INSTITUTIONAL REVIEW BOARD PROCEDURES

**Policy or Procedure Description:**
AR.002 provides the procedures for the Institutional Review Board (IRB). Included is an overview sequencing of the IRB Process, timetables for review and a detailed outline of the IRB Review Process.

**Related Links, Documents and Forms:**

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SEQUENCING OF IRB REVIEW PROCESS

1. Meeting dates are chosen for the coming semester.
2. Selection of deadlines for submission of IRB packets from principal investigators.
3. Receipt of submissions from principal investigators.
4. Input of submission into IRB Manager database.
5. IRB Administrator makes sure that the packets are complete, i.e. reading consent forms, making sure that elements are all there, and that the applications are correctly filled out.
6. The IRB chair reads the proposal making sure that a full review is needed before it is sent out.
7. IRB chair consults with principal investigator if submission is problematic.
8. Proposals are sent out to entire IRB at least one week before the committee meets.
9. Meetings are scheduled for once a month. If reviews are not finished during the meeting, another meeting is scheduled to complete the agenda within the week.
10. Minutes of IRB meeting produced.
11. Administrator begins writing letters for approval and requests for revisions.
12. Information in IRB Manager is updated.
13. Faculty advisors for student principal investigators are notified of IRB decisions.
14. When appropriate, requests to principal investigators for renewal applications are sent out.

After the meetings the IRB administrator begins writing letters to principal investigators. Approval letters are written first followed by letters that require revisions. The IRB Chair reads all of the letters and then signs them. Depending on the numbers of letters and their complexity, this can take up to a week. If the PI's are students, a copy of the letters requiring revisions is sent to the student’s advisor. Principal investigators are informed by the IRB administrator when they ask what transpired at the meeting.

While proposals are being prepared by the IRB office, new proposals are continuously being submitted for review.
# Institutional Review Board Procedures

## Timetable for Full Reviews

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submission of IRB Proposals</td>
<td>(Chair and IRB Administrator read and counsel PI’s)</td>
</tr>
<tr>
<td>Send out proposals to members/members read proposals</td>
<td>1 Week/ 1 Week (Input data into IRB Manager)</td>
</tr>
<tr>
<td>Minutes of meeting produced</td>
<td>2 day – 1 Week</td>
</tr>
<tr>
<td>Approval letters written/ Revision letters written and sent out</td>
<td>2 day – 1 Week</td>
</tr>
<tr>
<td>PI meets conditions in writing</td>
<td></td>
</tr>
<tr>
<td>Approval letters sent (as they come in)</td>
<td></td>
</tr>
<tr>
<td>Update IRB Manager</td>
<td></td>
</tr>
<tr>
<td>Renewal Applications considered (using identical process)</td>
<td></td>
</tr>
</tbody>
</table>

## Timetable for Expedited and Exempt Reviews

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI submits protocol</td>
<td>10 days</td>
</tr>
<tr>
<td>OR /</td>
<td>1-2 days</td>
</tr>
<tr>
<td>Members return coversheet with comments</td>
<td></td>
</tr>
<tr>
<td>Approval Letter or Revision Letter sent</td>
<td></td>
</tr>
<tr>
<td>PI’s advisor notified</td>
<td></td>
</tr>
<tr>
<td>Update IRB Manager</td>
<td></td>
</tr>
<tr>
<td>Renewal applications considered (using same process) except for exempted submissions</td>
<td></td>
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</tbody>
</table>

Input data into IRB Manager
7. IRB REVIEW PROCESS

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 Human Subjects Research Determination

The responsibility for determining whether an activity constitutes human subjects research rests with the IRB or the ORC. Since the University will hold the investigator responsible for incorrect determinations, investigators are urged to request a confirmation that an activity does not constitute human subjects research from the campus IRB Office or ORC. If the request is verbal (by phone or in person) or by email, it is the investigator's responsibility to maintain documentation of such a decision. Formal requests for a determination must be submitted on the Research Determination Form, which include sufficient documentation of the activity to support the determination. Formal submissions will be responded to in writing and a copy of the submitted materials and determination letter/email will be kept on file in the campus IRB Office and by the investigator.

7.2 Exempt Research [45 CFR 46101]

All research using human subjects must be approved by the institution. Certain categories of research (such as, “exempt research”) do not require convened IRB review and approval. Exempt research is subject to institutional review and must be approved by the IRB Chair or Vice Chair.

Exempt research, once approved, is non-renewable. The duration of study for exempt research is limited to that specified on the approved application, not to exceed three years. Any changes in the approved research must be submitted to the IRB for approval.

Students may assume roles as Principal Investigators conducting exempt research as long as they have a faculty sponsor who will serve as co-investigator and faculty advisor on the study

7.2.1 Categories of Research Permissible for Exemption

With the above exceptions, 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, but require institutional review, at CUNY:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
   a. research on regular and special education instructional strategies, or
   b. 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:

   a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   b. 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 7.2.2 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:

   a. the human subjects are elected or appointed public officials or candidates for public office; or
   b. 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.

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:

   a. Public benefit or service programs;
   b. procedures for obtaining benefits or services under those programs;
   c. possible changes in or alternatives to those programs or procedures; or
   d. possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies,

   a. if wholesome foods without additives are consumed; or
   b. 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.

7.2.2 Limitations on exemptions

- **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 10.1.1 for the definition of a child.)

- **Prisoners:** Research involving prisoners does not qualify for exemption. (See Section 10.3 for the definition of prisoner.)

7.2.3 Additional protections

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 may require additional protections for subjects in keeping with the guidelines of the Belmont Report.

7.3 Expedited Review of Research [45 CFR 46.110]

All non-exempt human subjects research must be reviewed by the IRB. However, not all research needs to be reviewed at a convened IRB meeting; some research is eligible for expedited review.

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 Chair from among members of the IRB. For IRB members to serve as designees to the IRB Chair for expedited review, they will be experienced in terms of seniority on the IRB, and will be matched as closely as possible with their field of expertise to the study. Alternate members are eligible to serve as expedited reviewers if they meet the above criteria.

When reviewing research under an expedited review procedure, the IRB Chair, or designated IRB member(s), should receive and review all documentation that would normally be submitted for a full-board review, including the complete protocol and funding applications.

In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers 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 7.4 below.
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 [See Section 7.3.1 below] and found by the reviewer(s) to involve no more than minimal risk;

2. minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

A minor change is one which, in the judgment of the IRB reviewer, makes no substantial alteration in (i) the level of risks to subjects; (ii) the research design or methodology; (iii) the number of subjects enrolled in the research (no greater than 10% of the total requested); (iv) the qualifications of the key personnel; (v) the facilities available to support safe conduct of the research; or (vi) any other part of the research that would otherwise warrant review of the proposed changes by the convened IRB.

7.3.1 Categories of Research Eligible for Expedited Review

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.

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

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

- 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.

Research Categories one (1) through seven (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 Pal 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, [Children are defined in the DHHS regulations as “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”][45 CFR 46.402(a)]

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. uncanulated 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 DHHS regulations for the protection of human subjects. 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 DHHS regulations for the protection of human subjects. 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.

[Of 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.

[Under Category (9), an expedited review procedure may be used for continuing review of research not conducted under an investigational new drug application or investigational device exemption where categories (2) through (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. The determination that “no additional risks have been identified” does not need to be made by the convened IRB.]

7.3.2 Informing the IRB of Expedited Review Approvals

All members of the IRB will be apprised of all expedited review approvals and exemptions by means of the Chair's Report. The local campuses, in consultation with the CUNY ORC, will determine the appropriate mechanism and frequency for distributing the Chair's Report to the IRB. Copies of expedited review approvals and exemptions will be made available for review at the request of any IRB member.

7.3.3 Full Review of Minimal Risk Research

If a protocol eligible for expedited review is reviewed at a convened meeting, the IRB may complete the review and may approve the protocol at the meeting. The IRB must determine that the protocol meets the criteria for expedited review, determine the appropriate category of expedited review and document all of 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.
7.4 Convened IRB Meetings

Except when an expedited review procedure is used (See Section 7.3), the IRB must review all non-exempt research at convened meetings (also known as Full-Board meetings) at which a quorum (see below) is present.

7.4.1 Schedule of IRB Meetings

Each campus IRB sets its own meeting schedule as appropriate for the amount of research reviewed, but the IRB must meet at least twice during the academic year. If there is no research to be reviewed at the semi-annual meeting, then the meeting will be used for educational purposes.

Each campus will make available the IRB meeting schedule in advance to all faculty and students. The campus IRB meeting schedule must be submitted to the CUNY ORC at the beginning of each academic year and ORC must be informed of any changes in the schedule promptly.

7.4.2 Quorum

A quorum consists of a simple majority of the voting membership, including at least one member whose primary concern is in a nonscientific area. The IRB Chair, with the assistance of the IRB staff, will confirm that an appropriate quorum is present before calling the meeting to order.

A quorum must be maintained for each vote to occur. If a quorum is not maintained the proposal must be deferred or the meeting must be terminated. In order for the research to be approved, it must receive the approval of a majority of those voting members present at the meeting.

It is expected that IRB members be physically present at the meeting. If physical presence is not possible, a member may be considered present if participating 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 CUNY ORC must be consulted in advance of utilizing teleconferencing or videoconferencing, except under emergency circumstances, in which case ORC must be notified immediately following the meeting.

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

As noted in Section 5.2, alternates may attend any IRB meeting and are encouraged to attend as many meetings as possible. The alternate member will not be counted as a voting member unless the primary member is absent. However, the alternate member may freely participate in the discussion.
7.4.3 New Protocol Applications

Applications are screened by the campus IRB Office staff for completeness and regulatory compliance prior to their placement on the agenda.

The Protocol 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
   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. Protocol-specific conflict of interest information
24. Indication whether the research requires review by other University research compliance committees.
25. Assurances:
   a. Principal Investigator: The PI must certify that
      i. the study has been designed to protect the human subjects;
ii. the PI is responsible for the scientific conduct of the research and for providing all reports and information to the IRB as required;

iii. all members of the research team are appropriately credentialed to perform the work undertaken in the protocol; and

iv. the PI and the other co-investigators are not in violation of the university’s Conflict of Interest Policy while participating in the research.

In addition to the Protocol Application, the investigator must submit any external or internal grant application or contract (for example, PSC CUNY).

Note: Investigators who have other individuals write their protocols and responses to the IRB must recognize that the ultimate responsibility of any study lies with the Principal Investigator (PI). It is incumbent upon the PI to check all material that is submitted to the IRB for review before signing the application.

7.4.4 Primary Reviewers

Each IRB will have a primary reviewer for all protocols requiring full IRB review. For some campuses the IRB Chair will serve as the primary review. For other campuses the campus IRB Office assigns a primary reviewer from the members of the IRB. Reviewers are assigned protocols based on related expertise. When making reviewer assignments, campus IRB Office staff takes into consideration the vulnerable populations involved in the research and assigns the protocol to at least one individual who has experience with this population.

The primary reviewer receives the following documentation, as applicable:

1. Protocol Application, including Description of the Study
2. Proposed Consent / Parental Permission / Assent Form(s)
3. Recruitment materials / subject information (including all surveys and questionnaires)

For Sponsored Research only:

1. Grant application(s) / Contracts
2. Budget(s)

Other IRB Members receive the following documentation:

1. Protocol Application, including Description of the Study
2. Proposed Consent / Parental Permission / Assent Form(s)
3. Recruitment materials/subject information (including all surveys and questionnaires)

Primary reviewers will use the CUNY Protocol Review Checklist as a guide to completing their review.
Copies of the full materials will be made available for any optional review at the request of any IRB member.

7.4.5 Pre-Meeting Distribution of Documents

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

The agenda, with review assignments, and all protocols and supporting documentation to be reviewed are provided to all IRB members approximately one week prior to each meeting. Before the meeting, each protocol application (including background information, project protocol, and informed consent) is carefully reviewed by the Primary Reviewers.

At the meeting, the Primary Reviewer presents an overview of the goals, design, study procedures, safety procedures, and qualifications of the investigators. Particular attention is paid to the Risk/Benefit relationship of the investigation and the adequacy of the consent form in conveying human subjects concerns. Problems identified by the Primary Reviewer or by other IRB members are discussed and suggestions for any necessary changes are agreed upon by the IRB. These issues are considered in the vote to decide IRB action.

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

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

Prior to committing to review, consultants will be informed of the IRB conflict of interest policy. Individuals who have a conflicting interest or whose spouse or family members have a conflicting interest in the sponsor of the research will not be invited to provide consultation. Ad hoc or informal consultations requested by individual members (rather than the full board) will be requested in a manner that protects the researcher’s confidentiality and is in compliance with the IRB conflict of interest policy (unless the question raised is generic enough to protect the identity of the particular PI and research protocol).
7.4.7 IRA Member Conflicts of Interest

As noted in Section 5.4, no IRB member will participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. IRB members are expected to self-identify conflicting interests. A primary reviewer or expedited reviewer with a conflict of interest must notify the IRB staff who will re-assign the protocol prior to the meeting or review.

Except when requested by the IRB to be present to provide information, IRB members will absent themselves from the meeting room when the IRB reviews research in which they have a conflicting interest. The Chair will allow for committee discussion once the conflicted member has recused him/herself. The absent member is not counted toward quorum and his/her absence during the discussion and vote on the protocol will be noted in the IRB meeting minutes. If the quorum is lost (either due to the number of members or the absence of a nonscientist) then the protocol must be deferred.

7.5 IRB Review Process

Except where noted, the following applies to both expedited review and review at a convened meeting.

7.5.1 Possible IRB Actions Taken by Vote:

Approval - the study is approved as submitted.

Deferred for Nonsubstantive (Directed) Changes - The protocol and/or consent form require minor revisions, such as wording changes, with replacement language provided. The needed revisions are agreed upon at the meeting. These revisions are presented to the Principal Investigator for incorporation by simple concurrence, The IRB Chair, Vice Chair, or a subcommittee of the IRB may approve the study upon receipt and approval of the revisions without further action by the IRB.

Note: Approval of the protocol application will not be granted and certification will not be issued until all deficiencies, if any, are corrected to the satisfaction of the IRB

The date of approval is the final date the fully convened IRB reviewed the protocol rather than the date that the minor changes were approved by the IRB Chair, Vice Chair or subcommittee.

Deferred for Substantive Issues - This action is taken if substantial modification or clarification regarding the protocol and/or consent form is required or if materials (such as questionnaires) are missing IRB approval of the proposed research must not occur until the modifications submitted by the investigator are reviewed at a convened IRB meeting.
If the application is deferred for substantive issues, the following will occur:

1. The campus IRB Office informs the investigator in writing of the IRB’s decision, questions and concerns.
2. The investigator’s response is sent to the campus IRB Office.
3. In order to receive approval for a deferred protocol, it must be submitted for full IRB review at a subsequent, convened meeting. The campus IRB Office provides the IRB with the investigator's response, the revised protocol and the previously submitted protocol. The item is placed on the agenda for the following meeting.
4. The protocol application is given full IRB review again. Whenever possible, the deferred protocol will be reassigned to the original reviewer(s).
5. The outcome of the IRB’s deliberations is once again communicated to the investigator in writing.
6. The IRB’s determination concerning the subsequent amended submission will be documented in the minutes of that meeting.

The date of approval 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 changes were approved by the IRB Chair, Vice Chair or subcommittee.

Deferred for Additional Information - Insufficient information is provided in the protocol or consent form to judge the protocol application adequately (for example, the risks and benefits cannot be assessed with the information provided). The protocol must be resubmitted with the necessary information and reviewed at a convened IRB meeting.

The date of approval 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 changes were approved by the IRB Chair, Vice Chair or subcommittee.

Disapproved - Questions are of such significance that the IRB feels approval of the study is unwarranted. Approval of a previously disapproved protocol requires full IRB review.

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. 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 Principal Investigator 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.
7.5.2 Determination of Risk

At the time of initial review, the IRB will make a determination regarding the risks associated with the research protocols. Risks associated with the research will be classified as either “minimal” or “greater than minimal” based on the “absolute” interpretation of minimal risk. The meeting minutes will reflect the Committee's determination regarding risk levels.

7.5.3 Period of Approval

At the time of initial review and at continuing review, the IRB will make a determination regarding the frequency of review of the research protocols. All protocols will 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, biannually, quarterly, or after accrual of a specific number of participants) may be required. The meeting minutes will reflect the IRB’s determination regarding review frequency.

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 principle investigator.

The following factors will 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 Principal Investigator and other key personnel.

4. The specific experience of the Principal Investigator 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.

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, it is understood that the approval period in no case can exceed 365 days and that the number of subjects studied or enrolled determines the approval period only when that number of subjects is studied or enrolled in less than 365 days.

7.5.4 **Independent Verification Regarding Material Changes.**

Protecting the rights and welfare of subjects sometimes requires that the IRB verify independently, utilizing sources other than the investigator, information about various aspects of the study including, but 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.

The IRB will 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 Principal Investigators who have previously failed to comply with 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.

The following factors will 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 promised.
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.

7.5.5 Conflict of Interest – Investigators

The IRB application asks protocol-specific questions regarding conflict of interest for the investigators and key personnel. The application asks whether they or any of their immediate family members (as defined in the University Conflict of Interest Policy) has:

a. A financial interest in the research with value that cannot be readily determined;

b. A financial interest in the research with value that exceeds the specified monetary threshold in the University Conflict of Interest Policy;

c. Received or will receive compensation with value that may be affected by the outcome of the study;

d. A proprietary interest in the research, such as a patent, trademark, copyright, or licensing agreement;

e. Received or will receive payments from the sponsor that exceed the specified monetary threshold in the University Conflict of Interest Policy in one year;

f. Serves as an executive or director of the agency or company sponsoring the research;

g. A financial interest that requires disclosure to the sponsor or funding source; or

h. Any other financial interest that the investigator believes may interfere with his or her ability to protect participants.

As part of its review process, the IRB will make a determination as to whether the conflict adversely affects the protection of human subjects. If the answer is yes and an approved conflict management plan exists, the IRB will review the plan to determine if it adequately protects the human subjects in that protocol.

If no approved conflict management plan exists, the IRB will forward the conflict information to the University Conflict of Interest program and an appropriate conflict management plan will be developed according to the procedures described above.

Review of conflict management plans are documented in the IRB minutes in the protocol file for expedited review. If a conflict of interest exists, final IRB approval cannot be given until an
approved conflict management plan that adequately protects the human subjects in the protocol is in place.

If the conflict of Interest status of an investigator changes during the course of a study, the individual is required to notify the IRB Office within ten working days of the change. The IRB will review the change as a modification to the protocol.

At the time of continuing review, the investigator will be asked whether there has been any change in the conflict of interest status relating to the research. The IRB will review conflict of interest as part of its continuing review.

7.5.6 Consent Monitoring.

In reviewing the adequacy of informed consent procedures for proposed research, CUNY’s 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.

7.5.7 Reporting IRB Actions
[45 CFR 46.109(e), 46.113]

All IRB actions are communicated to the Principal Investigator (PI), or designated primary contact person for the protocol, in writing within ten (10) working days by the Chair of the IRB or designee. The IRB will 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 must use CUNY standard templates when communicating IRB actions to the Principal investigator.

For approved research, investigators are informed regarding the following:

- **Continuing Review:** It is the investigator's responsibility to insure that an application for continuing review approval has been submitted before the expiration date noted above. If the investigator does not receive approval before the expiration date, all study activities must stop until a new approval letter is received.

- **Consent Form:** Investigators must use the approved and stamped consent form for all research subjects and investigators are responsible for maintaining signed consent
forms for each research subject for a period of at least three years after study completion.

- **Mandatory Reporting to the IRB**: The principal investigator must report any serious problem, adverse effect, or outcome that occurs with frequency or degree of severity greater than that anticipated within five business days. In addition, the principal investigator must report any event or series of events that prompt the temporary or permanent suspension of a research project involving human subjects.

- **Modifications**: All modifications of protocols involving human subjects must have prior IRB approval except those involving the prevention of immediate harm to a subject. Modifications for the prevention of immediate harm to a subject must be reported within 24 hours to the IRB.

For approved research, Principal Investigators must sign and return a verification statement acknowledging that they have received the approval letter and are aware of, and agree to abide by, all of its stipulations in order to maintain active approval status, including prompt reporting of adverse events/serious problems, proposed protocol modifications, and annual continuing review. They also acknowledge that they are aware that it is their responsibility to be knowledgeable of all federal, state and university regulations regarding human subjects research including CUNY’s Federalwide Assurance (FWA) with the Department of Health and Human Services Office of Human Research Protections.

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

The IRB reports its findings and actions to the institution in the form of its minutes and Chair’s Reports, which are available upon request by CUNY institutional officials and are stored permanently and securely in the campus IRB Office. All minutes and Chair's Reports are submitted to ORC upon approval.

### 7.5.8 CUNY Multi-Campus Review

Protocols sometimes involve more than one CUNY campus. The primary, or “lead” IRB will be that IRB associated with the CUNY campus with which the primary Principal Investigator is affiliated. In order to avoid unnecessary duplication of the review process, all other campus IRBs can accept the decisions of the lead IRB.

A proposal that has received approval on one CUNY campus should, when submitted to another CUNY campus IRB, be received with the presumption of approval.
The lead campus IRB should notify the PI that he/she cannot conduct research at other CUNY campuses without submitting an application to the subsequent campus IRBs. It is incumbent upon the PI to inform the lead IRB of his/her intentions for specific multi-campus research on the application or to request a protocol modification approval if in the future the PI wishes to extend the research to other CUNY campuses.

For research proposed by employees of CUNY Central Office or the Research Foundation Central Office, only the CUNY-Wide IRB will review the protocol.

The expiration date will be campus-specific based on the date of IRB Chair review, or will follow standard expiration date determination if a review beyond that of the Chair is necessary. (See Section 7.5.1)

The Multi-Campus Review process:

1. The lead campus conducts the IRB review and approval as usual.

2. The IRB office for the lead campus should send a copy of the IRB approval to the other campus IRB offices that will be affected. One important criterion for making this “single campus review for multi-campus research policy” work is for all affected campus IRBs to be informed.

3. Upon receipt by the subsequent IRS office(s), the IRB office will notify the IRB Chair of the receipt of a multi-campus protocol.

4. The IRB Chair, or designated Board member, of the subsequent campus IRB will familiarize him/herself with the proposal and, in most cases, simply accept the approval of the lead campus.

5. Further review is required only if specific problems with the proposal are identified by the IRB Chair (or the Chair’s designee) of the subsequent campus.

6. If specific problems are identified, the IRB Chair from the subsequent campus will consult with the IRB Chair at the lead campus to determine whether those problems were resolved in the initial review process.

7. Only if the problems were not previously resolved, or if identified problems remain, should the proposal be reviewed anew at the subsequent campus. If the problems were resolved, the IRB Chair of the subsequent campus should make a note to the file to that effect.

8. The subsequent campus sends approval to the PI.
7.6 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 45.109(e)], but not sooner than 30 days prior to the protocol termination (expiration) date. 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 are clearly noted on all IRB communications sent to the PI and must 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 participants, even when the research is permanently closed to the enrollment of new participants and all participants 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 (the analysis of de-identified data does not require continuing review).

To assist investigators the campus IRB Office staff will send out renewal notices to investigators a minimum of two months and one month in advance of the expiration date, 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.

7.6.1 Continuing review process

In accordance with Department of Health and Human Services (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 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 must 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.

In conducting continuing review of research not eligible for expedited review, all IRB members should at least receive and review a protocol summary (that is, Description of Study) and a status report on the progress of the research, including the following information from the past year (cumulative data must also be included after the first renewal):
• the number of subjects enrolled;
• number of subjects who withdrew prematurely and reason(s) for their withdrawal;
• a current copy of the Description of Study;
• 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;
• summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review;
• any other relevant information, especially information about risks associated with the research;
• a copy of the current informed consent document and any newly proposed consent document;
• a copy of the current HIPPA Authorization document; and
• any relevant multi-center trial reports.

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

When reviewing the current informed consent document(s), the IRB should ensure the following:

• The currently approved or proposed consent document is still accurate and complete;
• Any significant new findings that may relate to the subject's willingness to continue participation are provided to the subject in accordance with HHS regulations at 45 CFR 46.115(b)(5).

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

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

7.6.2 Expedited Review of Continuing Review

Generally, if research did not qualify for expedited review at the time of initial review, it does not qualify for expedited review at the time of continuing review, except in limited circumstances described by expedited review categories (8) and (9) at 63 FR 60364-60367 (see Expedited Review Categories). 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.

7.6.3 How is the Continuing Review Date Determined?

Department of Health and Human Services (DHHS) regulations at 45 CFR 46.108(b) and 109(e) require, respectively, that:

1. except when an expedited review procedure is used, the IRB must 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 must 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.

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 1 year.)