPAA-covered entity must keep track of disclosures made to persons outside the HIPAA-covered entity during the research project.

## **17.10 Investigator Duties**

Once an investigator is authorized to use or disclose PHI under a HIPAA Authorization or waiver, the investigator may use or disclose the PHI only in the manner and for the purposes expressly permitted by the authorization or waiver and must abide by all limitations, safeguards, and prohibitions expressly included or incorporated by reference in the authorization or waiver. In the absence of specific authorization to the contrary, PHI in research records cannot be reused or redisclosed for any other research study in the future without a new authorization or waiver. Most, if not all, PHI in research records is subject to the same HIPAA protections applicable to PHI in ordinary medical records, at least insofar as the research records are maintained by a HIPAA-covered entity or by an investigator employed by a HIPAA-covered entity. For example, a subject will have the right to inspect and obtain copies of his or her research records and to request amendments to those records. Investigators may suspend the subject's right to see and copy his or her research records while a research study is ongoing,

provided the individual consents to the suspension in writing in the HIPAA Authorization and the investigator agrees that access will be permitted upon termination of the study.

## 18 FDA REGULATED RESEARCH

FDA regulations apply when research involves the investigational use of FDA-regulated drugs, biologics, or devices, regardless of the source of funding. Since CUNY has an FWA from OHRP and has elected to apply the DHHS regulations to all research regardless of funding, both FDA and DHHS regulations apply to research involving products regulated by the FDA.

### 18.1 Definitions

The following definitions from 21 CFR 50.3 apply to FDA-regulated research:

**“Clinical investigation”** means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the FDA under these sections of the Act, but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. The term does not include experiments that must meet the provisions of 21 CFR 58, regarding nonclinical laboratory studies.

**“Human subject”** means an individual who is or becomes a subject in research, either as a recipient of the test article or as a control subject. A subject may be either a healthy human or a patient.

### 18.2 Research Involving an Investigational Drug or Device

**18.2.1 General.** When the principal intent of the investigational use of a test article is to develop information about the product’s safety or efficacy, an Investigational New Drug (IND) or Investigational Device Exemption (IDE) may be required.

**18.2.1.1** An IND may not be necessary if all of the conditions stated in [21 CFR 312.2\(b\)\(1\)](#) have been met. If the PI does not already have an IND, the IRB shall notify the PI in writing that IRB approval is pending receipt of an IND. If there is a debate regarding the need for an IND, the IRB shall require that the PI contact the FDA to obtain written documentation that an IND is not necessary.

**18.2.1.2** The IRB will review protocols involving investigational devices to determine if the device is a “Significant Risk Device” (SR) or a “Non-Significant Risk Device” (NSR). If the IRB determines that the

research involves a SR device, an IDE is necessary. If the PI does not already have an IDE, the IRB shall notify the PI in writing that IRB approval is pending receipt of an IDE.

- 18.2.1.3** Protocols. Protocols involving an IND or IDE require consideration and satisfaction of the pertinent FDA and the DHHS regulations (21 CFR 50, 21 CFR 56, 21 CFR 312, 21 CFR 812, and 45 CFR 46). When the CUNY PI is acting as the sponsor (i.e., there is no external funding involved) of research involving an investigational drug, the PI shall submit to the IRB documentation that the proposed drug preparation has been reviewed and compliance with Current Good Manufacturing Practices has been confirmed.
- 18.2.1.4** IRB Review. Protocols involving an IND or IDE shall undergo initial and continuing review at a convened meeting that includes at least one physician or pharmacist unless the protocol meets the criteria for expedited review (that is, all treatment components complete, in follow-up only, data analysis only).
- 18.2.1.5** Informed Consent. Consent for studies involving an IND and/or IDE shall be obtained as stated in Section 9 of these Policies and Procedures. FDA regulations allow waiver of consent if research meets the criteria specified in 21 CFR 50.23 or 21 CFR 50.24, and DHHS regulations allow a waiver of consent if research meets the criteria specified in 45 CFR 46 “Waiver of Informed Consent Requirements in Certain Emergency Research.” Otherwise, consent is required for all research that falls under FDA regulations or involves experimental treatment, tests, or drugs. In addition, the consent form must identify the test article as investigational and inform subjects that the FDA may inspect research records.
- 18.2.1.6** Reporting. The IRB shall use best efforts to obtain a final report from the PI at the close of a study.
- 18.2.1.7** Emergency treatment with an IND or IDE. In accordance with FDA regulations, the IRB may allow for the Emergency Use of an IND or IDE if the situation meets the definition of “Emergency Use” as stated in 21 CFR 56.102(d) and if the Emergency Use is reported to the IRB within five working days of the Emergency Use.
- 18.2.1.8** In general, the CUNY prefers that whenever possible the IRB Chair or designee approve an IND/IDE for emergency utilization prior to use of the test article. If the IRB Chair or designee provides approval to proceed prior to the emergency treatment with the IND/IDE, the emergency treatment will be reported to a full board for ratification.

**18.2.1.9** When emergency medical care is initiated without IRB approval, the patient may not be considered a research subject. Such emergency care may not be claimed as research, nor may any data regarding such care be included in any report of a prospectively conceived research activity. The emergency treatment must be reported within five working days by the PI to the IRB and any sponsor, and subsequent use of the test article must be reviewed by the IRB. However, the FDA and CUNY acknowledge that it would be inappropriate to deny emergency treatment to a second individual if the only obstacle is that the IRB has not had sufficient time to convene to review the situation. In instances when the IRB has received more than one request for emergency treatment (multiple requests from the same investigator or isolated requests from more than one investigator), the IRB will review the request but will ask the PI to submit a protocol for full board review of subsequent treatments. In instances where a second investigator requests approval for an identical use, the IRB will suggest that he or she collaborate with the PI who made the initial request.

### **18.3 Humanitarian Use Device (HUD)**

Treatment with a HUD is subject to full board initial and continuing review by the IRB. At the time of review, the IRB will determine if written consent from subjects for use of the HUD is necessary. (Refer to the FDA for guidance on Humanitarian Use Exemptions [HDEs]).

If a physician in an emergency situation determines that IRB approval cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be administered without prior IRB approval. In this instance, the PI is required to provide written notification of the use to the IRB Chair within five days after use of the device. The IRB requires that written notification include identification (specification without identifiers) of the patient, the date on which the device was used, and the reason for the use.

It is the responsibility of the PI to notify the FDA if the IRB were ever to withdraw approval for use of a HUD. The FDA should be notified within five days of notification of the withdrawal of approval.

HDEs are for clinical use only and HUDs can be used only for purposes outlined in the approved IRB application.

## **19 SPECIAL TOPICS**

### **19.1 Certificates of Confidentiality**

Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They allow the

investigator and others who have access to research records to refuse to disclose identifying information on research subjects in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. By protecting investigators and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to subjects. Any research project that collects personally identifiable, sensitive information and that has been approved by an IRB is eligible for a Certificate. Federal funding is not a prerequisite for a Certificate.

**19.1.1** Statutory Basis for Protection. Protection against compelled disclosure of identifying information about subjects of biomedical, behavioral, clinical, and other research is provided by the Public Health Service Act, 42 U.S.C. §241(d) as follows:

The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any federal, state or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

**19.1.2** Availability and Use.

- 19.1.1.1** Certificates are granted sparingly. The study's funding source, if any, is not relevant to the decision.
- 19.1.1.2** The Certificate goes beyond the consent form in ensuring confidentiality and anonymity. Without the certificate, investigators can be required by a court-ordered subpoena to disclose research results (usually as part of a criminal investigation of the subjects).
- 19.1.1.3** Any investigator engaged in research in which sensitive information is gathered from human subjects (or any person who intends to engage in such research) may apply for a Certificate of Confidentiality. Research can be considered "sensitive" if it involves the collection of:
  - 1. information about sexual attitudes, preferences, practices;

2. information about personal use of alcohol, drugs, or other addictive products;
3. information about illegal conduct;
4. information that could damage an individual's financial standing, employability, or reputation within the community;
5. information in a subject's medical record that could lead to social stigmatization or discrimination; or
6. information about a subject's psychological well-being or mental health.

This list is not exhaustive. Investigators contemplating research on a topic that might qualify as sensitive should contact the local IRB office for help in applying for a Certificate.

**19.1.1.4** An IRB may require investigators to apply for a Certificate of Confidentiality.

**19.1.2** Limitations. The protection offered by a Certificate of Confidentiality is not absolute. A Certificate protects research subjects only from legally compelled disclosure of their identity. It does not restrict voluntary disclosures.

For example, a Certificate does not prevent investigators from voluntarily disclosing to appropriate authorities such matters as child abuse, a subject's threatened violence to self or others, or from reporting a communicable disease. However, if investigators intend to make such disclosures, this should be clearly stated in the informed consent form which research subjects are asked to sign.

In addition, a Certificate of Confidentiality does not authorize the person to whom it is issued to refuse to reveal the name or other identifying characteristics of a research subject if:

- the subject (or, if he or she is legally incompetent, his or her legal guardian) consents, in writing, to the disclosure of such information;
- authorized personnel of the DHHS request such information for audit or program evaluation, or for investigation of DHHS grantees or contractors and their employees; or
- release of such information is required by the Federal Food, Drug, and Cosmetic Act or regulations implementing that Act.



## **19.2 Mandatory Reporting**

While preparing a research protocol, investigators must keep in mind that the State of New York mandates reporting by certain individuals to designated officials and/or agencies of the following:

- abuse and maltreatment of children must be reported to the NYS Central Registry for Child Abuse and Maltreatment, as well as the NYS Office of Children and Family Services (NYS Social Services Law § 413); and
- communicable diseases and conditions are reported to the local office of the NYS Health Department (New York State Sanitary Code 10 NYCRR 2.10).

Investigators should consult these sources to determine if they have an obligation to report and if potential subjects should be advised of that obligation during the informed consent process.

## **19.3 CUNY Students and CUNY and RFCUNY Employees as Subjects**

If an investigator wishes to recruit CUNY students and/or CUNY and RFCUNY employees as potential research subjects, the investigator must ensure that there are additional safeguards in place. The voluntary nature of their participation must be primary and without undue influence on their decision. Investigators must emphasize to these subjects that neither their academic status or grades, or their employment, will be affected by their decision to participate.

To minimize coercion, investigators should avoid, whenever possible, the use of their own students and employees in their research. Instead, investigators should solicit subjects through means such as bulletin board notices, flyers, advertisements in newspapers, and announcements in classes other than their own. If an investigator must recruit or conduct research in his or her own class, then the investigator must include additional safeguards to minimize coercion.

## **19.4 Student Subject Pools**

Investigators often recruit students to participate in research. Several ethical issues can arise in such recruitment, for example, coercion or undue influence. Students can feel pressured to participate in research when they perceive that their instructors favor their participation, when extra credit is offered in exchange for participation, or when research participation is made part of a course requirement.

In many beginning psychology and similar courses, research participation is a course requirement or offered for extra credit. A subject pool is often the method used to enroll students for participation in research. Researchers recruit subjects from this pool. In a well-regulated subject pool, the recruitment of students is systematic.

To ensure that participation in a research project is voluntary, an investigator creating a subject pool must ensure that undue influence by the instructor is minimized in the recruitment process and must provide alternatives to research participation to fulfill a course requirement or to earn extra credit.

#### **19.4.1**     Minimizing Undue Influence.

- 19.4.1.1** Investigators must obtain prior approval from instructors before recruiting subjects or conducting research in their classes.
- 19.4.1.2** Investigators should consider entering a classroom to recruit students and conduct research (for example, to administer a survey) at the end of the class period to allow nonparticipating students the option of leaving the classroom, thereby alleviating pressure to participate.
- 19.4.1.3** The instructors of the course(s) in which subject pool students are enrolled should not be the administrators of the subject pool. Instead, at the end of the semester, subject pool administrators should inform instructors about the credits obtained by each enrolled student. The administrators should not communicate to instructors (a) whether these credits were obtained through research participation or through participation in one or more of the alternatives or (b) in which research projects any particular student participated. Students should be informed of such an arrangement in writing at the beginning of the semester in which they are enrolled in a subject pool.

**19.4.2**     Alternatives to Participation in the Subject Pool. The purpose of the requirement to participate in a subject pool is pedagogical. The student can learn more about the research process by participating as a subject in one or more research studies. Alternatives to participation must meet the pedagogical purpose.

Alternatives cannot be more demanding, or reasonably be perceived as more demanding, in terms of time or effort, than participation in the research. The following are examples of acceptable alternatives to research participation:

1. Attend workshops or discussions on topics related to the research;
2. Observe the research process. For example, a student could observe data collection rather than provide data;
3. Work in research labs;
4. Conduct small observational research projects. The subject pool administration should provide written materials for such projects to draw attention to the issues involved in conducting and interpreting such research;

5. View a video about research or read a short research report and answer questions or write a brief summary of the video or report;
6. Participate in data collection for nonresearch purposes. For example, a student could act as a subject in a course-related research project or other course-related training where data are not collected for purposes of generalizable knowledge and falls outside of the definition of research;
7. Attend a research symposia in which PIs discuss their research; and
8. Complete an assigned number of CITI modules. (See Section 5.9.)

**19.4.3** Minors. Minors might be enrolled in the subject pool. Investigators must provide alternatives for those minors who are not eligible to participate in research projects. Opportunities must be provided for minors to fulfill a course requirement or to obtain extra credit. Alternatively, a college may adopt a policy exempting minors from any research participation requirement.

**19.4.4** IRB Responsibilities. Investigators wishing to recruit and use a subject pool must submit the proposed procedures for the pool to their local IRB for review and approval. Investigators must not begin enrolling students into the pool until the IRB has granted approval in writing. During its review, the IRB will determine if the pool and procedures meet the following requirements:

1. Each research project for which subjects will be recruited from the subject pool has an IRB protocol number and its PI has certified that the project has current IRB approval.
2. All faculty members who are registering to recruit subjects for a course-related project or other research project that falls outside the scope of research as defined in 45 CFR 46.102 have certified that
  - a. the project is not research as defined in 45 CFR 46.102;
  - b. data collected for the project will not be disseminated outside the training purpose; and
  - c. the project does not pose a risk beyond the ordinary minimal risks of daily life for university students.
3. The subject pool has a mechanism to maintain records for all projects that enroll subject pool subjects, including the IRB protocol number for each project, or the certifications that a research project is not research as defined in 45 CFR 46.102.

4. The subject pool has a mechanism to maintain records concerning the number of subjects accrued for each project and the number of students who participated in each of the alternatives as a way of obtaining credit.
5. The subject pool has clear written instructions that will be provided to students who are enrolled. These instructions must:
  - a. explain the pedagogical purpose of participation and how this pedagogical purpose will be fulfilled;
  - b. provide a clear description of the alternatives that are available to research participation; and
  - c. provide a clear description of how instructors will be insulated from the administration of the subject pool and why the course instructors will not know which students volunteered to participate in research.
6. The subject pool provides a clear written summary of the purposes and procedures of the subject pool to students at the beginning of the semester in which the students are enrolled in the subject pool, including a clear description of the alternatives to research participation.
7. The subject pool provides a sufficient number of alternatives to research participation, these alternatives fulfill the pedagogical purposes of the subject pool, these alternatives are neither more effortful nor more time consuming than participation in the research, and there are sufficient alternatives to research participation so that all students can fulfill a research requirement or earn extra credit even if the subject pool does not have enough research projects available.
8. The subject pool will not allow minors to enroll in any research project for which the IRB has not approved participation of minors. The recruitment materials provided to students enrolled in the subject pool must state clearly for each project whether minors are allowed to participate.
9. The subject pool administration certifies that it will not change or alter any of the procedures that have been agreed upon with the IRB without IRB approval.
10. The subject pool will inform the IRB if there are any issues that concern the subject pool.

In addition, when reviewing applications that propose to recruit subjects from a subject pool, the IRB must consider the following:

1. Subjects will be provided with links, references, or other materials for further information on the research topic.

2. Studies recruiting subjects through a subject pool may not involve more than minimal risk.
3. Students can withdraw from a study at any time without losing credit for participation.
4. The confidentiality of information will be maintained when subjects are recruited from a subject pool.

**19.4.5**     Continuing Review. All subject pools must obtain annual continuing review and approval by a CUNY IRB if they are to continue enrolling students. At each annual continuing review, the subject-pool administrator must provide the IRB with the following:

1. a list of all projects that recruited subjects from the pool since the last review;
2. the IRB protocol numbers that were registered with the subject pool for these projects;
3. the numbers of subjects recruited for each project;
4. a list those projects that collected data using subject-pool subjects, but were certified by the PI as being outside the scope of 45 CFR 46.102;
5. a list of all alternatives to research participation that were offered to students and the enrollments in these alternatives;
6. a description of any and all events that might be considered as adverse events during the preceding year;
7. a certification by the subject-pool administrator or other responsible official for the subject pool that no changes had been made to the procedures that were agreed upon with the IRB; and
8. the number of students who did not fulfill the course requirement or did not earn the offered extra credit.

**19.4.6**     Noncompliance. If an IRB becomes aware of any issues of noncompliance with ethical regulations involving a subject pool, the IRB Chair must inform the ORC. In consultation with the ORC, the IRB Chair shall consider possible remediation, including the possibility that the activities of the subject pool will be suspended if the possible misconduct appears sufficiently egregious and is a function of the subject pool and not merely of an individual study. The IRB and the ORC shall institute training procedures when appropriate to augment ordinary ongoing training and to remediate

possible instances in which the conduct of a subject pool fails to follow appropriate ethical principles. If an IRB discovers that the alternatives to research participation are rarely chosen by students, the IRB should seek to discover whether this indicates that the alternatives are perceived by students as requiring more effort or time than does research participation. If this is the case, the subject pool will be required to offer different or additional alternatives.

## **19.5 Student Research**

Research conducted by graduate and undergraduate students at CUNY is subject to the same Federal Regulations regarding research protocols involving human subjects as is other human subjects research at CUNY. However, these regulations allow certain types of course-related studies to be exempted from IRB review. The purpose of this section is to clarify when student research projects and activities must be reviewed by the IRB.

**19.5.1** Research Practica. Research practica (usually in the form of course-related research projects and/or directed studies) are designed to provide students an opportunity to practice various research methods such as interview, observation and survey techniques, measurement of behavior (for example, reaction time, speech, problem solving), as well as data analysis. Typically such projects are quite limited in scope, do not lead to generalizable knowledge and are not undertaken with that goal in mind. For example, a student may interview a peer when the interview does not involve any sensitive, personal information.

Such projects should not put the subjects at more than minimal risk, and the data must be recorded anonymously by the students (that is, with no names, social security numbers, or any other codes that can be linked to a list of names). These projects are considered "classroom exercises" and are not subject to review by an IRB unless the student investigator anticipates publishing the results or presenting at a professional meeting.

**19.5.2** Research Projects, Directed or Independent. Any research conducted by students, graduate or undergraduate that does not fall under the definition of a research practicum, that uses human beings as subjects, and that is intended to contribute to generalizable knowledge, must be reviewed and approved by an IRB. This includes, but is not limited to, all independent undergraduate research projects and honors theses, masters' theses and dissertations.

**19.5.2.1** Role and Responsibility of Faculty Advisor. Undergraduate students may not serve as PIs unless they have a faculty advisor who fulfills the PI eligibility criteria and who will sign the research application and serve as co-investigator and faculty advisor on the study. When students conduct research as part of a course of study, a faculty

member ultimately is responsible for the protection of the subjects, even if the student is the primary investigator and actually directs 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.

- 19.5.2.2** IRB Review. All nonexempt student research projects must be submitted for regular IRB review. Keep in mind that all requests for review of nonexempt projects must be submitted at least two weeks before the next scheduled IRB meeting on the relevant campus if the project requires full review by the IRB. The investigator should check with the IRB for the deadline on that campus.

Recognizing the time constraints imposed on projects that must be begun and completed within a single semester, the IRB will make every effort to work with instructors to process proposals promptly. However, instructors must plan for and allow adequate time for the review process to occur (approximately a week to a month, depending on the particular human subjects issues raised by the proposed research). The later in the term a proposal is received, the more difficult it will be to accomplish the review in time for the projects to be completed during the current semester. Instructors are urged to submit proposals within the first three weeks of the semester for projects that must be completed during the current semester. In some cases, when students in a course are all using similar methods of recruitment and data collection, instructors may submit an aggregate proposal.

- 19.5.2.3** Exempt Research. Student research projects may be submitted to the IRB for consideration as exempt research if they meet federal exemption criteria such as research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior in which data is collected anonymously (that is, with no names, social security numbers, or any other codes that can be linked to a list of names) or otherwise qualify under exemption category 2 of the Common Rule. The course instructor must submit exemption requests to the IRB. See Section 7.2 for more information regarding exempt research and the categories of research eligible for exemption.

## **19.5 Oral History**

CUNY policy requires that all projects involving oral history interviews be submitted to the IRB so that the IRB Chair can determine whether the project is research subject to the Common Rule and if so, whether or not it needs IRB review. In many cases oral history interviews determined to be human subjects research can be reviewed in the “exempt” category. However, in other situations, particularly those involving traumatic

experiences, the research may not be harmless and should receive IRB review at a convened meeting. IRB review is also particularly important for cases in which the nature of the generalizations drawn may change over time.

The following is based on guidance received from OHRP:

**19.6.1** Is it Research? A decision whether oral history or other activities solely consisting of open-ended qualitative type interviews are subject to the Federal Regulations is based on the prospective intent of the investigator and the definition of "research" under the Regulations at 45 CFR 46.102(d): "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

For the purposes of these Policies and Procedures the evaluation of such activities hinges upon whether the person is engaged in the creation of "generalizable knowledge," that is, whether the activity represents a systematic investigation in which the person engaged in such activities intends to develop or contribute to generalizable knowledge. See Section 2 for a definition of generalizable knowledge.

**19.5.2** General principles for evaluating Oral History type activities:

**19.6.2.1** Oral history activities, such as open-ended interviews, that ONLY document a specific historical event or the experiences of individuals without intent to draw general conclusions would NOT constitute "research" as defined by the Common Rule.

Example: An oral history video recording of interviews with holocaust survivors is created for viewing in the Holocaust Museum. The creation of the video tape does NOT intend to draw general conclusions. 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.

**19.6.2.2** Systematic investigations involving open-ended interviews that are designed to develop or contribute to generalizable knowledge (for example, designed to draw general conclusions) WOULD constitute "research" as defined by the Common Rule.

Example: An open ended interview of surviving Gulf War veterans to document their experiences and to draw general conclusions about their experiences.

**19.6.2.3** 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 the Common Rule, the creation of such an archive WOULD constitute research under Common Rule.

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 the Common Rule since the intent is to collect data for future research.

## **19.6 Genetic Studies**

Genetic research studies may create special risks to human subjects and their relatives. These involve medical, psychosocial, and economic risks, such as the possible loss of privacy, insurability, and employability, change in immigration status and limits on education options, and may create a social stigma. Knowledge of one's genetic make-up may also affect one's knowledge of the disease risk status of family members.

- 19.7.1** State Law. Investigators should be aware of the New York State Civil Rights Law § 79-L, Confidentiality of Records of Genetic Tests. Under this law, “genetic tests” are defined as “any laboratory test of human DNA, chromosomes, genes, or gene products to diagnose the presence of a genetic variation linked to a predisposition to a genetic disease or disability in the individual or the individual's offspring; such term shall also include DNA profile analysis.” Genetic tests do not include “any test of blood or other medically prescribed test in routine use that has been or may be hereafter found to be associated with a genetic variation, unless conducted purposely to identify such genetic variation.”
- 19.7.2** General IRB Review. When reviewing genetic research studies, the IRB needs to consider whether the protocol and the informed consent procedure adequately address the points listed below. Some points may not be relevant to a particular study.
1. Do the proposed recruitment procedures minimize the possibility of coercion or undue influence of potential subjects? This is of particular concern when the proposed study population consists of family members, who may feel strong pressure to participate.
  2. Are the psychological and social risks adequately disclosed in the consent process? Do investigators provide for appropriate counseling to subjects, both as part of the consent process and when communicating results?
  3. If there are social risks (jeopardy to insurability, employability, etc.), how will the data be protected from disclosure to third parties, such as employers and insurance companies?

4. Will the data be stored in a secure manner? Will the data be coded so as to protect the identity of subjects? Is a request for a certificate of confidentiality appropriate? Is this explained in the consent?
5. Are there procedures in place to insure that consent has been obtained before revealing medical or personal information about the subject to family members or vice versa?
6. Will subjects be given the option not to receive information about themselves or others? How will this option be recorded?
7. How and when will information, including interim or inconclusive research results, be reported to the subjects and their families? Will subjects receive an explanation of the meaning of the information they receive, including the limits on certainty of testing? New York law requires that the consent include the level of certainty that a positive test result for a disease or condition serves as a predictor for that disease or condition, if known.
8. Will subjects be informed about the possibility that incidental findings may be made (for example, paternity, diseases, or conditions other than the one(s) under study)? How will disclosure of such information occur?
9. Will vulnerable populations (for example, children, or persons with impaired mental capacities) be adequately protected? Under what circumstances can a research subject grant permission to involve a minor child or an incapacitated adult in a study?
10. Are appropriate provisions in place for handling data and tissue samples when a subject withdraws from a study? Do any practical limitations exist on the subject's right to withdraw from the research, withdraw data, and/or withdraw samples?
11. What procedures are in place for handling requests for secondary uses of the research data or samples (for example, by the investigator for different research purposes or by a different investigator)? Will the subject's identity be known by any new investigator? Are secondary uses adequately addressed in the consent? How can the subject opt out of any distribution or subsequent use of his or her genetic material?
12. If a new study proposes secondary use of samples, the IRB should assess whether or not the consent that was obtained for the first study also applies to the new study. If the purpose of the new study differs significantly from the purposes of the original protocol, and the samples are identifiable, the investigator should obtain new consent. On the other hand, if the samples are anonymous and the original consent both did not specify time limits and

authorized use for general research purposes, the IRB may determine, in its discretion, that additional consent is not required.

13. If sample banking is anticipated, where will the samples be kept? Who will have access and for what purposes? Who will own the samples? Can the subject consent or decline to be contacted in the future by the investigator to obtain updated clinical information? Are these issues addressed in the consent?
14. How long will samples be kept? Under New York law anonymous samples may be kept indefinitely. However, identifiable samples may only be kept for a limited time unless the subject has given consent for a longer period. Subjects may consent that samples be kept for as long as deemed useful for research purposes.
15. Do the investigator's publication plans threaten the privacy or confidentiality of subjects? Has adequate consideration been given to ways in which subjects' privacy and confidentiality can be protected (for example, providing for consent to publication of identifying information)?
16. Is the subject permitted to participate in the study while refusing to have genetic testing (such as in a treatment study with a genetic testing component)?

- 19.7.3** Expedited Review and Exemption from Review. The fact that genetic studies are often limited to the collection of family history information and blood drawing should not, automatically classify them as "minimal risk" studies qualifying for expedited IRB review.

The expedited review process is available for minimal risk research where the research activity is limited to one of a specified category, including the provision of blood samples. However, in genetic studies that involve a blood draw, the additional psychosocial risks are likely to raise the risk beyond the "minimal risk" level allowable for expedited review. When an expedited review is requested, IRBs should review the question of minimal risk carefully.

With respect to exemption from review, the development of a pedigree through interviews with family members is likely to create identifying information, even where individuals will not be identified. Such research would not, therefore, qualify for exemption from review under the Federal Regulations.

## **19.7 Research Involving Coded Private Information or Biological Specimens**

CUNY policy is based on the OHRP guidance document entitled, "Guidance on Research Involving Coded Private Information or Biological Specimens" (August 10, 2004 <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>). This document:

provides guidance as to when research involving coded private information or specimens is or is not research involving human subjects, as defined under the Common Rule, and reaffirms OHRP policy that, under certain limited conditions, research involving only coded private information or specimens is not human subjects research. It also provides guidance on who should determine whether human subjects are involved in research.

#### **19.8.1** Definitions and Clarifications.

- 19.8.1.1** “Coded” means that: (1) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain, has been replaced with a number, letter, symbol, or combination thereof (that is, the code); and (2) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.
- 19.8.1.2** Under the definition of human subjects in Section 2 of these Policies and Procedures, obtaining identifiable private information or identifiable specimens for research purposes constitutes human subjects research. As defined in Section 2, “Obtaining” means receiving or accessing identifiable private information or identifiable specimens for research purposes. This includes an investigator’s use, study, or analysis for research purposes of identifiable private information or identifiable specimens already in the possession of the investigator.
- 19.8.1.3** In general, private information or specimens are considered to be individually identifiable when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems. Private information or specimens are not considered to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.
- 19.8.1.4** Research involving only coded private information or specimens does not involve human subjects if the following conditions are both met:
1. the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and
  2. the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:
    - a. the key to decipher the code is destroyed before the research begins;

- b. the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that the DHHS regulations do not require the IRB to review and approve this agreement);
- c. there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or
- d. there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

In some cases an investigator who obtains coded private information or specimens about living individuals under one of the conditions cited in 2(a)-(d) above may (1) unexpectedly learn the identity of one or more living individuals, or (2) for previously unforeseen reasons now believe that it is important to identify the individual(s). If, as a result, the investigator knows, or may be able to readily ascertain, the identity of the individuals to whom the previously obtained private information or specimens pertain, then the research activity now would involve human subjects. Unless this human subjects research is determined to be exempt (see Section 7.3), IRB review of the research would be required. Informed consent of the subjects also would be required unless the IRB approved a waiver of informed consent (see Section 9.3).

**19.7.2 Who Should Determine Whether Coded Private Information or Specimens Constitutes Human Subjects Research?** The investigator in consultation with the IRB Chair or the ORC Executive Director will determine if the research involving coded information or specimens requires IRB review. The investigator may make either a verbal (by phone or in person) or written (including e-mail) request for a determination. Investigators should include sufficient information regarding the activity to allow a determination to be made. The IRB Chair or the ORC may require that a verbal request be re-submitted in writing or supported with documentation, if necessary for the determination. If the request and determination are verbal, it is the investigator's responsibility to retain his or her own documentation of the request and the IRB Chair's or the ORC's decision in accordance with Section 6.5.2. If the request is in writing, the IRB Chair or the ORC will also respond in writing. The local IRB office will keep a copy of all submitted materials and determination notices, and a record of determinations made, in accordance with Section 6.5.1.

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