NEW YORK MEDICAL COLLEGE

A MEMBER OF THE TOURO COLLEGE AND UNIVERSITY SYSTEM

Policies and Procedures for the Conduct of Research Involving Human Subjects

Adopted August 4, 2004

Revised March 1, 2008

Revised June 2018

Revised April 18, 2019

TABLE OF CONTENTS

IRB AUTHORITY AND INSTITUTIONAL COMMITMENT 4

Ethical Principles Regarding Research Involving Humans as Subjects and Institutional Oversight 4
The Committee for Protection of Human Subjects 6
Schedule of CPHS Meetings 7
Activities Subject to IRB Jurisdiction 8

IRB REVIEW PROCEDURES 12

Principal Investigator 12
Full Board Review 12
Initial Application Materials to be Reviewed at Full Committee Meeting 14
IRB Quorum Required for Full Committee Review 15
Expedited Review 16
Exempt Research 21
Amendments to Previously Approved Applications or Claims for Exemption 25
Continuing Review 27
Procedure for Notification of Continuing Review 30
Case Reports 30
IRB Responsibility for Review and Further Reporting of Unanticipated Problems 32
CPHS Audits or Monitoring 33
Suspension/Termination of Approval for Cause 35

INFORMED CONSENT PROCESS 36

Legally Effective and Prospectively Obtained Informed Consent 36
Elements of Informed Consent 38
Documentation of Informed Consent 43
Waiver of Informed Consent 45
Assent 49
Approval Dates on Informed Consent Documents 50
Request for Waiver or Alteration of HIPAA Authorization 50

RECORDS AND DOCUMENTATION 51

CPHS Records 51
Meeting Agenda and Minutes 53
Records Retention 56

INVESTIGATOR RESPONSIBILITIES 57

General Responsibilities 57
Reporting of Unanticipated Problems to the IRB 59
Reporting Requirements when a DSMB is Designated for a Clinical Trial 61
Appendix A - Definitions 62
Appendix B - Algorithm for Determining Whether an Adverse Event is an Unanticipated Problem 65

IRB MEMBERSHIP 66

GENERAL CPHS POLICIES 69

Educational Activities for the Protection of Human Subjects 69
Clinical Trials Registration and Reporting of Results 71
Emergency Use of Investigational Articles 73
Ensuring Prompt Reporting of Any Serious or Continuing Noncompliance with 45 CFR Part 46 or the Requirements or Determinations of the IRB 75

PEDIATRIC CENTRAL IRB (CIRB) STANDARD OPERATING PROCEDURES 76

THE NATIONAL INSTITUTES OF HEALTH (NIH) SINGLE IRBS (SIRB) POLICY 81

RELYING ON COMMERCIAL IRBS 81

SIGNATURE PAGE 82

IRB AUTHORITY AND INSTITUTIONAL COMMITMENT

Ethical Principles Regarding Research Involving Humans as Subjects and Institutional Oversight

New York Medical College, its staff, employees, faculty, and students are guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the "Belmont Report") regardless of whether the research is subject to Federal regulation or with whom conducted or the source of support.

The three basic principles relevant to the protection of human subjects in biomedical and behavioral research as set forth in the Belmont Report are:

a. Respect for Persons: recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy;
b. Beneficence: the obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm; and
c. Justice: fairness in the distribution of research benefits and burdens.

New York Medical College holds a Federalwide Assurance approved by the Office for Human Research Protections (OHRP) in which it agrees to uphold the ethical principles of the Belmont Report and to apply appropriate federal regulations to all federally-supported research involving human subjects.

The Chancellor and the Vice-President for Research are responsible for exercising appropriate administrative oversight to ensure that New York Medical College's policies and procedures designed for protecting the rights and welfare of human subjects are effectively applied.

Any (i) unanticipated problems involving risks to subjects or others, (ii) serious or continuing noncompliance with the Federal Regulation or IRB requirements, and (iii) suspension of termination of IRB approval will be reported to the Chancellor and Vice-President for Research. The Chancellor and Vice-President for Research in turn will report these to the appropriate panel of the Committee for Protection of Human Subjects and the Dean of the appropriate school or college, the relevant federal Department or Agency Head, any applicable regulatory body, including but not limited to the Food and Drug Administration (FDA), and the Office for Human Research Protections (OHRP).

New York Medical College has specified procedures for determining whether any proposed human subject research activity qualifies for exemption from the requirements of the Revised Common Rule. (See the relevant section of these Policies and Procedures for Exempt Research.)

New York Medical College, including its School of Medicine, its Graduate School of Basic Medical Sciences, and its School of Public Health, and the following institutions are subject to

these policies regarding research involving human subjects and New York Medical College's Assurance to OHRP: (a) Westchester County Health Care Corporation, (b) Metropolitan Hospital Center, (c) Westchester Institute for Human Development, (d) Terence Cardinal Cooke Health Care Center.

In addition, NYMC and Westchester County Healthcare Corporation have designated the NCI Pediatric CIRB under their respective Federal wide Assurances, allowing the CIRB to become the IRB of record for Children's Oncology Group (COG) studies. The NYMC Pediatric Central IRB (CIRB) Standard Operating Procedures are incorporated into this document.

The Committee for Protection of Human Subjects

Safeguarding the rights and welfare of human subjects in research and other activities is a general institutional responsibility delegated by the President and Chief Executive Officer through the Vice President for Research to the Committee for Protection of Human Subjects (the "CPHS"), the Institutional Review Board (IRB) at New York Medical College.

Reference to the CPHS throughout this document shall encompass both panels of the CPHS, the General Medical and Behavior Panel and the Oncology Panel. Both panels are Institutional Review Boards, registered with OHRP and the IRB of record under the College's federal assurance.

The CPHS is appointed as a standing Committee of the Faculty and is a University Committee. As such, the CPHS serves New York Medical College as a whole, rather than a particular school or department.

Except for research expedited, exempted or waived in accordance with sections 46.104(d)(1-8); 45 CFR 46.110 and 21 CFR 56.110 of the Revised Common Rule, all human subject research will be reviewed, prospectively approved, and subject to continuing oversight and review at least annually by the CPHS. The CPHS has the authority to require continuing review of any research (even if designated expedited or exempt) if the CPHS decides continuing review is warranted. This decision and the rationale will be appropriately documented.

The CPHS has the authority to approve, require modification in, or disapprove all research activities that fall within its jurisdiction.

Approval of the CPHS is required prior to initiation of an investigation or recruitment of subjects.

Except for research exempted or waived in accordance with sections 46.104(d)(1-8) of the Revised Common Rule, informed consent will be: a) sought from each prospective subject or the subject's legally authorized representative in accordance with and to the extent required by section 116 of the Common Rule; b) appropriately documented in accordance with and to the extent required by section 117 of the Common Rule.

Research that has been reviewed and approved by the CPHS is subject to review and approval or disapproval by officials of New York Medical College. However, no official of New York Medical College may approve research if it has been disapproved by the CPHS.

New York Medical College's FWA presently designates three –IRBs (General Medical and Behavioral IRB, Oncology and NCI CIRB). Designation of additional IRBs under the FWA requires prior notification of and approval by OHRP.

The Office of Research Administration (ORA) is responsible for the operational support and oversight of the CPHS.

Schedule of CPHS Meetings

The CPHS General Medical and Behavioral Panel meets on the second Monday of each month except August unless a holiday prevents; the CPHS Oncology Panel meets on the third Monday of each month except August unless a holiday prevents. In the case of a holiday, the meeting will be rescheduled, preferable to the next day.

The meeting schedule for the academic year will be sent to the membership before the start of the academic year. Any change in the meeting schedule will be sent to the membership as soon as practicable.

Additional meetings, if determined by either Chairperson to be required, will be announced to the membership as soon as possible. E-mail, fax, and telephone messages may be used in addition to or instead of the electronic notification via the electronic-IRB if necessary to insure that members are informed in a timely manner.

Activities Subject to IRB Jurisdiction

All research involving human subjects (as defined below), and all other activities which even in part involve such research, regardless of sponsorship, must be reviewed and approved by the CPHS unless such research has been determined to be exempt from the regulations by the ORA. No non-exempt intervention or interaction with human subjects in research, including recruitment, may begin until the CPHS has reviewed and approved the research protocol. "Research" and "human subject" are defined below. The application of these definitions to any given activity is determined by the ORA.

New York Medical College's Assurance with the federal government specifies that all research activities which involve human subjects, regardless of sponsorship, must be reviewed by the CPHS if one or more of the following apply:

a. The research is sponsored by New York Medical College; or

b. The research is conducted by or under the direction of any employee, faculty, staff, residents, student, or agent of New York Medical College in connection with his or her institutional responsibilities; or

c. The research is conducted by or under the direction of any employee, faculty, staff, student or agent of New York Medical College using any property or facility of New York Medical College; or

d. The research involves the use of non-public information of New York Medical College or whichever of its affiliated institutions are covered by its FWA to identify or contact human research subjects or prospective subjects.

Definition of "Research" "Research" is defined as any "systematic investigation (including research development, testing, and evaluation) designed to develop or contribute to generalizable knowledge." Often, the key to determining whether an activity is "research" depends upon the investigator's intent to "contribute to generalizable knowledge." Thus, a key aspect of research is that there be a systematic design in advance, generally utilizing a scientific approach or protocol, for the defined purpose of contributing to generalizable knowledge. The following activities have been defined as not being "research" as per the Revised Common Rule:

- Certain scholarly and journalistic activities,
- Certain public health surveillance activities,
- Collection and analysis of information, specimens, or records, by or for a criminal justice agency for certain criminal justice or investigative purposes, and
- Certain authorized operational activities for national security purposes

Specific examples of activities that may or may not constitute research and may or may not require CPHS review follow:

a. **Standard Diagnostic or Therapeutic Procedures.** The distinction between research and treatment can become blurred in patient care settings, as well as in some

educational and training settings. An established and accepted diagnostic or therapeutic procedure that is performed only for the benefit of a patient is generally not subject to CPHS review. However, collection of data about a series of such procedures or treatments for dissemination or generalization does constitute research that requires CPHS review. Additionally, if patient care or assignment to intervention is altered for research purposes in any way, the activity must be submitted for CPHS review. Also, a diagnostic procedure for research purposes that is added to a standard treatment requires CPHS review.

b. **Innovative Procedures or Treatments.** Innovations in diagnosis or therapy are not generally subject to CPHS review if they are applied to a patient for the sole purpose of aiding that individual, although such innovations are governed by the appropriate professional ethics (e.g., obtaining informed consent). CPHS review is required when a "systematic investigation" of such innovations is considered. For example, if a physician plans to collect information about the innovation for scientific purposes or will repeat the innovation in other patients in order to compare it to standard treatment, the physician must receive prior CPHS approval.

c. **Emergency Use of an Investigational Drug or Device.** Emergency Use is defined by the FDA as the use of an investigational drug or biological product with a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain CPHS approval [21 CFR 56.102(d)]. The emergency use provision allows the physician to use a test article, one time, prior to CPHS review and approval; the Director of Human Subjects Administration (HSA) and IRB Chairperson must be notified of the emergency use and the College Emergency Use form must be completed. Any additional use of the test article requires prior IRB approval.
Federal regulations do not permit research activities to be started, even in an emergency, without prior CPHS review and approval. When emergency medical care is initiated without prior CPHS review and 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 research activity. When emergency care involves investigational drugs, devices, or biologics, U.S. Food and Drug Administration (FDA) requirements must be satisfied. However, nothing in these policies is intended to limit the authority of a physician to provide emergency medical care for patients who need such care. Rather, the use of information collected about that treatment for research purposes is prohibited.

d. **Human Cell or Tissue Repository.** Human cell or tissue (genetic tissue) research typically involves repositories that collect, store, and distribute human tissue materials for research purposes. Repository activities involve three components: (i) the collectors of tissue samples; (ii) the repository storage and data management center; and (iii) the recipient investigators. Human cell or tissue repositories would not qualify as involving human subjects research when material submitted to the repository satisfies both of the following conditions: (1) The material, in its entirety, was collected for purposes other than submission to the repository (e.g., the material was collected solely for clinical purposes, or for legitimate but unrelated research purposes, with no "extra" material collected for submission to the repository); and (2) The material is submitted to the repository without any identifiable private data or information (i.e., de-identified; no codes

or links of any sort may be maintained, either by the submitter or by the repository, that would permit access to identifiable private data or information about the living individual from whom the material was obtained).

e. **Student Conducted Research.** All activities that meet the definition of research with human subjects and that are conducted by students for a class project or for work toward a degree must be reviewed by the CPHS. For example, activities that must be reviewed and approved by the CPHS include: (i) all master's theses and doctoral dissertations that involve human subjects; and (ii) all projects that involve human subjects and for which findings may be published or otherwise disseminated.

Definition of "Human Subject" A human subject is defined broadly by federal regulation as "a living individual about whom an investigator (whether professional or student) conducting research obtains: (i) information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens or (ii) Obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

a. Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or of the subject's environment that are performed for research purposes.
b. Interaction includes communication or interpersonal contact between investigator and subject.
c. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).
d. Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information

Activities Not Subject to CPHS Jurisdiction. Activities such as quality assurance or quality control; program and fiscal audits, and certain disease monitoring as prescribed by the Public Health Department generally do not qualify as research.

Failure to Submit Project for IRB Review. The implications of engaging in activities that qualify as research that is subject to CPHS review without obtaining such review are significant. Results from such studies may not be published unless CPHS approval had been obtained prior to collecting the data. To do either activity referenced in the previous to sentences would be a violation of New York Medical College policy. It is also against College policy to use that data to satisfy thesis or dissertation requirements. See the Policy on "Ensuring Prompt Reporting of Any Serious or Continuing Noncompliance with 45 CFR 46 or the Requirements or Determinations of the CPHS." If an investigator begins a project and later finds that the data gathered could contribute to generalizable knowledge or that he or she may wish to publish the results, it is important that the investigator submit a proposal to the ORA for review as soon as possible. Investigators who request approval to continue research that was not previously reviewed or to use data that was collected without proper CPHS approval face the possibility that the CPHS will disapprove their application. It is therefore in the investigator's best interest to consider carefully the likelihood that he or she will want to use the data for research purposes in the

future, and to err on the side of inclusion and seek CPHS approval prior to commencing the work.

Principal Investigator

All Principal Investigators must have NYMC Full-Time Faculty Status to conduct research at NYMC and its affiliates.

Full Board Review

The CPHS has the authority to approve, require modification in, or disapprove, all research activities that fall within their jurisdiction.

Full board review is used for non-exempt research that does not qualify for expedited review (See Policies and II.C). Review of such non-exempt protocols may occur only at convened meetings of the CPHS at which a quorum is present.

Substantive review of protocols must take place at convened meetings.

a. Applications undergoing review must be individually presented and discussed at a convened meeting of the CPHS.
b. One or two primary reviewers from among the Committee members are assigned for each protocol. The primary reviewers should conduct an in-depth review of all pertinent documentation and present the protocol to the full Committee.
c. In order for the application to be approved, it must receive the approval of a majority of the voting members present at the meeting.

The CPHS may only approve an application when its decision is based on consideration of the following (45 CFR 56.111(a) 1-7):

a. 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.
b. 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 CPHS should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The CPHS 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.
c. Selection of subjects is equitable. In making this assessment the CPHS 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.d.

d. 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 federal regulation.
e. Informed consent will be appropriately documented, in accordance with, and to the extent required by federal regulation.
f. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
g. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Review Interval. The CPHS must determine an appropriate review interval at which to conduct continuing review of all protocols. The review interval must be appropriate to the degree of risk, but not more than once per year. For example, Phase I studies or dose ranging studies may require review at six months. The minutes of the CPHS meeting should clearly reflect the approval period.

Vulnerable Populations. 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, the CPHS must determine that additional safeguards have been included in the study to protect the rights and welfare of these subjects.

CPHS Decisions. When the CPHS requests substantive clarifications, substantive protocol modification or substantive informed consent revisions, CPHS approval must be deferred, unless the Committee can specify revisions that require only concurrence by the investigator, in which case, after satisfactory revisions by the Investigator, the CPHS Chairperson or designated reviewer may approve the research on behalf of the CPHS.

The decisions and requirements for modifications by the CPHS will be promptly conveyed to investigators in writing by the Office of Research Administration. Written notification of decisions to disapprove a protocol will be accompanied by the CPHS's reasons for the decision and an invitation for an opportunity for reply by the investigator.

All actions of the CPHS (approvals, approvals with specified changes, deferred actions, and disapprovals) are communicated to the principal investigator, the College and to the designated official of any institution that has agreed to use the College's CPHS as its designated IRB.

All approval notices will inform investigators that no modification may be made in the protocol (except when necessary to eliminate apparent immediate hazards to the subject) or in the wording of the official consent form with the prior approval of the CPHS.

Initial Application Materials to be Reviewed at Full Committee Meeting

In conducting the initial full Committee review of proposed research, the CPHS must obtain information in sufficient detail to make the determinations required under federal regulations.

Materials Provided to the CPHS:

a. The following materials should be provided to the primary reviewers via the electronic IRB:
   i. A completed IRB application with an electronic signature to the Principal Investigator Assurance Statement;
   ii. Complete grant application or, if no grant is sought, full investigator's or sponsor's protocol;
   iii. Research Study Abstract;
   iv. Proposed informed consent document(s), assent document(s) and script as appropriate or request for waiver of informed consent;
   v. Copies of surveys, questionnaires, or transcribed videotapes or audiotapes;
   vi. Copies of letters of assurance or cooperation with research sites;
   vii. Investigator's Brochure for experimental drugs, package insert for approved drug, description of investigational device, or Instructions for Use for approved device
   viii. Advertising intended to be seen or heard by potential subjects, including e-mail solicitations.

b. Materials Provided to Non-Primary Reviewers: All CPHS members will have access to the materials listed above (i – viii) via the electronic IRB for review prior to the convened meeting.

c. These materials are made available to CPHS members at least one week in advance of the meeting date to allow sufficient time for review.

Grant Application. The primary reviewers should review the full grant application, if any. A copy of the grant application or proposal is retained by the ORA and made available to any CPHS member who may wish to review it.

IRB Quorum Required for Full Committee Review

Quorum requirement: Except when an expedited review procedure is used, the CPHS may only review proposed research at meetings at which a majority of the voting members of the CPHS are present, including at least one member whose primary interests are in nonscientific areas.

No official actions may be taken except at a properly convened meeting.

Failure of Quorum During Meeting. Should the quorum fail during a meeting (e.g., those with conflicts being recused, early departures, loss of a non-scientist), the Committee cannot review or vote on any matter until the quorum can be restored.

Conflict of Interest. No CPHS member may participate in the Committee's review of a project in which the member has an actual conflicting interest or the appearance of a conflict exists, except to provide information requested by the Committee.

a. CPHS members should recuse themselves from the meeting room when the CPHS votes on research in which they have a conflicting interest and such should be noted in the CPHS meeting minutes.

b. In order to avoid real or perceived conflicts of interest, (i) no participating IRB Committee member may hold interests or projected annual income valued at greater than $10,000 or a 5% equity interest (e.g., partnership, stock, or profit-sharing) in the organization requesting CPHS review; (ii) no participating IRB Committee member may be paid more than reasonable compensation or receive more than reasonable benefits for CPHS-related activities; and (iii) no IRB Committee member may receive compensation or benefits under arrangements that could impede or discourage objective decision-making on behalf of human subjects. Any Conflict of interest must be disclosed by each IRB Committee member prior to discussion of the research study pertaining to the organization requesting CPHS review.

Expedited Review

Federal regulations allow the CPHS to review certain applications on an expedited basis if they (a) present no more than minimal risk to human subjects except for category 4 (h) below, and (b) involve only procedures listed in one or more of the specific nine categories (see paragraph 4 below. Additionally, the standard requirements for informed consent (or its waiver, alteration, or exception) apply to all CPHS approvals regardless of the type of review - expedited or full Committee - utilized by the CPHS.

An expedited review consists of a review of research involving human subjects by the CPHS Chairperson or designee. In reviewing the research, the reviewer may exercise all of the authorities of the full Committee except that the reviewer may not disapprove the research. Additionally, the reviewer may refer the application to the full Committee for a standard review.

Minimal Risk. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

An example of minimal risk is the risk of drawing a small amount of blood from a healthy individual for research purposes (because the risk of doing so is no greater than the risk of doing so as part of a routine physical examination).

The nine categories should not be deemed to be of minimal risk simply because they are included on the list.

Inclusion on the 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.

Categories of Research Eligible for Expedited Review. The following nine categories pertain to both initial and continuing expedited CPHS review:

a. *Clinical studies of drugs and medical devices* only when condition (i) or (ii) is met.
   i. Research on drugs for which an investigational new drug application (*see* 21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.); or
   ii. Research on medical devices for which (A) an investigational device exemption application (*see* 21 CFR Part 812) is not required; or (B) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

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

i. 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
ii. from other adults and children, when 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 are considered. 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 federal 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." (See 45 CFR 46.402(a).) In New York, this age is 18 years old.

c. *Prospective collection of biological specimens for research purposes by noninvasive means*, for example:
   i. hair and nail clippings in a nondisfiguring manner;
   ii. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
   iii. permanent teeth if routine patient care indicates a need for extraction;
   iv. excreta and external secretions (including sweat);
   v. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue;
   vi. placenta removed at delivery;
   vii. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
   viii. 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;
   ix. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
   x. sputum collected after saline mist nebulization.

d. *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:
   i. 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;
   ii. weighing or testing sensory acuity;
   iii. magnetic resonance imaging;
   iv. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;

v. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

e. *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 requirement that it obtain CPHS approval. This listing refers only to research that is not exempt.)

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

g. *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 requirement that it obtain CPHS approval. This listing refers only to research that is not exempt.)

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

i. *Continuing review of research*, not conducted under an investigational new drug application or investigational device exemption where categories b through h do not apply but the CPHS has determined and documented at a full Committee convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Reviewers Must Make Certain Determinations to Approve Application. In conducting the expedited review, the designated reviewers must review materials in sufficient detail (see Materials to be Reviewed Section on next page) to make the following determinations required under federal regulation and CPHS Policies:

a. 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.

b. 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 reviewers should consider only those risks and

benefits that may result from the research (as distinguished from risks and benefits of therapies those subjects would receive even if not participating in the research). The reviewers 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.

c. Selection of subjects is equitable. In making this assessment the reviewers 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.

d. 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 federal regulation and institutional policies.

e. Informed consent will be appropriately documented, in accordance with, and to the extent required by federal regulation and institutional policies.

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

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

h. As per the Revised Common Rule, expedited protocols no longer require annual review by the CPHS, however, the IRB can or will require annual review if the protocol was previously approved under the pre-Revised Common Rule or if the CPHS determines that annual review is warranted.

i. Vulnerable subjects. Additionally, 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, the CPHS reviewers must determine that additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Materials to be Reviewed. The following materials should be provided to the Chairperson or designee via the electronic IRB for expedited review applications:

a. A completed IRB Application to Conduct Research with an electronic signature to the Principal Investigator Assurance Statement;
b. Grant application or full investigator's or sponsor's protocol;
c. Research Study Abstract;
d. Proposed informed consent document(s) or script as appropriate, or request for waiver or alteration of informed consent;
e. Copies of surveys, questionnaires, or transcribed videotapes or audiotapes;
f. Copies of letters of assurance or cooperation with research sites;
g. Advertising intended to be seen or heard by potential subjects, including email solicitations.

Notification of Committee. As a means of notifying the Committee and allowing for comments regarding a review conducted utilizing expedited review procedures, a listing of the application must be entered in the agenda provided to the full Committee for the next possible convened meeting.

All approvals given by the Chairperson or the Chairperson's designee are communicated to the principal investigator, the College, and to the designated official of any institution that has agreed to use the College's CPHS as its designated IRB.

Exempt (from IRB review) Research

Research activities involving human subjects that are exempt from IRB review are identified in 46.104(d)(1-8). The CPHS may not create new categories of this exempt research. Only the Director of HSA, or the CPHS may determine which activities qualify for an exempt review. Investigators do not have the authority to make an independent determination that research involving human subjects is exempt and must contact the ORA concerning the status of proposed research or changes in ongoing research.

A member of the CPHS will review the application and will validate or decline the researcher's request for exemption. The request for exemption must meet one of the eight specific categories of activities listed below.

The determination that a research activity is exempt from CPHS approval must be documented on the Application for Exemption. This documentation must include a citation of the specific category justifying the exemption (e.g., 46.104(d)(1-8)).

Results of this review will be promptly conveyed in writing to the investigator and will list the exemption category number. If the proposed research activities do not meet the criteria for exemption, the ORA must promptly send a letter outlining any additional information and the proper category for review (e.g., expedited or standard) to the principal investigator.

Eight specific categories of activities are exempt from the requirement that they receive approval from the CPHS prior to initiation. They are:

1. *Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.*

2. *Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:*
    i. information obtained is recorded by the Investigator in such a manner that the identity of the human subjects can not be readily be ascertained,directly or through identifiers linked to the subjects; and
    ii. any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
    iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review.

Note: Applicability to vulnerable populations:

- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is *not* eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
-Research involving children is eligible for this exemption only when it is related to educational tests or observations in which the investigators don't participate in the activities being observed. Additionally, children are not eligible for this exemption if the project requires limited IRB review.

3. *Research involving* benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a *limited IRB review.*

Note: Applicability to vulnerable populations:
- Pregnant women who are adults *may* be included in this type of research
- Research that targets a prisoner population is *not* eligible for this exemption.
- Research that could include children is *not* eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving decisionally-impaired persons is *not* eligible for this exemption.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
(i) The identifiable private information or identifiable biospecimens are publicly available;
(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on

information technology that is subject to and in compliance with applicable federal privacy standards found in the E-Government Act, Privacy Act and the Paperwork Reduction Act. iii

Note: Applicability to vulnerable populations:

- Data/specimens from pregnant women would be allowed
- Data/specimens from prisoners could be allowed as long as the research wasn't designed to recruit prisoners and prisoners were only incidental subjects of the research.
- Data/specimens from children would be allowed
- Data/specimens from persons with decisional impairment would be allowed

5. *Research and demonstration projects* that are conducted or supported by a Federal Department or Agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

   Note: Projects eligible for this exemption will be posted on a Federal website

6. *Taste and food quality evaluation and consumer acceptance studies*: if wholesome foods without additives are consumed, or 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.

Note: Applicability to vulnerable populations:

- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is *not* eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children is eligible for this exemption.

- Research involving decisionally-impaired persons could be allowed if their inclusion was justified.

7. *Storage or maintenance for secondary research for which broad consent is required:* Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §__.111(a)(8).

   This exemption is new with the Revised Common Rule. It will be implemented at NYMC when capacity to meet technical and regulatory requirements has been confirmed.

   Note: Research with vulnerable populations may be approvable with this exemption:
   - Pregnant women may be included in this type of research.
   - Research that targets a prisoner population is *not* eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
   - Research involving children is eligible for this exemption.

8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
   (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §__.116(a)(1) through (4), (a)(6), and (d);
   (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §__.117;
   (iii) An IRB conducts a limited IRB review and makes the determination required by §__.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and 479
   (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from any legal requirements to return individual research results.

   This exemption is new with the Revised Common Rule. It will be implemented at NYMC when capacity to meet technical and regulatory requirements has been confirmed.

   Note: Research with vulnerable populations may be approvable with this exemption:
   - Pregnant women may be included in this type of research.
   - Research that targets a prisoner population is *not* eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
   - Research involving children is eligible for this exemption.

Amendments. Because no continuing review is required for exempt research, any proposed or anticipated changes in the exempt study initiated after approval of the Claim for Exemption must

be submitted to the ORA for review. Certain changes may disqualify the research from receiving exempt status.

Amendments to Previously Approved Applications or Claims for Exemption

For previously approved applications or Claims for Exemption -, all planned changes in the conduct of a study and/or changes to the consent document must be approved by the CPHS prior to initiation.

a. Investigators must submit the exact text of an amendment or other revision to the protocol and any proposed changes to the consent document to the IRB. When there are numerous changes to the research protocol, a brief summary of the changes should also be submitted.

b. Modifications to the informed consent document must take into account both prospective research subjects and, if applicable, research subjects already enrolled in the study. The latter may be addressed using an addendum to the initial informed consent document or, by re-consenting the subject using the modified informed consent document.

Minor changes proposed for previously approved research may be reviewed in an expedited manner. A minor modification is defined as a change that would *not* materially affect an assessment of the risks and benefits of the study or does not substantially change the specific aims or design of the study. Examples of minor modifications include:

a. The addition of research activities that would be considered exempt or expedited if considered independent from the main research protocol;
b. An increase or decrease in proposed human research subject enrollment;
c. Narrowing the range of inclusion criteria;
d. Broadening the range of exclusion criteria;
e. Alterations in the dosage form (e.g., tablet to capsule or oral liquid) of an administered drug, provided the dose and route of administration remain constant;
f. Decreasing the number or volume of biological sample collections, provided that such a change does not affect the collection of information related to safety evaluations;
g. An increase in the length of confinement or number of study visits for the purpose of increased safety monitoring;
h. A decrease in the length of confinement or number of study visits, provided that such a decrease does not affect the collection of information related to safety evaluations;
i. Alterations in human research subject payment or liberalization of the payment schedule with proper justification;
j. Changes to improve the clarity of statements or to correct typographical errors, provided that such a change does not alter the content or intent of the statement;
k. The addition or deletion of qualified investigators;
l. The addition of study sites (which may require a Cooperative Agreement and appropriate IRB approval) or the deletion of study sites;

More than minor changes. When a proposed change in a research study is not minor, then the IRB Committee must review and approve changes at a convened meeting before changes can

be implemented. A major modification (i.e., an amendment that is not minor) is defined as any change which materially affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study. Examples of major modifications include:

a. Broadening the range of inclusion criteria;
b. Narrowing the range of exclusion criteria;
c. Alterations in the dosage or route of administration of an administered drug;
d. Extending substantially the duration of exposure to the test material or intervention;
e. The deletion of laboratory tests, monitoring procedures, or study visits directed at the collection of information for safety evaluations;
f. The addition of serious unexpected adverse events or other significant risks to the Informed Consent Document; or
g. Changes that, in the opinion of the CPHS Chairperson or his/her designee, do not meet the criteria or intent of a minor modification.

The CPHS has the authority to approve, require modification in, or disapprove, all amendments to research activities previously reviewed by the Committee at any time. In addition, the CPHS may request any and all documents associated with an approved study.

All actions of the CPHS (approvals, approval with specified changes, deferred actions, disapprovals) are communicated to the principal investigator, the College and to the designated official of any institution that has agreed to use the College's CPHS as its designated IRB.

Continuing Review

Periodic review of research activity is necessary to determine whether the risk/benefit ratio has changed, whether there are unanticipated findings involving risks to subjects, and whether any new information regarding the risks and benefits should be provided to subjects. All research protocols (except protocols determined by the CPHS to qualify for exempt or expedited status) must be periodically reviewed by the CPHS, including research for which data analysis is the only on-going research activity.

Based on its review, the CPHS may approve, require modifications, or disapprove the research. Additionally, special precautions or IRB imposed restrictions may be relaxed.

If reports have been received by the Institution or the CPHS that unapproved changes have been initiated by the investigator, the CPHS may determine that such projects require independent verification that no material changes have occurred in the research since the previous IRB review. The CPHS is free to query other study investigators, study staff, or others as necessary. In addition, the CPHS is free to randomly select projects for such independent verification, to select projects based on complexity or high risk to subjects, and to select projects conducted by investigators who have previously failed to comply with regulations or College policies.

Type of Review. Review by the full Committee is required unless the research is appropriate for expedited review or is exempt.

a. *Standard Review.* The full IRB Committee must conduct a continuing review of a protocol using standard review procedures when that protocol was originally reviewed using standard review procedures, unless the protocol has been modified such that it can be reclassified as eligible for expedited review. Alternatively, research activities that have previously been judged as exempt, or were qualified for expedited review, may change such that standard review would be required for the continuing review.

   Primary Reviewer System. When conducting continuing review by full Committee the Committee may use a primary reviewer system for continuing review. However, the full IRB Committee must be informed of the reviewers' findings at a convened meeting. Primary reviewers should receive and review a copy of the complete protocol including any modifications previously approved by the IRB Committee. Even when using a primary reviewer system, the full, convened Committee must discuss the protocol and make a determination with recorded vote.

b. *Expedited Review.* A standard-review protocol may be reviewed using the expedited review procedure under these circumstances:

   i. the research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions, and the research is active only for long-term follow-up of subjects *[all three conditions must apply]*;
   ii. no subjects have yet been enrolled in the research and no additional risks have been identified *[both conditions must apply]*; or
   iii. the research remains open only for analysis of identifiable data.

When conducting research under an expedited review procedure, the Committee Chair or designated Committee member conducts the review on behalf of the full Committee.

Criteria. Continuing review must be substantive and meaningful. The criteria for continuing review are the same as those for initial review. Therefore, the Committee (or the reviewer for protocols reviewed under an expedited procedure) must determine:

a. Risks to subjects are minimized.
b. Risks to subjects are reasonable in relation to anticipated benefits.
c. Selection of subjects is equitable.
d. Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
e. Informed consent will be appropriately documented
f. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
g. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Materials to be reviewed.

a. The full Committee should receive and review, at a minimum via the electronic IRB:
   i. The Research Study Abstract;
   ii. A completed Continuing Review Form electronically signed by the Investigator. Included in the report should be:
      (a) the number of subjects accrued;
      (b) a description of any adverse events or unanticipated problems involving risks to subjects or others and of any withdrawal of subjects from the research or complaints about the research;
      (c) a summary of any recent literature, findings obtained thus far, amendments or modifications to the research since the last review, reports on multi-center trials and any other relevant information, especially information about risks associated with the research; and
   iii. A clean copy of the current informed consent document. Primary reviewers should also receive a copy of the complete protocol and supporting documentation including any modifications previously approved by the Committee.

Review of Consent Document. Review of the currently approved consent document must ensure that the information is still accurate and complete. Any significant new findings that may relate to the subject's willingness to continue participation should be provided to the subject in an updated consent document. Review of currently approved or proposed consent documents must occur during the scheduled continuing review of research by the Committee but may be done more frequently if new information becomes available.

Amendments to Protocol. Amendments to a research protocol and/or consent form should be submitted prior to continuing review to avoid a gap in IRB approval in the case of an amendment which is not approved; however, Amendments may also be submitted at the time of continuing review. A separate cover letter describing the change(s) and all appropriate documentation must accompany the continuing review application. The amendments may not be implemented by an investigator prior to review and approval by the Committee.

Cooperative Protocol Research Program (CPRP) protocols. Continuing CPHS review is required as long as individually identifiable follow-up data are collected on subjects enrolled in HHS-supported Cooperative Protocol Research Program (CPRP) protocols. This remains the case even after a protocol has been closed at all sites and protocol-related treatment has been completed for all subjects.

Continuing Review of DSMB-Monitored Clinical Trials. When a multi-site clinical trial is subject to oversight by a Data Safety Monitoring Board (DSMB) whose responsibilities include review of adverse events, interim findings and relevant literature (e.g. DSMBs operating in accordance with the National Cancer Institute (NCI) Policy for Data and Safety Monitoring of Clinical Trials), the Committee conducting continuing review may rely on a current statement from the DSMB indicating that it has reviewed study-wide adverse events, interim findings and any recent literature that may be relevant to the research, in lieu of requiring that this information be submitted directly to the Committee. However, the Committee must still receive and review reports of local or off-site unanticipated problems involving risks to subjects or others and any other information needed to ensure that its continuing review is substantive and meaningful.

Review Interval. The CPHS must conduct continuing review of protocols at intervals appropriate to the degree of risk but not less than once per year. The IRB approval date would be the date of the convened meeting. "Not less than once per year" means that the research must be reviewed on or before the one-year anniversary date of the previous CPHS review, even though the research activity may not have begun until some time after the CPHS has given approval.

No Grace Period. There is no grace period extending the conduct of the research beyond the expiration date of IRB approval. Extensions beyond the expiration date will not be granted.

a. If the IRB does not re-approve the research by the specified expiration date, no new subjects may be enrolled in the study and all research must cease pending re-approval by the CPHS. Continuation of research interventions or interactions in already enrolled subjects should only continue when the CPHS finds that it is in the best interests of individual subjects to do so.
b. Enrollment of new subjects cannot occur after the expiration of IRB approval.

All actions of the CPHS (approvals, approval with specified changes, deferred actions, disapprovals) are communicated to the principal investigator, the College, and to the designated official of any institution that has agreed to use the College's CPHS as its designated IRB.

Procedure for Notification of Continuing Review

Instructions:

The electronic IRB system will send email reminders to the Principal Investigator for projects whose approval period expires in 60 days. Subsequent email reminders are sent every 3 days until the requirements for continuing review submission are met or the project lapses approval.

In the event of lapsed approval, the Principal Investigator will be notified via the electronic IRB that their project has expired and no longer has IRB approval, meaning all study-related interventions must cease. If a project lapses approval for 30 days or more beyond the expiration date, the study will be administratively terminated and will need to be resubmitted as a new application should the Principal Investigator wish to continue the project.

If a project attains continuing review approval, the Notice of Action will be based upon the outcome of the review. The electronic IRB will generate and send a Notice of Action will include a date of preparation, date of approval and date of expiration.

Case Reports

Case reports submitted for publication do not strictly meet the criteria of research. Although a case report (defined as a retrospective analysis of one (1), two (2), or three (3) clinical cases) may be illustrative, it does not meet the Federal Policy for the Protection of Human Subjects definition of Research, which requires an investigation that contributes to generalizable knowledge about a disease or condition. Instead, a case report is intended to develop information to be shared for medical or educational purposes.

The institution's policy, therefore, is that a case report is not research that must be approved by the IRB. If an author wants to have a project assessed by the IRB to determine whether it meets the institution's definition of a case report the author may contact the IRB.

Although there is no requirement of IRB approval for a case report, the HIPAA Privacy Rule restricts how protected health information (individually identifiable health information) may be used and disclosed. HIPAA requires written authorization for certain uses and disclosures of an individual's protected health information, including publication of a single case report.

An author may be exempted from obtaining a signed authorization from the patient discussed in the case report if certain identifiers are removed from the case report prior to disclosure (i.e., before the case report is submitted to a journal). It is the responsibility of the author to ensure compliance with patient privacy, institutional rules, and federal regulations. It is also the responsibility of the author to ensure that (i) no photos or illustrations that contain identifiable features are included the case report (e.g. pictures of a patient's face or tattoos should not be included or the identifying information should not be visible) and (ii) the case(s) described in the report are not so unique or unusual that it might be possible for others to identify the patients in the case reports.

If an author wants to publish a case report that is not completely de-identified pursuant to the standards set forth in HIPAA or if there is any concern that a patient could be identified or likewise could identify themselves or a family member (for example, because the condition or diagnosis is distinct or identifiable features appear in photographs), the institutional privacy officer or his/her designee should be consulted and explicit authorization from the patient must be sought for the use of identifiable information. If a patient is deceased, authorization for the use of identifiable patient information must be obtained from the personal representative of the patient's estate.

For De-identified Case Reports

If case reports are not identifiable, there is no need to obtain the patient's signed authorization, to contact or to submit any documents to the IRB.

For Identifiable Case Reports

If a case report will contain information that directly or indirectly identifies a patient, the author is to contact the IRB. In addition, the author must attain authorization for the use of this identifiable information from the patient, or the patient's estate if the patient is deceased. Please contact the IRB if you have questions about whether the data in your case report may directly or indirectly identify a patient.

IRB Responsibility for Review and Further Reporting of Unanticipated Problems

When a report of an unanticipated problem is received via the electronic-IRB, it is initially reviewed The Director of HSA for completeness. The Director will follow-up with the Principal Investigator and/or Research Staff as needed. When the unanticipated problem submission is complete, the Chairperson is notified and the unanticipated problem submission is placed on the appropriate committee agenda for discussion at a convened IRB meeting.

When reviewing a report of an unanticipated problem, the CPHS Chair or designee should:

Consider whether the affected research protocol still satisfies the requirements for IRB approval: Are risks to subjects still minimized and reasonable in relation to the anticipated benefits, if any, to the subjects and to the importance of the knowledge that may reasonably be expected to result?

The CPHS Chair or designee will review the adequacy of the proposed protocol, consent modification, or suspension. Any proposed changes to a research protocol or consent form modification in response to an unanticipated problem must be reviewed and approved by the CPHS Chair or designee. If the change(s) is/are more than minor, a convened CPHS must review and approve the change(s).

For multi-center research protocols, if the IRB proposes changes to the protocol or informed consent documents/process in addition to those proposed by the study sponsor, coordinating center, or local investigator, the CPHS should request in writing that the local investigator discuss the proposed modifications with the study sponsor or coordinating center and submit a response or necessary modifications for review by the CPHS.

All reports of unanticipated problems will be reported to the Director of HSA, CPHS Chair or designee and to the CPHS.

Unanticipated problems occurring in research covered by an OHRP-approved assurance also must be reported by the institution to the supporting HHS agency head (or designee), OHRP [45 CFR 46.103(a)] and the Food and Drug Administration (FDA) [(21 CFR 56(b)]. The Vice-President for Research or designee is responsible for reporting unanticipated problems to the supporting DHHS agency head (or designee) and OHRP promptly following notification of the incident. All such reporting will conform to the OHRP Guidance on Reporting Incidents to OHRP.

For multicenter research projects, only the institution at which an unanticipated problem occurred must report the event to the supporting agency head (or designee), OHRP, and the FDA.

Authority to Terminate or Suspend Approval

The CPHS has the authority to suspend or terminate IRB approval of research that has been associated with unexpected serious harm to participants. When the CPHS takes such action, it

is required to provide a statement of reasons for the action and to promptly report this action to the Investigator, the appropriate NYMC officials, ORA, and appropriate regulatory authorities.

CPHS Audits or Monitoring

In order to help ensure compliance with federal regulations and local CPHS policies regarding research with human subjects, and to ensure that human subjects are adequately protected, the Director, HSA may conduct routine, targeted, or random audits subject to their jurisdiction. In addition, the Director, HSA or the CPHS may request monitoring of approved projects that may take the form of routine, targeted, or random audits. These activities may include, but are not limited to the following:

a. Request continuing review and/or regulatory documents from investigators;
b. Examine research records;
c. Review consent forms;
d. Contact research subjects;
e. Verify from sources other than investigators that no material changes in the study have occurred;
f. Audit advertisements and other recruiting materials to confirm proper CPHS approval;
g. Dispatch observers to the sites where research involving human subjects and/or the informed consent process is being conducted.

Safety Monitoring. The CPHS may request additional safety monitoring or the creation of an independent data safety and monitoring board.

CPHS May Suspend or Terminate Research. If the information gained during its monitoring or auditing process indicates that human subjects of a research project are exposed to unexpected serious harm or that the policies of the IRB are not being met, the CPHS may suspend or terminate the research.

Additional Requirements for Activities Involving Fetuses, Pregnant Women, or Human *In Vitro* Fertilization. For activities involving fetuses, pregnant women, or human in vitro fertilization, the CPHS must determine that adequate provision has been made by the investigator for monitoring the actual informed consent process. For example, the CPHS may, when appropriate, require participation by the CPHS or subject advocates in (i) overseeing the actual process by which individual consents are secured either by approving induction of each individual into the activity or verifying, perhaps through sampling, that approved procedures for induction of individuals into the activity are being followed, or (ii) monitoring the progress of the activity and intervening as necessary through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen.

Reporting of Audit Results to Full Committee. The results of any targeted or random audits by the ORA or CPHS will be reported to the CPHS at the next convened meeting after the audit. However, if the information gained during the monitoring or auditing process indicates that human subjects of a research project are exposed to unexpected serious harm, the CPHS,

acting through the Chairperson, may suspend or terminate the research prior to the next regularly scheduled CPHS meeting.

Suspension or Termination of Approval for Cause

The CPHS has the authority to suspend or terminate approval of research that is not being conducted in accordance with the CPHS Policies, is not in compliance with federal regulations, or has been associated with unexpected serious harm to subjects. Examples of suspensions or terminations *for cause* include: inappropriate involvement of human subjects in research, serious or continuing noncompliance with federal regulations or IRB policies, and new information regarding increased risk to human subjects.

A Notice of Action suspending or terminating approval of a project must include a statement of the reasons for the CPHS's action. All suspensions or terminations of approval for cause must be promptly reported to the Vice-President for Research. The Vice-President for Research will notify the Department Chair and the Dean of the the associated School of any suspensions or terminations for cause initiated by the CPHS.

The CPHS Chair will confer with the Director, HSA in determining the appropriate regulatory agencies, including the Food and Drug Administration (FDA), or sponsoring agencies, that should be notified by the Investigator of such suspension or termination.

INFORMED CONSENT PROCESS

Legally Effective and Prospectively Obtained Informed Consent

The CPHS must ensure that provisions are made to obtain legally effective informed consent prospectively from each research subject or the subject's legally authorized representative/healthcare proxy unless a waiver of the requirement for informed consent has been granted by the CPHS.

The CPHS must review all informed consent documents and assure the adequacy of the information contained in the consent document.

Each subject or his/her legally authorized representative/healthcare proxy must sign and date a copy of the current CPHS-approved consent form prior to enrollment or participation in any phase of the study, unless the requirement is waived by the CPHS. One copy of the consent form must be given to the subject and, if applicable, a second copy of the full, completed and signed consent form must be placed in the patient's chart. The original completed and signed consent form must be retained for inclusion in the PI's research records.

Definitions of Legally Authorized Representative/Healthcare Proxy:

a. **Minors.** For minor subjects (children under 18 years of age) their parents or legal guardians are the legally authorized representatives who may consent to their participation in research.

   i. **Parents.** Only the parents may consent to their child's participation in research. Grandparents and other relatives or caregivers may not consent unless they have been granted formal custody of the child by a court. In such cases, the Principal Investigator must obtain a copy of the court's order as evidence of that person's authority to consent on the child's behalf.

   ii. **Emancipated Minors.** Some individuals under the age of 18 may assert that they are emancipated minors and thus the consent of a parent is not required. However, the presumption shall be that the individual is not emancipated and the burden of proof shall rest on the individual asserting it. Each situation should be judged on a case-by-case basis, and the Office of Research Administration as well as the appropriate hospital administration (in the case of hospitalized subjects) must be consulted before enrolling such a minor in a research study. Documentation of those decisions must be included in the research file.

   iii. **Cognitively Impaired Adult Subjects.** If a prospective adult subject lacks the capacity to consent, his/her legally authorized representative, and in some cases, a healthcare proxy, may consent on behalf of the subject. The CPHS must review all requests for utilizing surrogate consent.

   New York State law, Section 2442, limits who is authorized to consent on behalf of a subject who lacks the capacity to provide informed consent to the following:

- Legally authorized representative: A legally authorized representative means an individual or judicial or other body authorized under New York State law to consent on behalf of a prospective subject to the subject's participation in the research. Family members and close friends cannot be considered to be a legally authorized representative for the adult subject unless they have been formally appointed as that person's legal guardian or conservator.

- Healthcare proxy: In order for a healthcare proxy to be effective, it must have been signed at a time when the subject had decision making capacity and the healthcare proxy must not specifically prohibit research. If an investigator plans on obtaining surrogate consent employing a healthcare proxy, the IRB must determine that the research provides potential therapeutic benefit to the subject.

  If a subject previously determined to lack capacity to consent regains capacity during the study, the investigator must obtain the consent of the individual promptly. The consent process should include information regarding all research procedures performed to date and allow the subject an opportunity to remain in or withdraw from the study. If the subject chooses to remain in the study, he/she must sign the IRB approved consent form. The investigator must document what research procedures were already performed and/or remain to be performed in the research record.

Elements of Informed Consent

Federal Regulations require that specific elements be contained in all informed consent documents unless waived by the IRB. Required elements of informed consent may not be omitted unless waived by the IRB and there may not be discrepancies between the College Forms and protocol and the informed consent documents regarding the purpose, risks, and benefits of the research. The College provides investigators with a template informed consent format as well as guidelines for developing consent documents.

Required Elements. The basic elements of consent to be included in every informed consent document are:

11 REQUIRED ELEMENTS:

(1) **Purpose of Study:** A statement that the study involves research, an explanation of the purposes of the research, 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) **Study Summary:** Consent process must begin with a concise summary of essential study info that individuals would want to know in order to make an informed decision about participation.

(3) **Risks and discomforts:** A description of any reasonably foreseeable risks or discomforts to the subject;

(4) **Benefits:** A description of any benefits to the subject or to others which may reasonably be expected from the research;

(5) **Alternatives to participation:** A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject; The option to receive no treatment should be mentioned but not as a form of therapy.

(6) **Consenting to Additional Research:** Consent form must disclose any plans to conduct future research using info and/or biospecimens collected during the research.

(7) **Identifying information / biospecimens:** You must include one of these statements if you collect identifying information/biospecimens:

I. If the research involves the collection of identifiable private information or identifiable biospecimens, a statement on whether the identifiers might be removed and information or biospecimens could be used for future research without additional informed consent.

II. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

(8) **Confidentiality:** A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(9) **Research-related Injury:** An explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(10) **Offer to answer questions***:* 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

(11) **Voluntary Participation:** 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.

ADDITIONAL ELEMENTS:

When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) **Additional Risks:** 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) **Outcomes:** If applicable, consent form must disclose whether: (a) subjects will share in commercial profit; (b) clinically relevant research results will be returned; and (c) research will or might include whole genome sequencing.

(3) **Termination:** Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(4) **Costs:** Any additional costs to the subject that may result from participation in the research;

Use the following language when appropriate.
"Your participation in this study should not result in any costs other than those associated with the treatment of your disease. The study sponsor will supply study drug and cover treatment and procedures related to the study at no cost to you. Some tests and procedures that are provided as part of regular care will not be paid for by the study sponsor. You or your insurance

carrier will be charged or held responsible for the costs of that care. Some insurance companies or government health care programs may limit what they will pay for certain routine services that are performed in a research study, in which case you may be responsible for paying."

(4) **Withdrawal:** The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) **Significant findings:** A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) **Number of subjects:** The approximate number of subjects involved in the study.

(7) **Genetic Information:** Genetic Information Nondiscrimination Act (GINA) is a Federal law that prohibits discrimination in health coverage and employment based on an individual's genetic information. If your research includes obtaining genetic information from subjects, such as genetic tests done as part of the research or any request for, or receipt of, genetic services (genetic testing, counseling, or education), then the following language should be added to the consent:

> "A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:
>
> Health insurance companies and group health plans may not request your genetic information that we get from this research.
>
> Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
>
> Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance."

(8) **FDA Mandatory ClinicalTrials.gov statement:**

FDA has published a new regulation at 21 CFR 50.25(c) regarding a mandatory clinicaltrials.gov consent form statement for applicable clinical trials* initiated on or after March 7, 2012.

Under this new regulation, the following statement must be reproduced word-for-word in informed consent documents for applicable clinical trials:

> "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as

required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

"Applicable clinical trials" generally include controlled interventional studies (with one or more arms) of drugs, biological products, or devices that are subject to FDA regulation, meaning that the trial has one or more sites in the United States, involves a drug, biologic, or device that is manufactured in the United States (or its territories), or is conducted under an investigational new drug application (IND) or investigational device exemption (IDE). Trial sponsors and investigators have the responsibility of determining whether or not a trial is an "applicable clinical trial." Definitions vary for applicable device and drug trials including biologics. [FDA Guidance Feb 2012]

No Unproved Claims of Effectiveness. No unproved claims of effectiveness or certainty of benefit, either implicit or explicit, may be included in the documents.

Exculpatory Language in Informed Consent Documents. Informed consent documents may not contain any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the College, or its agents from liability for negligence.

a. Examples of Acceptable Language
    i. Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.
    ii. By consenting to participate, you authorize the use of your bodily fluids and tissue samples for the research described above.

b. Examples of Unacceptable Exculpatory Language:
    i. By agreeing to this use, you should understand that you would give up all claims to personal benefit from commercial or other use of these substances.
    ii. I voluntarily and freely donate any and all blood, urine, and tissue samples to the U.S. Government and hereby relinquish all right, title, and interest to said items.
    iii. By consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research.
    iv. I waive any possibility of compensation for injuries that I may receive as a result of participation in this research.

Second Person. The language of the consent document should be in the second person style (i.e., "you") which may help convey that there is a choice to be made by the subject rather than presumption of the subject's consent with the use of the first person style.

Informed Consent Document Language May Not Be Too Complex. The information provided in the informed consent documents must be in language understandable to the subject. The informed consent document should not include complex language that would not be understandable to all subjects. Technical and scientific terms should be adequately explained using common or lay terminology.

FDA-Regulated Test Articles. For all research involving test articles regulated by the U.S. Food and Drug Administration (FDA), informed consent documents must include a statement to the effect that the purpose of the study includes evaluation of the safety and/or effectiveness of the test article.

Documentation of Informed Consent

Two Options for Documentation of Informed Consent. The CPHS may approve procedures for documentation of informed consent that involve either (a) a written consent form signed by the subject and (b) in limited circumstances, waiver of signed written consent form. Each of these two options is described in detail below. It is the responsibility of the CPHS Panel to determine which of the procedures described below is appropriate for documenting informed consent in protocols that it reviews.

Option One: Written Consent Form Signed by Subject or Legally Authorized Representative. In most circumstances, the CPHS should require that informed consent is documented by the use of a written consent form approved by the CPHS and signed by the subject or the subject's legally authorized representative. This consent form must embody the elements of informed consent. This form may be read to the subject or the subject's legally authorized representative. However, the investigator should allow the subject or the legally authorized representative adequate opportunity to read the consent document before it is signed. A copy of the document must be given to the person signing the form.

a. The written informed consent document should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent.

b. Subjects who do not speak English should be presented with an informed consent document written in a language understandable to them. Generally, foreign language consent forms will be allowed by the CPHS only when there is the reasonable expectation that there are appropriate personnel available to address concerns of the subject in the subject's language throughout their participation in the project.

Option Two: Waiver of Documentation (Waiver of signed consent).

a. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if the CPHS finds:
    i. That 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; and

        Note: When the CPHS waives the requirement for documentation under this condition, each subject must be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

    ii. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

        Note: 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 of psychological examinations or tests. An example of minimal risk is the risk of drawing a small amount of blood from a healthy individual for research purposes (because the risk of doing

so is no greater than the risk of doing so as part of a routine physical examination).

b. In cases in which the documentation requirement is waived, the CPHS may require the Principal Investigator to provide subjects with a written statement regarding the research.

Use of Facsimile or Mail to Document Informed Consent. The informed consent document may be delivered by mail or facsimile to the potential subject or the potential subject's legally authorized representative and the consent interview conducted by telephone when the subject or the legally authorized representative can read the consent document as it is discussed. All other applicable conditions for documentation of informed consent must also be met when using this procedure.

Translation of Informed Consent Document into Non-English Languages.

If the study may include a significant percentage of subjects whose primary language is not English (i.e., 25% or more), then the English Consent form must be translated into the subject's language. The CPHS requires that a letter from a certified translation service, attesting to the accuracy of the translation, be submitted. CPHS approval of the translated consent document is required prior to use.

Short form written consent document for subjects who do not speak English

If the study may include a smaller percentage of subjects whose primary language is not English (i.e., less than 25%), a Short Form Written Consent Document may be used (45 CFR 46.117(b)). The College has translated the Short Form Consent Templates into three languages: Spanish, Korean and Portuguese. Investigators are required to complete specific information on the short form template including Principal Investigator's name, Study Title, and contact phone number. The Short Form consent includes language addressing HIPAA requirements.

A short form written consent document stating that the elements of English informed consent have been presented orally may be used to enroll a potential subject. Prior CPHS approval for this type of use is required. The short form must be translated into a language understandable to the potential subject. When this method is used, the English consent form is orally presented to the subject. There shall be an independent witness to the oral presentation who is fluent in both English and the language of the subject. The short form itself is to be signed by the subject or the representative. The witness shall sign both the short form and a copy of the English consent form. The person obtaining consent (i.e., principal investigator or designee) shall sign a copy of the English consent form. The subject shall be provided with a copy of the English consent form, the English HIPAA Authorization form, and the short form. Language addressing HIPAA and permission to use or disclose subject's protected health information is included in the short form.

Waiver of Informed Consent

Generally, the CPHS must ensure that provisions are made to obtain legally effective informed consent prospectively from each research subject or the subject's legally authorized representative. There are only three circumstances under which the regulations give the IRB authority to waive the required informed consent.

Option One: Waiver for Research Activities Designed to Study Certain Aspects of Public Benefit or Service Programs. The CPHS may approve a consent procedure which does not include, or which alters some or all of the elements of informed consent or waives the requirement to obtain informed consent entirely, provided the CPHS finds and documents that:

a. 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
b. the research could not practicably be carried out without the waiver or alteration

Option Two: Waiver for Minimal Risk Studies. Additionally, the CPHS may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent or waives the requirement to obtain informed consent entirely provided the CPHS finds and documents that:

a. the research involves no more than minimal risk to the subjects;
    Note: 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 of psychological examinations or tests. An example of minimal risk is the risk of drawing a small amount of blood from a healthy individual for research purposes (because the risk is no greater than the risk as part of a routine physical examination).
b. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
c. the research could not practicably be carried out without the waiver or alteration; and
d. whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Option Three: Emergency Research Consent Waiver. A third strictly limited exemption from the informed consent requirements exists for a class of research activities that may be carried out in human subjects who are in need of emergency therapy and for whom, because of the subjects' medical condition and the unavailability of legally authorized representatives, no legally effective informed consent can be obtained.

a. This waiver does not apply to research involving (i) fetuses, (ii) pregnant women, (iii) human in vitro fertilization, or (iv) research involving prisoners.
b. For the purposes of this waiver "family member" means any one of the following legally competent persons: spouses; parents; children (including adopted children); brothers, sisters, and spouses of brothers and sisters; and any individual related by blood or affinity whose close association with the subject is the equivalent of a family relationship.
c. The CPHS may extend this waiver only for a class of research consisting of activities, each of which has met the following strictly limited conditions detailed under either (i) or (ii) below:
    (i) *Research subject to FDA regulations.* The CPHS must have approved both the activity and the waiver of informed consent and found and documented:
        A. that the research activity is regulated by the Food and Drug Administration (FDA) and will be carried out under an FDA investigational new drug application (IND) or an FDA investigational device exemption (IDE), the application for which has clearly identified the protocols that would include subjects who are unable to consent; and
        B. that the requirements for exception from informed consent for emergency research detailed in the FDA's regulations (at 21 CFR Section 50.24) have been met relative to those protocols, or
    (ii) *Research not subject to FDA regulations.* The CPHS has approved both the research and the waiver of informed consent and has (i) found and documented that the research is not subject to regulation by the FDA, and (ii) found and documented and reported to the OHRP that the following conditions have been met relative to the research:
        A. The human subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.
        B. Obtaining informed consent is not feasible because: (i) the subjects will not be able to give their informed consent as a result of their medical condition; (ii) the intervention involved in the research must be administered before consent from the subjects' legally authorized representatives is feasible; and (iii) there is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the research.
        C. Participation in the research holds out the prospect of direct benefit to the subjects because: (i) subjects are facing a life-threatening situation that necessitates intervention; (ii) appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects; and (iii) risks associated with the research are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.
        D. The research could not practicably be carried out without the waiver.
        E. The proposed research protocol defines the length of the potential therapeutic window based on scientific evidence, and the investigator has

committed to attempting to contact a legally authorized representative for each subject within that window of time and, if feasible, to asking the legally authorized representative contacted for consent within that window rather than proceeding without consent. The investigator will summarize efforts made to contact representatives and make this information available to the IRB at the time of continuing review.

F. The IRB has reviewed and approved informed consent procedures and an informed consent document in accord with federal regulations (45 CFR 46.116 and 46.117). These procedures and the informed consent document are to be used with subjects or their legally authorized representatives in situations where use of such procedures and documents is feasible. The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a subject's participation in the research consistent with paragraph (v) below of this waiver.

G. Additional protections of the rights and welfare of the subjects will be provided, including, at least: (i) consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the research will be conducted and from which the subjects will be drawn; (ii) public disclosure to the communities in which the research will be conducted and from which the subjects will be drawn, prior to initiation of the research, of plans for the research and its risks and expected benefits; (iii) public disclosure of sufficient information following completion of the research to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results; (iv) establishment of an independent data monitoring committee to exercise oversight of the research; and (v) if obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the subject's family member who is not a legally authorized representative, and asking whether he or she objects to the subject's participation in the research. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.

In addition, the CPHS must ensure that procedures are in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, of the subject's inclusion in the research, the details of the research and other information contained in the informed consent document. The CPHS shall also ensure that there is a procedure to inform the subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, that he or she may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. If a legally authorized representative or family member is told about the research and the subject's condition improves, the subject is also to be informed as soon as feasible. If a subject is entered into research with waived consent and the subject dies before a legally authorized representative or family

member can be contacted, information about the research is to be provided to the subject's legally authorized representative or family member, if feasible.

Studies involving subjects who are decisionally impaired may take place over extended periods. The CPHS should consider whether periodic re-consenting of individuals should be required to ensure that a subject's continued involvement is voluntary. The CPHS may require that investigators re-consent subjects after taking into account the study's anticipated length and the condition of the individuals to be included (e.g., subjects with progressive neurological disorders). Additionally, the CPHS should consider whether and when to require a reassessment of decision making capacity.

"Deferred Consent" or "Ratification" Not Allowed. Informed consent procedures which provide for other than legally effective and prospective obtained consent fail to constitute informed consent under the federal regulations for the protection of human subjects. Therefore, waiving informed consent using a method other than those described above and specified in the federal regulations is a violation of this policy.

Documentation. When approving a procedure which alters or waives the requirements for informed consent, the minutes of the CPHS meeting must document that the Committee made the findings required above.

Assent

In instances where the subject is not legally capable of giving informed consent (e.g., minors), the CPHS must find that adequate provisions are made for soliciting the assent of the subject when, in the judgment of the CPHS, the subject is capable of providing assent.

For minors, in addition to parent or guardian consent/permission, the child's assent is required. "Assent" is defined by the regulations as follows: "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent." (45 CFR 46.402(b)).

The CPHS should require child assent unless it can be appropriately waived, or if the child is not capable of providing assent. In determining whether subjects are capable of assenting, the CPHS shall take into account the age, maturity, and psychological state of the subject involved. This judgment may be made for all subjects to be involved in research under a particular protocol or for each subject, as the CPHS deems appropriate. The regulations at 45 CFR 46.408(a) identify three types of circumstances where the IRB may determine that waiver of children's assent is appropriate:

1. if the capability of some or all of the children is so limited that they cannot reasonably be consulted;

2. if the intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research.

3. if the research meets the same conditions as those for waiver or alteration of informed consent in research involving adults, as specified in the regulations at either 45 CFR 46.116(c) or 45 CFR 46.116(d).

Oral assent if possible should be obtained from children under the age of 7 years with the capacity to understand their participation. Written assent should be obtained from children ages 7 years and above. A separate assent form should be used for children ages 7 to 11 years and 12-17 years. The assent form should present the purpose of the research, procedures, risks, and benefits in simplified language appropriate for the age range. The assent form should generally be limited to one or two pages and be presented in an easy to read typeface such as Comic Sans. Children 14 to 17 years may also sign the consent form in addition to the Assent Form if they retain the capacity to understand the document.

Approval Dates on Informed Consent Documents

The IRB approval period dates on all approved informed consent documents are an effective means of insuring that only currently approved consent documents are used and that only those documents bearing approval and expiration dates are used when obtaining informed consent of study participants.

If the CPHS approves (full board or expedited) a change in the consent form for annual renewal or amendment, the Director of HSA or the IRB assistant will employ the electronic system to insert the IRB approval period dates, with the date the IRB approved the consent modification to the end date of the approved IRB period.

Request for Waiver or Alteration of HIPAA Authorization

Investigators conducting database or retrospective medical records research may need to collect protected health information and may requests a Waiver or Alteration of HIPAA. The Principal Investigator must complete the College's Request for Waiver of HIPAA Authorization form. All requests must be submitted to the CPHS for approval.

The CPHS must ensure the following criteria are satisfied before approval is granted ((45 CFR 164.512(i)(2)(ii)(A-C)):

- The research involves no more than minimal risk to the subjects.
- There is an adequate plan to protect identifiers from improper use and disclosure.
- There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
- There is adequate written assurance that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted by the Privacy Act.
- The research could not practicably be conducted without the waiver or alteration.
- The research could not practicably be conducted without access to and use of the PHI.
- The waiver will not adversely affect the rights and welfare of subjects.

RECORDS AND DOCUMENTATION

CPHS Records

CPHS records must be maintained in a manner that contains a complete history of all CPHS actions related to review and approval of a protocol, including continuing reviews, amendments, and adverse event reports.

Document Retention. The Office of Research Administration (ORA) must retain all records regarding an application (regardless of whether it is approved) for at least three (3) years. For all applications that are approved and the research initiated, the ORA must retain all records regarding that research for at least three (3) years after termination of the research study.

Access to Documents. The ORA must make all records accessible for inspection and copying by authorized representatives of the sponsoring Department or Agency at reasonable times and in a reasonable manner.

The ORA must prepare and/or maintain the following documents:

a. *Applications.* Copies of all research applications reviewed, scientific evaluations (if any), approved sample consent/assent documents, data safety monitoring board reports, and reports of injuries to subjects.

b. *Continuing Review.* Continuing Review reports submitted by investigators and attached documentation, CPHS reviewers notes (if any).

c. *Correspondence with Investigators.* Copies of all correspondence between the IRB and the investigators including Notices of Action from the CPHS and responses from investigators.

d. *New Findings.* Statements of significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation provided to subjects.

e. *Minutes.* The minutes of all CPHS meetings.

f. *List of IRB Committee Members.* A list of CPHS members for each Panel identified by (i) name; (ii) earned degrees; (iii) representative capacity; and (iv) indications of experience sufficient to describe each member's chief anticipated contributions to CPHS deliberations. Changes in CPHS membership must be reported to OHRP/FDA by the ORA.

g. *Policies and Procedures.* Written procedures which the ORA and the CPHS Panels will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for ensuring prompt reporting to the CPHS of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which CPHS approval has

already been given, may not be initiated without CPHS review and approval except when necessary to eliminate apparent immediate hazards to the subject; (iv) for ensuring prompt reporting to the CPHS, appropriate institutional officials, and the Department or Agency head of (A) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the CPHS; and (B) any suspension or termination of CPHS approval.

Meeting Agenda and Minutes

The minutes of all CPHS meetings must be in sufficient detail to show attendance at the meetings as well as initial and continued presence of a majority of members including at least one non-scientific member. Minutes shall also note whether an alternate is voting and when a member is not present for the discussion and vote on an item.

For each protocol discussed, the minutes shall record the actions taken by the Committee and the vote on these actions including the number of members that vote: for; against; abstain. In order to document the continued existence of a quorum, votes should be recorded in the minutes using the following format:

Vote: FOR: AGAINST: ABSTAIN: RECUSED: EXCUSED:

The minutes shall include written summary of the discussion of controverted issues and their resolution. When protocol revisions are requested or a proposal is disapproved, the minutes shall record the basis for doing so.

The minutes shall include that the risks require more frequent reporting to the CPHS.

The minutes of IRB meetings should clearly reflect the CPHS's determination regarding the approval period (review interval).

Telephonic Participation. At a meeting in which a Committee member participates via telephone (speakerphone), meeting minutes must document that participation was via speakerphone. Participation by telephone is expected to be the exception, not the rule, and may be used when a quorum is not otherwise obtainable or to allow a member who cannot be physically present to participate in the discussion. Members who participate via telephone must also have access to IRB review materials in advance of the CPHS meeting. Members who participate via telephone must also disclose any conflict of interest disclosures in order to participate in the meetings.

Specific Findings. When specific findings on the part of the CPHS are required, these findings should be fully documented in the Minutes and should include protocol-specific information justifying each finding.

Research Involving Prisoners. When approving research involving prisoners, the minutes mustdocument that the CPHS made the seven additional findings and the specific category which authorizes the research required.

Categories of research that may be approved:

(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, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research; or

(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. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the CPHS to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research.

Additional findings required:

(a) the research under review represents one of the categories of research permissible under §46.306(a) (2);

(b) 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;

(c) the risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

(d) 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 Board 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;

(e) the information is presented in language which is understandable to the subject population;

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

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

Additionally, the minutes must reference that either a majority of the CPHS (exclusive of prisoner members) has no association with the prison(s) involved, apart from their membership on the Committee; or at least one member of the Committee is 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.

If a prisoner representative is selected to serve on the CPHS, the person must have a close working knowledge of prison conditions and the life of a prisoner. Suitable individuals could include present or former prisoners; prison chaplains; prison psychologists, prison social workers, or other prison service providers; persons who have conducted advocacy for the rights of prisoners; or any individuals who are qualified to represent the rights and welfare of prisoners by virtue of appropriate background and experience.

Research Involving Children. When approving research involving children, the minutes must document that the Committee made the findings required in Subpart D of 45 CFR 46 regarding level of risk.

Wards of the State or Other Agency. When reviewing research involving children who are wards of the state or any other agency, institution, or entity, the CPHS must find and document in the minutes that 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.

CPHS Minutes. The minutes of the previous committee meeting will be listed on the agenda of the next committee meeting to be are approved by the CPHS Panel prior to discussion of submitted applications for approval.

Records Retention

Purpose: To reduce the amount of space devoted to records whose retention is not required.

Definitions:
FDA Food and Drug Administration
IRB Institutional Review Board

Scope: This policy shall apply to sponsored program and research documents on file in the Office of Research Administration (ORA) for:

a. Research or other sponsored programs externally-funded and activated at New York Medical College,
b. Applications for external support that do not involve human subjects and are not funded,
c. Research that does not involve human subjects, activated at New York Medical College with internal funding,
d. Human subjects research reviewed by the IRB, whether or not funded or activated,
e. Human subject research determined by ORA to be exempt from the requirement for IRB review.

Policy: Records will not be retained beyond the retention period identified for a specific class of documents.

a. Records for research and other sponsored programs externally-funded and activated at New York Medical College will not be retained beyond a period of three years from the date of the termination of the research study.
b. Applications for external support that do not involve human subjects and are not funded will not be retained beyond a period of two years from the date of last submission.
c. Records for research that does not involve human subjects, activated at New York Medical College with internal funding, will not be retained beyond a period of three years from termination.
d. Records for human subjects research reviewed by the IRB, whether or not funded or activated, will not be retained beyond a period of three years after IRB receipt of the final report or for such longer period as has been specified in a contract between New York Medical College and the sponsor of the research.
e. Records for human subject research determined by ORA to be exempt from the requirement for IRB review, will not be retained beyond a period of three years from termination.
f. In the case of overlap between the five categories listed above, records will be retained for the longer period.

INVESTIGATOR RESPONSIBILITIES

General Responsibilities

Human Subject Protections. The individual Investigator is the ultimate protector of the subject's rights and safety. Each Investigator is obligated to be certain that each subject is adequately informed and freely consents to participate in the Investigator's research. The Investigator must assure that every reasonable precaution is taken to reduce to a minimum any risk to the subject. The Investigator also assumes responsibility for compliance with all federal, state, and institutional rules and regulations related to research involving human subjects and human subject-derived information and materials. Specifically, the Investigator may not initiate any research involving human subjects without IRB review, approval, and Permission to Start.

The Use of Investigational Devices and/or Investigational Drugs. Prior to the initiation of any research involving an investigational device or drug, it is the responsibility of the individual investigator to obtain the IND or IDE from the FDA in accordance with federal regulations. In the case of commercially sponsored studies or when the IND or IDE number is not held by the investigator here, the investigator should provide the sponsor's IND or IDE number where requested on the College Forms.

Additional Approvals. Prior to the initiation of any research approval from the ORA is required. An IRB Notice of Action to the investigator or, in the case of funded research, a Digest of Terms will provide notification of that approval. If research is to be conducted at Westchester Medical Center, approval from Westchester Medical Center Clinical Research Institute is required. If research is conducted at Metropolitan Hospital Center, approval from the Health and Hospitals Corporation (HHC) is required.

Supervision and Auditing of Research Process. It is the responsibility of each Investigator to assure that all procedures in a study are performed, with the appropriate level of supervision, only by individuals who are licensed or otherwise qualified to perform them under the laws of the State of New York. Further, it is the responsibility of Investigators to regularly review their research procedures and address any deficiencies identified.

Investigator Training. It is the responsibility of each Investigator to complete the New York Medical College Human Subjects Protection Training program online. Further, it is the responsibility of each Investigator to ensure that key personnel who are responsible for the design and conduct of the study are adequately trained with regard to the use of human subjects in research. All persons participating in any research activity involving human subjects are required to complete the appropriate (Biomedical Research Personnel or Social & Behavioral Research Personnel) *Collaborative Institutional Training Initiative* (CITI) course, available on-line at: www.CITIprogram.org. Completion reports must be submitted to the ORA for recordkeeping purposes.

Amendments/Requests for Change in CPHS Application. It is the responsibility of the Investigator to not deviate in any way from the CPHS-approved protocol until the Investigator

has received written approval from the CPHS unless the deviation is required for the safety of the individual research subject.

Researchers' Records. At a minimum, Investigators must maintain research records for at least three (3) years from the date of termination of the research study. All records must be accessible for inspection and copying by authorized representatives of the CPHS and the department or agency supporting the research. Beyond three (3) years, requirements for record retention vary with the type of research conducted and provisions of the Investigator's funding source. It is the Investigator's responsibility to clearly understand the retention requirements of the sponsor.

Confidentiality. The necessity for maintaining confidentiality of the subjects and the research records continues for the life of the data. These rules apply equally to faculty, staff, and students. Protocols conducted with FDA regulated articles must be kept in accordance with current FDA regulations.

Additional Requirements for Activities Involving Fetuses, Children, Pregnant Women, or Human *In Vitro* Fertilization. For activities involving fetuses, children, pregnant women, or human *in vitro* fertilization, the Investigator must ensure that adequate provision has been made for monitoring the actual informed consent and or assent process. For example, the Investigator may, when appropriate, require participation of subject advocates in (a) overseeing the actual process by which individual assents and or consents are secured, or (b) monitoring the progress of the activity and intervening as necessary.

Prisoner Research. If a subject becomes a prisoner after enrollment in research, the Investigator is responsible for reporting in writing this situation to the CPHS immediately. Approval of the research by the CPHS will then be required.

Continuing Review. All approved research proposals, with the exception of those which qualify for exemption and expedited status in accordance with 46.104(d)(1-8); 45 CFR 46.110 and 21 CFR 56.110, must receive continuing review at intervals appropriate to the degree of risk as determined by the CPHS. Continuing review must be conducted not less than once per year. It is the responsibility of the Investigator to provide the CPHS with all of the information requested on the Progress Report Form and associated instructions.

Reporting of Unanticipated Problems to the IRB

The Investigator must report to the IRB, Data Safety and Monitoring Boards, sponsors and appropriate federal agencies all unanticipated problems, whether they represent adverse events or other problems, involving risks to human subjects or others that occur in the course of the research. If a protocol and/or informed consent form modification is required, a description of the proposed modification(s) or other corrective actions must be submitted to the IRB.

It is the Investigator's responsibility to keep the IRB informed of unanticipated problems that affect the risk/benefit ratio of the research on an ongoing basis.

This policy incorporates guidance provided by the Office for Human Research Protections (OHRP) titled: "Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events" http://www.hhs.gov/ohrp/policy/AdvEvntGuid.htm as well as the Food and Drug Administration (FDA) titled: "Guidance for Clinical Investigators, Sponsors, and IRB: Adverse Event Reporting to IRBs- Improving Human Subjects Protection": http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126572.pdf

Reporting Requirements.

a. **Internal unanticipated problems:** Events occurring in a subject enrolled at a location for which New York Medical College's IRB is the IRB of record and/or occurring at New York Medical College, Westchester County Health Care Corporation, Metropolitan Hospital Center, or Westchester Institute for Human Development.

   Each unanticipated problem must be reported to the College's IRB within 5 working days of the Investigator becoming aware of the event.

b. **External Unanticipated Problems:** Events occurring in a subject enrolled at a location other than New York Medical College, Westchester County Health Care Corporation, Metropolitan Hospital Center, or Westchester Institute for Human Development and for which New York Medical College's IRB is not the IRB of record.

   Reports of unanticipated problems received by the Sponsor must be reported to the College's IRB within 5 working days of the Investigator becoming aware of the event. The summary and analyses from the Sponsor including why the event constitutes an unanticipated problem and information about whether or not the consent form or protocol will be revised due to the unanticipated problem (e.g., add the additional, previously unknown risk) -.

c. For human gene transfer protocols, investigators must report ***any* serious adverse event, anticipated or unanticipated,** promptly to the IRB, the Institutional Biosafety Committee, the NIH Office of Biotechnology Activities, and other applicable agencies (e.g., Office for Human Research Protection, Food and Drug Administration).

Consult Appendix A and the algorithm in Appendix B to determine which events are reportable.

For those protocols involving Westchester Medical Center, a copy of the report should be submitted to the Westchester Medical Center Clinical Research Institute. For those protocols involving Metropolitan Hospital, a copy of the report should be submitted to Metropolitan Hospital.

Reporting Requirements when a DSMB is Designated for a Clinical Trial.

Investigators must identify to the ORA the DSMB that will be reviewing interim results and include a brief description of the monitoring plan as well as procedures for transmitting the DSMB's summary reports to the ORA. The PI of multi-site trials with DSMBs are expected to promptly forward to the ORA, summary reports of adverse events that reveal unexpected non-serious and serious adverse events and other unexpected findings *that affect the risk/benefit ratio*. Such reports should also be referenced in the summary of the Continuing Review Report Form. Submission of DSMB summaries, is in addition to, and does not supplant, other reporting requirements of the IRB.

Appendix A

Definitions:

The following definitions apply to events occurring after initiation of research activities:

a. **Unanticipated Problem**:

Any incident, experience, or outcome that meets **ALL** of the following criteria:

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

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

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

Unanticipated problems include both serious adverse events and other adverse events if those events suggest that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized [45 CFR 46.103(d)(5)]; [21 CFR 56.1069(b)(1)].

Unanticipated Problems *(FDA regulated clinical studies):*

- Any adverse experience that, even without detailed analysis, represents a serious, unexpected adverse event that is rare in the absence of drug exposure

- A series of adverse events that, on analysis, is both unanticipated and a problem for the study. Need to determine that series of adverse events are not just isolated occurrences and were significant to the rights and welfare of subjects.

- An adverse event that is described or addressed in the Investigator's Brochure, protocol, informed consent documents, or expected to occur in study subjects at an anticipated rate but that occurs at a greater frequency or greater severity than expected; [21 CFR 56.1069(b)(1)].

b. **Adverse Event:**

Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

c. **Unexpected Adverse Event:**

Any adverse event occurring in one or more subjects participating in a research protocol, the nature, severity, or frequency of which is *not* consistent with either:

- The known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol-related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; **OR**

- The expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

d. **Serious Adverse Event:**

Any adverse event that:

- Results in death;
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred);
- Results in inpatient hospitalization or prolongation of existing hospitalization;
- Results in a persistent or significant disability/incapacity;
- Results in a congenital anomaly/birth defect; *or*
- Based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

f. **Unanticipated adverse device effect (includes Humanitarian Use Devices (HUD))**

Unanticipated adverse device effect is any serious adverse effect on health or safety, any life-threatening problem or death caused by, or associated with a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the application; or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects. [21 CFR 812.3(s)]

g. **Relatedness:**

Adverse events that are determined to be at least partially caused by the procedures involved in the research would be considered related to participation in the research. On the other hand, adverse events determined to be solely caused by the underlying disease, disorder, or condition of the subjects or by other circumstances unrelated either to the research or to any underlying disease, disorder, or condition of the subjects would all be considered to be unrelated to participation in the research.

h. **Human Gene Transfer:**

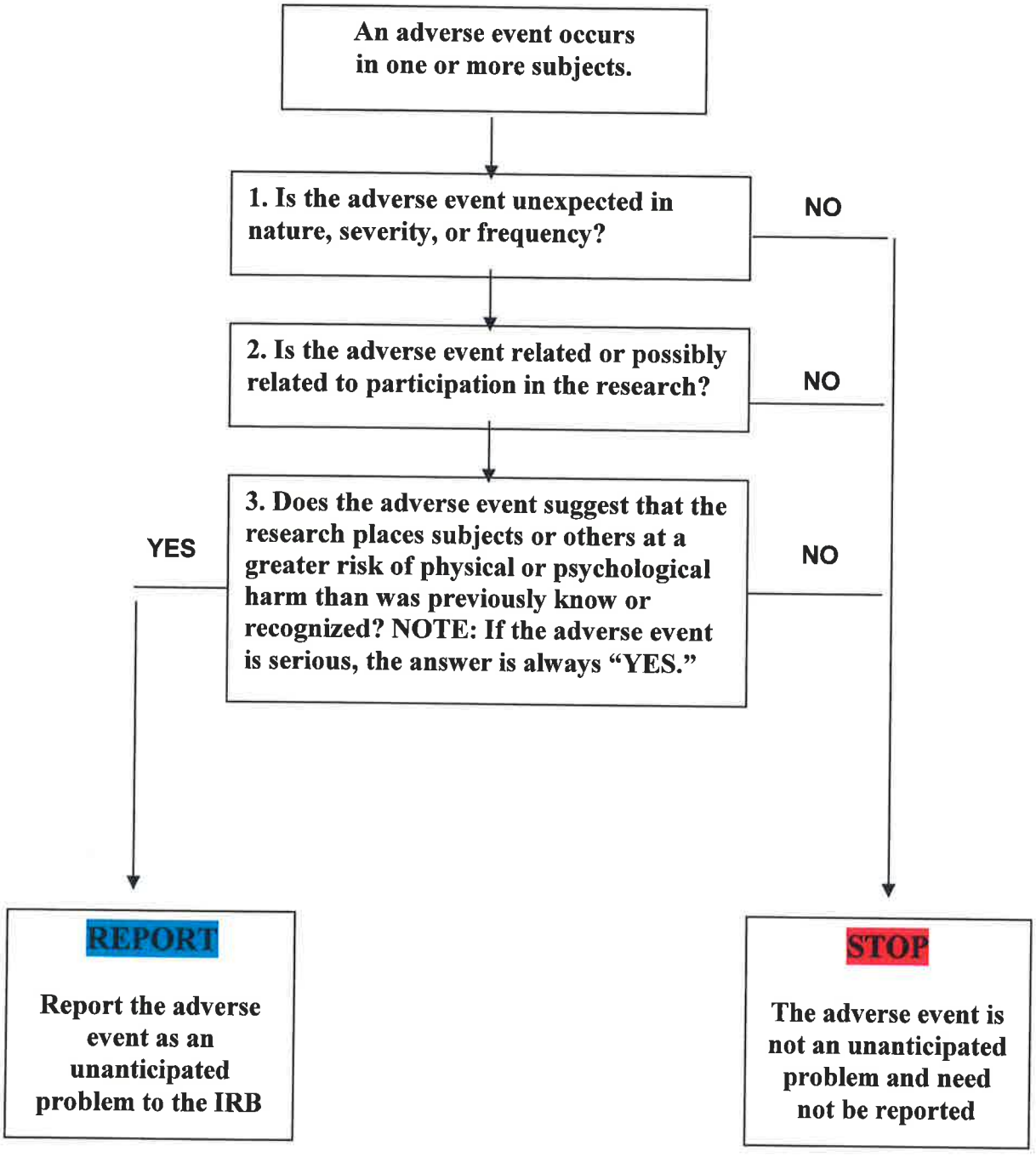
The deliberate transfer of recombinant DNA (or of DNA or RNA derived from recombinant DNA) into human research participants.

i. **New York Medical College PI Initiated:**

An NYMC Investigator who both initiates and conducts, alone or with others, a clinical trial. In the case of NYMC PI initiated studies, it is the Investigator's responsibility to keep the ORA informed of unanticipated problems. If an independent safety monitor (DSMB) is created, all DSMB reports must be forwarded to the IRB.

Appendix B

Algorithm for Determining Whether an Adverse Event is an Unanticipated Problem



IRB MEMBERSHIP

Each CPHS Panel must include at least three members whose primary interests are in a scientific area, one member whose primary interests are in a non-scientific area and one member who is not affiliated with New York Medical College (i.e. not a family member or spouse of an employee, not an alumnus).

***Ex officio*/administrative members** appointed to the Committee or invited guests or consultants do not have voting privileges and are not counted towards the quorum. *Ex officio* administrative members on the Committees may include (a) persons who are members by virtue of the position held, and (b) persons necessary to the Committee by virtue of special knowledge or experience.

Nomination for Membership. Nominations for faculty positions on the CPHS Panels are made to the Director for the Office of Research Administration. Nominations are forwarded to the Dean and Provost with supporting documentation including the approval of the chair of the panel and the nominee's CV.

Appointments. Appointments to membership on the CPHS Panels are extended in writing by the Dean. Membership lists for the CPHS Panels are on file in the Office of the Dean and the ORA.

The Chairperson and Vice Chairperson have the primary responsibility for the following:

1. Maintain a thorough understanding of federal regulations pertaining to human subject protections, FDA, OHRP and local regulations

2. Assist the Director, HSA in the determination as to whether a project is considered "human subject research" in accordance with the regulatory requirements under 45 CFR 46 and 21 CFR 56

3. Approve, when appropriate, expedited submissions in accordance with regulatory requirements under 45 CFR 46.110 and 21 CFR56.111

4. Approve, when appropriate, research that is considered "exempt" in accordance with regulatory requirements 46.104(d)(1-8)

5. Review (or assign the review to other designated CPHS members, as appropriate) adverse event reports (AEs) and unanticipated problems/protocol deviations (UAP's/D) to determine if the event affecting the safety of subjects and, the conduct of the trial. As warranted, also determine course of immediate action to address the safety of subjects; provide recommendation to the Assistant Dean and if necessary, convene an emergency meeting of the CPHS with the assistance of the Office of Research Administration

6. With the assistance of the Director, HSA, monitor the members present at convened meetings to determine that the meetings are appropriately assembled and remain appropriately convened.

7. Accept appropriate motions from voting members of the CPHS

8. As necessary, ensure that the specific elements pertaining to the motion are clearly understood by the CPHS members and accurately recorded in the meeting minutes

9. Ensure that committee decisions are made in accordance with federal, state and local regulations and with the NYMC IRB Policies and Procedures and

10. Review the minutes of IRB meetings and votes of the IRB members to ensure it accurately reflects discussions and actions.

Prior to each convened meeting, along with Director, HSA, the Chairperson or Vice Chairperson responsible for the meeting will:

1. Review IRB meeting schedule and agenda

2. Provide guidance to the IRB Administration Office on the assignment of reviewers to studies requiring convened IRB review if requested

3. Recommend consults and/or external reviews when appropriate to assist in IRB reviews

Number of Members. The CPHS Panels are required to have a minimum of five members each, with varying backgrounds and expertise to provide complete and thorough review of research activities commonly conducted by the institution. Membership in the General Medical and Behavioral Panel must include at least three clinicians and at least two members expert in the behavioral sciences. Membership in the Oncology Panel must include at least three clinicians expert in oncology.

Alternates. Formally appointed alternates may vote in place of an absent regularly appointed member. Meeting minutes must document when an alternate member replaces the regular member.

Qualifications of IRB Members. The CPHS Panels must be (i) sufficiently qualified through 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; and (ii) able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

Composition of the Panels must be adequate in light of the anticipated scope of the College's research activities, the types of subject populations likely to be involved, and the size and complexity of the institution.

Pediatric representation. A CPHS Panel considering protocols involving children as subjects should include at least one pediatrician.

Prisoner representative. Federal Regulations require that the CPHS membership be modified if it is to review research involving prisoners. Therefore, if any CPHS Panel will review research involving prisoners, at least one member shall be a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity.

Consultants. On a case-by-case basis, the CPHS Panels may request review by an individual with competence in an area not represented by the Committee membership.

GENERAL CPHS POLICIES

Educational Activities for the Protection of Human Subjects

The education of faculty and staff engaged the conduct and oversight of human subject research is the responsibility of the Office of Research Administration. Both initial and continuing education is directed by the Director for the Office of Research Administration and conducted by the Director, Human Subjects Administration who acts as the Human Protections Administrator for the College.

Education of the Director for Human Subjects Administration (HSA)

The Director of HSA is expected to be certified by a Nationally recognized organization in Human Subjects Research such as the Association for Clinical Research Professionals (ACRP), the Society of Certified Research Associates (SOCRA), the National Association of IRB Managers, the Council for Certification of IRB Professionals (CCIP), or Public Responsibility in Medicine and Research (PRIMR) which offers the Certified IRB Professional (CIP),. Certification, once obtained, is expected to be maintained.

The HSA is expected to attend at least one professional meeting every other year. More frequent attendance is encouraged. Attendance at special meetings that address topics of immediate import to the area of human subject research is expected.

Education of the CPHS Members

CPHS members are expected to complete the College's required educational program. *Collaborative Institutional Training Initiative* (CITI) course, IRB Member module, which is available on-line at: www.CITIprogram.org. A passing grade is 85% and completion reports shall be submitted to the ORA for recordkeeping. Regularly, at the start of IRB meetings, time will be devoted to the continuing education of the members. Some of these sessions will be devoted to reminders of their responsibilities; others will be devoted to keeping the members current with regulations, news, and controversies in the human research area.

IRB members are encouraged to attend professional meetings on human subject issues.

Education of Investigators and Research Personnel

All persons participating in any research activity involving human subjects are required to complete the appropriate (Biomedical Research Personnel or Social & Behavioral Research Personnel) *Collaborative Institutional Training Initiative* (CITI) course, which is available on-line at: www.CITIprogram.org. A passing grade is 85% and completion reports shall be submitted to the ORA for recordkeeping purposes.

In addition, the Director of HSA will conduct education sessions, upon request, for departments and clinical services.

Support for Education Program

Support for the continuing education program is provided by the College mainly through the ORA. Such support provides for meeting fees, travel expenses, and educational materials.

Clinical Trials Registration and Reporting of Results

Registration at ClinicalTrials.gov: As required by Public Law 110-85, Title VIII

The 2007 Food and Drug Administration Amendments Act (FDAAA) expands the types of clinical trials that must be registered in ClinicalTrials.gov, increases the number of data elements that must be submitted, and mandates submission of results data.

In order to comply with the requirements set forth in the 2007 FDAAA and to promote transparency in clinical and translational research, all clinical trials (Phase 2-4 drug and device trials) must be registered at ClinicalTrials.gov within 21 days of enrollment of the first subject.

Clinical Trials include:

- Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation;
- Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric postmarket surveillance.

The entity responsible for registering the study is the sponsor of the clinical trial (as defined in 21 CFR 50.3) or, for investigator-initiated studies, the Principal Investigator.

When must the trials be registered?

- Trials initiated after 9/27/2007, or trials initiated before that date and ongoing on 12/26/2007 that involve a "serious or life threatening disease or condition," must be registered in full by: the later of 12/26/2007 or 21 days after the first patient is enrolled.
- Trials that were initiated before 9/27/07 that are "ongoing" as of 12/26/2007, and which do not involve a "serious or life threatening disease or condition," must be registered by 9/27/2008.
- Trials that were initiated before 9/27/07 and are "ongoing" as of 12/26/2007, which do involve a "serious or life threatening disease or condition," and are completed (meaning, not "ongoing") by 12/26/2007 are not subject to these requirements, though they may be subject to pre-existing registering requirements.

  ("Ongoing" in this context means a trial had one or more patients enrolled, but had not reached its "completion date," meaning, examined the final subject or provided the final subject an intervention for the purposes of final collection of data for the primary outcome as of 9/27/2007.)

Posting of Data:

The results from all clinical trials studying drugs, biologics, and devices not yet initially approved or cleared by the FDA must be submitted no later than 30 days after FDA-approval or clearance.

The results from all clinical trials studying FDA-approved drugs and biologics and FDA-approved or cleared devices must be submitted within 1 year of the study completion date.

Additional information can be found on the ClinicalTrials.gov website.

Emergency Use of Investigational Articles

Definitions:

Life-threatening, for the purposes of this policy and in conformity with FDA guidance, includes the scope of both life-threatening and severely debilitating, as defined below.

> **Life-threatening** means diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases of conditions with potentially fatal outcomes where the end point of clinical trial analysis is survival. The criteria for life-threatening do not require the condition to be immediately life-threatening or to immediately result in death. Rather, the subjects must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible.
>
> **Severely debilitating** means diseases or conditions that cause major irreversible morbidity. Examples of severely debilitating conditions include blindness, loss of arm, leg, hand, or foot, loss of hearing, paralysis, or stroke.

Federal regulations do not permit research activities to be started, even in an emergency, without prior IRB review and approval. The treating physician should contact the Director of HSA or the appropriate IRB Chairperson when an IRB Approval for Emergency Use is needed. When emergency medical care is initiated without prior IRB review and 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 research activity. When emergency care involves investigational drugs, devices, or biologics, U.S. Food and Drug Administration (FDA) requirements must be satisfied.

a. According to the FDA, each of the following conditions must exist to justify emergency use:
    i. The patient is in a life-threatening situation;
    ii. no standard acceptable alternative for treating the patient is available; and
    iii. there is not sufficient time to obtain IRB approval for the use.

b. The FDA expects the physician to follow as many subject protection procedures as possible. These include:
    i. obtaining an independent assessment by an uninvolved physician;
    ii. obtaining informed consent from the patient or a legal representative;
    iii. notifying the Director, HSA or the Chair of the CPHS; and
    iv. obtaining authorization from the IND or IDE holder, if possible.

c. According to the FDA, after an unapproved drug or device is used in an emergency, the physician should:
    i. report to the IRB within five days and otherwise comply with provisions of the IRB regulations;

ii. evaluate the likelihood of a similar need for the test article occurring again, and if future use is likely, immediately initiate efforts to obtain IRB approval and an approved IND/IDE for the test article's subsequent use; and
iii. if an IND/IDE for the use does exist, notify the sponsor of the emergency use, or if an IND/IDE does not exist, notify FDA of the emergency use and provide FDA with a written summary of the conditions constituting the emergency, subject protection measures, and results.

d. Nothing in these policies is intended to limit the authority of a physician to provide emergency medical care for patients who need such care. Rather, the use of information collected about that treatment for research purposes is prohibited.

Informed Consent Issues. A strictly limited exemption from the informed consent requirements exists for a class of research activities that may be carried out in human subjects who are in need of emergency therapy and for whom, because of the subject's medical condition and the unavailability of legally authorized representatives, no legally effective informed consent can be obtained.

Even for an emergency use, the investigator is required to obtain informed consent of the subject or the subject's legally authorized representative unless both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all the following:

a. The subject is confronted by a life-threatening situation necessitating the use of the test article.
b. Informed consent cannot be obtained because of an inability to communicate with, or obtain a legally effective consent form from the subject.
c. There is not sufficient time to obtain consent from the subject's legal representative.
d. No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.

If, in the investigator's opinion, immediate use of the test article is required to preserve the subject's life and if time is not sufficient to obtain an independent physician's determination that the four conditions above apply, the clinical investigator should make the determination and, within 5 working days after the use of the article, have the determination reviewed and evaluated in writing by a physician who is not participating in the clinical investigation.

Investigator Reporting of Emergency Use of Investigational Article to CPHS

The internal form titled: Emergency Use of an Investigational Article (Drug or Device) must be completed and received by the Office of Research Administration (ORA) no later than 5 days after the Emergency Use. If the sponsor/manufacturer will not ship the test article immediately for an emergency use situation, without an IRB acknowledgment letter from the IRB Chair, then this form must be completed and submitted to ORA before the use. The IRB Chair will review this form and any attachments and will provide a written statement that the IRB is aware of the proposed use and considers the use to meet the requirements of the FDA at 21 CFR 56.104(c). The Chair's concurrence should NOT be construed as IRB approval.

The investigator must notify the IRB within 5 working days after the use of the test article.

Ensuring Prompt Reporting of Any Serious or Continuing Noncompliance with 45 CFR Part 46 or the Requirements or Determinations of the IRB

All reports of any unanticipated problems involving risks to subjects or others must be investigated by the Director, HSA. The results of the investigation will be reported to the CPHS Chair, the Department Chairperson, the Director for the Office of Research Administration, and the Faculty Advisor, if appropriate. Regulatory authorities or sponsors may also be notified if appropriate. Such reports may come from any source including CPHS members, investigators, subjects, institutional personnel, the media, anonymous sources, or the public.

Instances of serious or continuing noncompliance with 45 CFR 46 or the requirements or determinations of the CPHS and any suspension or termination of IRB approval must be reported by the Associate Dean for Research Administration

a. to OHRP for studies funded by DHHS;
b. to the FDA for studies involving an IND held by NYMC faculty; and
c. to the Provost and to the Associate Dean for Research for all studies.

Between CPHS continuing reviews of a protocol and at the time of continuing review of a protocol, it is the Investigator's responsibility to keep the ORA informed of unexpected non-serious and serious adverse events and other unexpected *findings that affect the risk/benefit ratio of the research*. An investigator is responsible for the accurate documentation, investigation, and follow-up of all possible study-related adverse events. Investigators are also responsible for informing government and other sponsors of any unanticipated events, as appropriate.

The CPHS has the authority to suspend or terminate approval of research that is not being conducted in accordance with the CPHS Policies, is not in compliance with federal regulations, or has been associated with unexpected serious harm to subjects.

PEDIATRIC CENTRAL IRB (CIRB) STANDARD OPERATING PROCEDURES

Application

Multi-center Children's Oncology Group (COG) studies, approved by the Pediatric CIRB, and submitted by an NYMC investigator to the Office of Research Administration for Facilitated Review.

Overview

The Pediatric CIRB is sponsored by the National Cancer Institute (NCI), in consultation with the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP). The purpose of this national, centralized ethical review board is to facilitate a consolidated review and approval of multi-center COG studies. A complete description of this initiative may be accessed via the CIRB website: http://www.ncicirb.org/.

NYMC and Westchester County Healthcare Corporation have designated the NCI Pediatric CIRB under their respective Federalwide Assurances (FWAs), allowing the CIRB to become the IRB of record for COG studies. Additionally, an IRB Authorization Agreement between NYMC and the NCI Pediatric CIRB allows for a "facilitated review" process which provides the NYMC IRB an opportunity to decide, on a study-by-study basis, whether to accept CIRB review or to request that the convened NYMC IRB review the project.

The Pediatric CIRB Process

1. The Pediatric CIRB receives a completed application, protocol, informed consent form and related materials from the Cooperative Group via the NCI.
2. The convened Pediatric CIRB conducts initial review and approves the protocol.
3. The protocol is activated by the Cooperative Group and all review documents are posted on the CIRB website (www.ncicirb.org) for access by participating institutions.

Only CIRB-approved and activated NCI-Approved studies appear on the CIRB website.

Investigator Submission and Review Process

1. The investigator accesses their IRB User Account via the electronic IRB system to complete an application and upload relevant CIRB application documents and study materials.

2. The electronic IRB system will assign a unique study identification number to the study application.

3. The Investigator must designate the review type for CIRB studies as "Delegate to an external IRB".

4. The Investigator must upload the CIRB approval when received to the electronic IRB. The Investigator cannot commence with the research study until all other applicable approvals (e.g. Westchester Medical Center) are received.

Recordkeeping.

The ORA will maintain the electronic files. **Study updates, Amendments, Continuing Review**

Study Updates.

The investigator is responsible for submitting all CIRB review materials to the appropriate study file via the electronic IRB.

Amendments.

The investigator is responsible for uploading all CIRB approved amendments into the appropriate study file via the electronic IRB. If revisions to consent/assent forms have been made, the CIRB approved amended consent form must be placed onto the NYMC consent template.

Continuing Review.

The investigator is responsible for uploading all CIRB approved continuing review materials and scanning the approved NYMC informed consent/assent forms into the appropriate study file via the electronic IRB.

Investigator Request to Transfer Active Protocols to CIRB Review

An Investigator may request that an active NYMC IRB approved pediatric oncology studies be transferred over to CIRB's oversight. The Investigator should contact the Director of HSA or designee. The CIRB documentation requesting the transfer of the COG study to CIRB Review should be submitted to the IRB. The Director of HSA or designee will initiate and complete the transfer to CIRB Review in alignment with CIRB. The unique Study ID number will remain the same. The study will remain under the oversight of NYMC IRB until CIRB confirmation of the study transfer to CIRB Review. Documentation of the transfer must be submitted to the IRB.

The responsibilities of New York Medical College are to:

- Ensure the safe and appropriate performance of the research at NYMC. Provide a mechanism by which complaints about the research can be made by local study participants or others. Any actions taken as a result of problems that are identified in these areas will be shared with the CIRB and reported as required by the procedures established by the study's lead organization;
- Require that the investigators and other staff at NYMC who are conducting the research are appropriately qualified and meet NYMC's standards for eligibility to conduct research;
- Notify the CIRB immediately if there is a suspension or restriction of an NYMC investigator;
- Provide to the CIRB and keep current the names and addresses of NYMC contact persons who have authority to communicate for the local IRB;
- Establish a written procedure by which the local IRB will receive and review the CIRB materials for studies to be performed at the local institution;
- Report to the CIRB the decision about local acceptance/rejection of the CIRB review via the Facilitated Review Acceptance Form. Notify the CIRB if there is ever a change in the acceptance/rejection of the CIRB review;
- Add local restrictions, stipulations, or substitutions to CIRB approved informed consents. Deletion of CIRB approved requirements in the protocol and informed consent form is not allowed, and substantive changes that affect the meaning of CIRB approved requirements are also not allowed;
- If the NYMC IRB accepts the CIRB approval of a study, maintain documentation of the decision and evidence that it has received and considered all CIRB material relevant to the study (the investigator's notification to the ORA, that the folder for a particular project is complete, shall be considered evidence that the local site has received all CIRB

documents related to the study).

- Maintain a local IRB whose membership satisfies the requirements of 45 CFR 46 and 21 CRF 56;
- Maintain a human subjects protection program as required by the DHHS OHRP;
- Ensure that NYMC IRB members and local investigators receive proper initial and continuing education on the requirements related to human subjects protections;
- Notify the CIRB immediately if there is ever a suspension or restriction of the local IRB's authorization to review studies; and
- Maintain compliance with any additional state, local, or institutional requirements related to the protection of human subjects.

The responsibilities of the CIRB are to:

- Perform initial reviews of new research studies, discuss any issues with the lead organization and Study Chair, and make a final decision of approval or disapproval of the study;
- Maintain and make accessible to the NYMC IRB the CIRB application, protocol reviews, letters to Study Chairs, approvals and disapprovals, and minutes of the CIRB meetings;
- Carry out Continuing Reviews, reviews of submitted Serious Adverse Events, reviews of protocol amendments, reviews of DSMB reports, and reviews of any other documents submitted by the lead organization or Study Chair;
- Notify each local institution that has accepted the CIRB review of any new materials that have been reviewed for an active study and any changes in the study approval status;
- Maintain a Board membership that satisfies the requirements of 45 CFR 46, 21 CRF 56 and provide special expertise as needed from Board members or consultants to adequately assess all aspects of each study;
- Make available to the NYMC IRB the roster of CIRB membership and the CIRB Standard Operating Procedures and policies;
- Provide CIRB members with proper initial and continuing education on topics relevant to human subjects protections;
- Notify NYMC immediately if there is ever a suspension or restriction of the CIRB's authorization to review studies; and
- Notify the local institution of any CIRB policy decisions or regulatory matters that might affect NYMC's reliance on CIRB reviews or performance of the research at the local institution.

The National Institutes of Health (NIH) Single IRBs (sIRB) Policy

The National Institutes of Health (NIH) issued this policy effective January 25, 2018 on the use of a single Institutional Review Board (IRB) for multi-site research to establish the expectation that a single IRB (sIRB) of record will be used in the ethical review of non-exempt human subjects research protocols funded by the NIH that are carried out at more than one site in the United States.

The Principal Investigator should contact the Director of HSA to inform the IRB when (s)he will need to have their NIH funded study reviewed by a sIRB. This process usually involves an IRB Authorization Agreement that is reviewed by NYMC Office of General Counsel (OGC).

The IRB Authorization Agreement should be sent to the NYMC Contracts Coordinator for review by the OGC. Research on an NIH-funded study cannot be initiated without an executed IRB Authorization Agreement.

Relying on Commercial IRBs

NYMC will consider allowing investigators to utilize a commercial IRB for industry-sponsored, multi-center, clinical research studies if that is a requirement to participate as a site, and if the commercial IRB has been appointed by the Sponsor or Contract Research Organization and the commercial IRB has already approved the study.

The Principal Investigator should contact the Director of HSA to inform the IRB that (s)he would like to participate in a study reviewed using a commercial IRB as a requirement. This process usually involves an IRB Authorization Agreement that is reviewed by NYMC Office of General Counsel (OGC).

The IRB Authorization Agreement should be sent to the NYMC Contracts Coordinator for review by the OGC. Research cannot be initiated without an executed IRB Authorization Agreement.

SIGNATURE PAGE

The New York Medical College Policies and Procedures for the Conduct of Research Involving Human Subjects were adopted on August 9, 2004 and revised on April 18, 2019.

Prepared:

April 18, 2019
Date

Director, Human Subjects Administration

Approved:

April 30th, 2019
Date

Vice President for Research

Approved:

5/1/19
Date

Chancellor and Chief Executive Officer