

**NEW YORK CHIROPRACTIC COLLEGE**

**INSTITUTIONAL REVIEW BOARD**

**STANDARD OPERATING PROCEDURES**

**(IRB SOP)**

Version 2 - Effective September 1, 2011

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Appendix A: Important Definitions

Appendix B: Example Scenarios of Unanticipated Problems Involving Risks to Subjects or Others

## 1) Office of Human Research Protections (OHRP)

- a) The Office of Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and well-being of subjects involved in research conducted or supported by the US Department of Health and Human Services (DHHS). OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and behavioral research.
- b) OHRP's Division of Policy and Assurances prepares policies and guidance documents and interpretations of requirements for human subject protections and disseminates this information to the research community. This Division also administers the assurances of compliance.
- c) As a registered IRB with OHRP, NYCC has an OHRP-approved assurance of compliance with the DHHS regulations ([45 CFR 46.103](#)) for the protection of human subjects. As such, NYCC must be compliant with policies, regulatory and guidance documents from OHRP ([OHRP Home Page](#)).
- d) Institutional Review Board (IRB) Registration:
  - i) IRB registration must be renewed periodically through OHRP DHHS. The registration must be renewed by the scheduled expiration date or when there have been significant changes to the IRB (i.e. multiple changes in membership or a change in chairperson). The IRB Registration paperwork will be kept on file in the Research Office. Past Registration paperwork will remain on file for a period of ten (10) years.
  - ii) NYCC will review its IRB registration upon change of membership and/or every six (6) months in January and July.
- e) Federal Wide Assurance (FWA):
  - i) The IRB will obtain and maintain FWA through OHRP as outlined in [45 CFR 46.103](#). The FWA acceptance and FWA number will be kept on file in the Research Office. Past FWA paperwork will remain on file for a period of ten (10) years.
  - ii) When NYCC reviews its IRB registration it will also confirm FWA has not expired.
- f) Reporting Incidents to OHRP:
  - i) DHHS regulations at [45 CFR 46.103\(a\) and \(b\)\(5\)](#) require that institutions have written procedures to ensure that the following incidents related to research conducted under an OHRP-approved assurance are promptly reported to OHRP:
    - (1) Any unanticipated problems involving risks to subjects or others
    - (2) Serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and
    - (3) Any suspension or termination of IRB approval
  - ii) IRB will follow the decision chart in the document entitled "[Guidance on Reporting Incidents to OHRP](#)" for determining what incidents should be reported to OHRP.
  - iii) Guidance on Reporting Incidents to OHRP specify the information to be included in an incident report submitted to OHRP related to issues identified above in [section 1\(f\)\(i\)](#).
    - (1) The IRB Administrator in collaboration with the IRB Administration Assistant and IRB Chairperson will collect the appropriate information to complete the incident reports to OHRP.

- iv) Time Frame for Reporting Incidents
  - (1) See [Section 7\(n\)](#) for the time frame investigators must follow for reporting incidents of adverse events to the IRB.
  - (2) See [Section 8\(j\)](#) for the time frame the IRB must follow for reporting incidents of noncompliance to OHRP
  - (3) See [Section 9\(h\)](#) for the time frame the IRB must follow for reporting suspension or termination of protocols to OHRP.

## 2) Other Relevant Authorities

- a) Other Federal Laws/Regulations:
  - i) The IRB will refer to and abide by [45 CFR 46](#): Protection of Human Subjects
  - ii) The IRB will refer to and abide by the [Belmont Report](#): Ethical Principles and Guidelines for the Protection of Human Subjects of Research
  - iii) For questions and clarifications, the IRB may refer to the [OHRP](#) and/or the [DHHS](#).
- b) State and Local Laws/Regulations:
  - i) N/A
- c) Foreign Laws/Regulations/Regulatory Standards:
  - i) N/A
- d) Other
  - i) Institutional Commitments and policies:
    - (1) N/A
  - ii) Funding Entities:
    - (1) Primary Investigator needs to complete Human Subjects Information according to funding opportunity guidelines.
    - (2) The IRB Administrator will compare the grant application with the IRB application for discrepancies prior to submission of the application to IRB review.

## 3) IRB Standing Committee

- a) The IRB Standing Committee consists of NYCC and community representatives, both scientists and non-scientists. Members are chosen by the IRB Administrator and/or IRB Chairperson. The IRB must consist of:
  - i) At least 5 members
  - ii) Both genders
  - iii) Variety of professions/experience
  - iv) At least one non-scientist
  - v) At least one scientist
  - vi) At least one member of the community (non NYCC-affiliated)
- b) Methods for ensuring IRB knowledge of local research context

- i) See the Division of Human Subjects Protection memo regarding Knowledge of Local Research Context: <http://www.hhs.gov/ohrp/policy/local.html>
- ii) Members of the IRB must consist of at least one community member not affiliated with the college, and at least one non-scientist representative. Other members should come from the various departments within the college to ensure a knowledgeable representative on the board for any type of protocol encountered.
  - (1) The IRB Board members may invite an “expert” to their review meetings if their membership does not reflect expertise in a given area addressed by a protocol application.
- c) Terms for IRB Members:
  - i) The IRB Chairperson may serve up to three (3) consecutive 3-year terms.
    - (1) Re-appointment may occur after one (1) 3-year term break.
  - ii) IRB committee members may serve unlimited consecutive 3-year terms.
    - (1) Re-appointment may occur by members previously on the board without a mandatory term break.
- d) IRB member responsibilities:
  - i) All IRB members are responsible for reviewing each protocol they receive. They must use their background and experience to determine if the protocol is ethical, viable, equitable, and has an acceptable benefit: risk ratio. (See Section e below)
  - ii) Members are responsible for determining the readability and understandability of Informed Consent documents.
  - iii) Members are responsible for bringing up any concerns or questions regarding the protocol to the PI or his/her representative at the meeting.
  - iv) Members must recuse themselves from the meeting and subsequent vote if they feel they have a conflict of interest with the submitted protocol.
  - v) Members must attend, send an alternate in their place, or send their comments to a convened IRB meeting. Written comments sent prior to the meeting in lieu of attendance do not count towards the member’s attendance for the year. In addition, although the comments are of great value and will be taken under consideration at the meeting, the written comments will not count towards quorum or voting outcomes.
  - vi) Members must watch/review the IRB training videos at the beginning of their term and at their reappointment every 3 years.
  - vii) Members will occasionally be asked to review an expedited or continuing review, and must submit their comments/concerns/questions to the IRB Chairperson and Administrative Assistant in a timely fashion (within two (2) weeks of receipt or as otherwise required).
- e) The IRB Standing Committee operates under the three major ethical principles set down in the Belmont Report (1979):
  - i) Respect for persons (consent, privacy, confidentiality)
  - ii) Beneficence (benefits vs. risks)
  - iii) Justice (equity)
- f) By majority vote, the IRB may:

- i) Approve, disapprove, or make recommendations for revisions to protocols
  - ii) Conduct continuing review of all approved research studies
  - iii) Approve or disapprove Amendment requests for change in protocol ([Section 6](#))
  - iv) Approve the observation of data collection and/or the Informed Consent process by the IRB membership or another appropriate oversight committee or individual.
  - v) Determination of unanticipated problems involving risks of subjects or others. ([Section 7](#))
  - vi) Determination of serious or continuing noncompliance with this policy or the requirements or determinations of the IRB ([Section 8](#))
  - vii) Suspend or terminate IRB approval ([Section 9](#)).
- g) The IRB Standing Committee meets on the first Friday of every month at 1:00 p.m. Exceptions include:
- i) When the first Friday of the month falls on a day outside of NYCC's trimester rotation or on a recognized holiday. In this case the next available Friday will be substituted.
  - ii) When there are no new protocols for the committee to review. The committee will be made aware of the submission of new protocols, and therefore whether or not the scheduled meeting will occur, within two (2) weeks of the scheduled meeting date by the IRB Administrative Assistant.
- h) IRB Meeting Attendance:
- i) All IRB members are expected to attend each scheduled IRB meeting. Attendance will be taken at each meeting and the minutes will reflect present and absent members. Alternate members may stand in for a committee member, without any attendance repercussions. Members who miss more than ½ of the convened meetings in one year without assigning an alternate may forfeit their position on the IRB. Alternate members must have comparable skills and experience as the member(s) they are replacing.
- i) Conflicts of Interest:
- i) Each IRB member is responsible for recognizing if they have a conflict of interest with a submitted protocol. Conflicts of interest may result from:
    - (1) The possibility of personal, professional or financial gain or loss from the success or failure of a protocol
    - (2) A personal relationship with the Investigator or member of the study team which may sway the member's vote
    - (3) A religious, personal, or political belief addressed by the protocol
    - (4) Other reasons which may sway the member's vote.
  - ii) Any IRB member who feels they have a conflict of interest should recuse themselves from the IRB proceedings and any subsequent vote relating to the protocol. The conflicted member may ask an alternate to sit in their place if available. If quorum is broken by the recusal of the conflicted member, a vote may not take place. Recused members may not take part in any future action regarding the protocol (i.e. amendments, continuation reviews, etc.).
- j) Documentation of IRB membership. ([Section 19\(d\)](#))

#### **4) Procedures IRB will follow for conducting initial review of research (OHRP Required Element 1)**

- a) Initial applications for research studies may be processed in 3 ways:
  - i) Convened IRB meeting
  - ii) Expedited IRB review (Chair plus 1 scientist and 1 non-scientist)
  - iii) Exempt certification (Chair, IRB Administrator and Administrative Assistant)
  - iv) Any requests for Expedited Review or Exemption made by the investigator will be reviewed by the IRB Administrator and Chairperson to verify and document that the request meets the criteria for Expedited Review or Exemption
- b) Documents received and distributed for convened and expedited review:
  - i) All [documents may be downloaded from NYCC's Webpage](#) or obtained through the IRB Administrative Assistant.
  - ii) Application:
    - (1) Each application requires an [IRB General Information Form](#). This is a fill-in form.
  - iii) Protocol:
    - (1) Each application must address all 15 sections of the [Research Description Form](#).
  - iv) Informed Consent:
    - (1) If required, Informed Consent documents must follow the [Informed Consent fill-in Form](#).
  - v) Other Necessary Documents:
    - (1) A signed [IRB Submission Checklist](#) that lists all required documents and supplemental documents, and verifies current educational certifications must be included in the application package.
      - (a) Signatures on the IRB Submission Checklist are required from all investigators listed in the application and the IRB Administrator.
    - (2) [Signature Assurance Sheets](#) and IRB Submission Checklist with appropriate signatures are necessary before IRB applications may be reviewed.
  - vi) Recruitment and Data Collection Materials:
    - (1) Within the [Research Description Form](#), accurate recruitment strategies and data collection procedures must be provided.
    - (2) Any materials the investigator plans to use to recruit subjects or as data collection sheets within the study must accompany the application package.
- c) Criteria for IRB review, findings, and determinations
  - i) Criteria for approval :
    - (1) The IRB must follow [45 CFR 46.111](#) "Criteria for IRB approval of research" in approving research. [45 CFR 46.111](#) outlines the following requirements:
      - (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 for each prospective subject

- (e) Informed Consent will be appropriately documented, in accordance with, and to the extent required by 45 [CFR 46.117](#)
  - (f) Research Description makes adequate provision for monitoring the data collected to ensure the safety of subjects ([Section 7cv](#)).
  - (g) Safeguards are in place to protect the rights and welfare of vulnerable subject populations. [45 CFR 46.111.7](#)
- ii) Informed Consent considerations
- (1) The IRB must follow 45 [CFR 46.116](#), [408](#), [401](#), [117](#)
    - (a) [46.116](#): “General requirements for Informed Consent”
    - (b) [46.408](#): “Requirements for permission by parents or guardians and for assent by children”
      - (i) [46.401](#): “Additional protections for children involved as subjects in research: To what do these regulations apply?”
    - (c) [46.117](#): “Documentation of Informed Consent”
- d) Method of Review/Reviewer Process
- i) Convened IRB Review
- (1) All applications must include all pertinent documents from the IRB Application package.
  - (2) Applications that do not qualify for expedited review or exemption will be reviewed by a Convened, IRB meeting
  - (3) All new applications for Convened review must be submitted to the IRB Administrative Assistant within 2 weeks of the next scheduled IRB meeting. Applications deemed incomplete will be returned to the Investigator. If submitted later than 2 weeks, the application will be put on the agenda for the following month’s meeting.
  - (4) The IRB Administrative Assistant will distribute all materials to IRB members via email or postal mail upon receipt, thereby confirming the upcoming meeting.
  - (5) If no applications are received, the meeting will be cancelled. The IRB members will be notified of the cancellation by email or phone call from the Administrative Assistant.
  - (6) All IRB members are responsible for reviewing the application and attending the meeting ready to discuss any questions or concerns regarding the protocol and informed consent. The Primary Investigator, Co-Investigator or representative is encouraged to attend the meeting.
  - (7) At the meeting, the committee will review the application section-by-section, asking questions of the Investigator or representative for clarification. Once the protocol has been reviewed, the Investigator or representative will be asked to leave the room. The IRB members will then discuss the protocol and vote to approve, disapprove, or approve pending changes.
    - (a) In order to vote on any protocol application, quorum must be met: the majority of IRB members including at least 1 non-scientist and at least 1 community member must be present at the meeting, either in person or via conference line. If quorum is not met (or broken by a member leaving the meeting), no action may be taken.
    - (b) The IRB may approve research by majority vote.

- (c) The IRB may approve research pending required, discussed changes.
  - (d) The IRB may disapprove research by majority vote.
- (8) Communication of action to the Investigator, all IRB members, and IRB administration
- (a) Once approval is obtained, an Initial Approval Letter will be drafted by the IRB Administrative Assistant, signed by the IRB Chairperson, and distributed to the Investigator, along with Informed Consent documents with a dated IRB approval stamp.
  - (b) If approval is granted pending changes, a letter with the summary of changes and action steps to be completed will be distributed to the Investigator. The Investigator will have 30 days to return the protocol with changes, at which point the IRB Chair and Administrative Assistant will review the changes for accuracy and distribute an Initial Approval Letter.
  - (c) If the IRB disapproves the protocol, the Investigator may resubmit a new full application, if desired, with substantial changes that would address the IRB's concerns. A letter of disapproval will be distributed to the Investigator with the reasons for the disapproval.
- (9) Protocol information will be updated by the IRB Administrative Assistant in the Protocol Listing Database.
- ii) Expedited Review
- (1) All applications must include all pertinent documents from the IRB Full Application packet.
  - (2) Research protocols qualify for expedited review only if: ([45 CFR 46.110](#))
    - (a) The research involves no more than minimal risk.
      - (i) Examples may include any of the following:
        1. Collection of hair and nail clippings in a non-disfiguring manner; deciduous teeth and permanent teeth if patient care indicates need for extraction.
        2. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, amniotic fluid at time of rupture prior to or during labor.
        3. Recording of data from subjects 18 or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, etc. It does not include exposure to electromagnetic radiation outside the visible range (x-rays, microwaves).
        4. Collection of both supra-and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
        5. Voice recordings made for research purposes such as investigations of speech defects

6. Moderate exercise by healthy volunteers
  7. Research on individual or group behavior or characteristics of individuals such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve subject stress.
  8. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.
  9. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
- (b) Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.
- (3) [Categories of Research](#) that may be reviewed by the IRB through an expedited review procedure: ([Link to OHRP Categories](#))
- (a) Categories of Research that may receive an Expedited Review (Categories 1-7 pertain to both initial and continuing IRB review)
    1. Clinical studies of drugs and medical devices only when:
      - a. Research on drugs for which an investigational new drug application ([21 CFR Part 312](#)) is not required OR
      - b. Research on medical devices for which (1) an investigational device exemption application ([21 CFR Part 812](#)) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
    2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
      - a. From healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, 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.
      - b. From other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, 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.
    3. Prospective collection of biological specimens for research purposes by noninvasive means.
    4. Collection of data through noninvasive procedures (not including 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.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: some research in this category may be exempt from the HHS regulations for the protection of human participants [45 CFR 46.101\(b\)\(4\)](#)). This listing refers only to research that is not exempt).
6. Collection of data from voice, video, digital or image recordings made for research purposes.
7. Research on individual or group characteristics of 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 HHS regulations for the protection of human participants [45 CFR 46.101\(b\)\(2\)](#) and [\(b\)\(3\)](#)). This listing refers only to research that is not exempt)
8. Continuing review of research previously approved by the convened IRB as follows:
  - a. Where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants
  - b. Where no participants have been enrolled and no additional risks have been identified
  - c. Where the remaining research activities are limited to data analysis
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories 2 through 8 do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

(4) Assignment of Reviewers: [\(45 CFR 46.110\(b\)\)](#)

- (a) Expedited review applications will be reviewed by the IRB Chairperson as well as two additional IRB members (one non-scientist and one scientist). Members will be chosen at random based on availability and/or expertise by the IRB Administrator or IRB Chair.
- (b) In the case of an Amendment submitted for Expedited Review, if the Amendment includes only minor changes to the protocol and does not increase the risk to the safety and welfare of the subjects, the Amendment may be reviewed and approved by the IRB Administrator or IRB Chairperson in lieu of a 3-person review stated in (a) above.

(5) Documents distributed for review:

- (a) All required documents ([Section 4\(b\)](#)) should be sent to the IRB Administrative Assistant. The Administrative Assistant will distribute the documents to the IRB Chairperson and 2 designated members via email or postal mail.

(6) Range of possible actions by IRB:

- (a) Approve Research
  - (i) The expedited protocol is approved if the majority of members vote to approve the research.
- (b) Require modifications in order to secure approval (Conditional Approval)
  - (i) The IRB may approve the research pending required, discussed changes with a majority vote
- (c) Disapprove research
  - (i) Protocols cannot be disapproved by the expedited review process. If the IRB members assigned to the expedited protocol do not approve the research, the application must be sent to a Convened IRB Review.

(7) Communication of action to Investigator, all IRB members, and IRB Administration:

- (a) After review, the IRB Chair and two members will confirm via email or in writing of their approval of the expedited protocol to the IRB Administrative Assistant and each other.
- (b) Once approval has been obtained, an Initial Approval Letter will be drafted, signed by the IRB Chair, and distributed to the Investigator along with stamped Informed Consent documents.
- (c) If approval is granted pending changes, a letter with the summary of changes and actions steps to be completed will be drafted, signed by the IRB Chair and distributed to the Investigator. The Investigator will have 30 days to return the protocol with the changes, at which point the IRB Chair and Administrative Assistant will review changes for accuracy and distribute an Initial Approval Letter.
- (d) Other IRB members will be notified of the approval at the next convened IRB meeting.
  - (i) At each convened IRB meeting, the IRB Administrative Assistant will distribute all IRB actions that have taken place since the last convened meeting.

(8) The Protocol Listing Database will be updated with the approval date and expiration of the protocol.

iii) Exemption Status

(1) Criteria for Exemption Status:

- (a) Protocols may be exempt from the IRB review if they meet one or more of the criteria outlined in [45 CFR 46.101.b.1-6](#).
- (b) Exemption does not apply when the research activities include:
  - (i) Prisoners, fetuses, pregnant women or human in vitro fertilization
  - (ii) The review of medical records if the information is recorded in such a way that subjects can be identified, directly or through identifiers linked to the subjects.
  - (iii) Survey or interview techniques which include minors as subjects
  - (iv) Research involving the observation of the public behavior of minors

- (v) Techniques which expose the subject to discomfort or harassment beyond levels encountered in daily life.
  - (vi) The deception of the subjects
- (2) Application materials
- (a) Investigators must submit to the IRB a letter addressing the 15 sections of the Research Description as found as part of the IRB application package. The Investigator needs to indicate within the study design (Section 5 of the Research Description) why this study is exempt from IRB review citing the applicable Section from 45 CFR 46.
- (3) Method of Review
- (i) Exempt protocols are reviewed by the IRB Chair, IRB Administrator and IRB Administrative Assistant.
- (4) Notification to Investigator
- (a) If the review process determines that the project qualifies for the exemption status, a letter stating such will be sent to the Investigator.
- (5) Exempt protocols will be assigned an IRB number and kept in IRB files. Investigators must still submit Continuation Reports and Final Report as necessary.
- (6) If any changes to an exempted protocol should occur, the IRB must be notified, and the protocol may no longer qualify as exempt, necessitating a Convened or Expedited review.
- iv) Case Reports
- (1) Case Reports are prepared for the purpose of illustrating some points in the care of a patient, to educate and formulate new research questions which may eventually lead to generalizable knowledge.
  - (2) Many journals now require a letter, or other acknowledgement, from an IRB prior to publication of a case report. Specifically, they wish to know whether IRB approval was obtained or was not required for the described case.
  - (3) A case report is a medical/educational activity that does not meet the DHHS definition of “research” which is: “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”
  - (4) Case reports do not fall under the [45 CFR 46.102.d](#) definitions of research, and do not require IRB review.
  - (5) A case report for IRB purposes is an analysis of one, two, or three clinical cases. If more than three cases are involved in the analytical activity, the activity will constitute “research”.
  - (6) Investigators wishing to conduct case reports must contact the IRB Administrator, IRB Chairperson, or IRB Administrative Assistant to determine if their study qualifies as “research”. The Investigator must complete a [Case Report Form](#) as part of the process to determine if the study qualifies as research.
  - (7) Under the Health Insurance Portability and Accountability Act (HIPAA), a case report is an activity to develop information to be shared for medical/educational purposes. Although the use of protected health information to prepare the paper does not require

IRB review, the author of a case report must comply with HIPAA. Ideally, the author of the article will obtain the signed authorization of the subject, or the subject's legally authorized representative if the subject is deceased, to use the subject's information in the article. If it is not possible to obtain authorization, the author should be aware that one of the identifiers described by HIPAA as requiring written authorization is "Any other unique identifying number, characteristic, or code..." Moreover, HIPAA requires that, at the time of publication, "the covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information."

- (a) Authors who remove HIPAA identifiers (including unique patient characteristics) from the data prior to submission and publication of the article do not need to obtain a signed privacy authorization.
- (b) Investigators who wish to publish case report data with HIPAA identifiers will need to obtain from the patient a signed HIPAA compliant authorization.
- (c) If the author strips off all HIPAA identifiers, but the information associated with the subject of the article includes a "unique characteristic" which would make it identifiable to the subject, or the author has actual knowledge that the information about the subject could be used alone or in combination with other information to identify the subject, the author must obtain a signed HIPAA compliance authorization from the patient.

e) Further review by institution

i) Responsible party

(1) N/A

ii) Institutional policies relevant to review

(1) N/A

iii) Actions that may be taken by institution

(1) N/A

f) Mechanisms for ensuring no changes in research

i) All protocols and data records are subject to audit by the IRB at any time.

ii) All investigators are bound by the Researchers Responsibilities to ensure notification of any changes to the IRB

iii) At any time, members of the IRB, the IRB Administrator, Administrative Assistant, and other representative officials may request to participate in the data collection process and/or Informed Consent process with the investigators and subjects.

iv) Refer to [Section 6a](#), Steps to ensure approval of all changes in research activities by IRB review.

## 5) Informed Consent Process

a) Documentation of Informed Consent

i) According to the federal guidelines, the three necessary elements of the informed consent process are:

- (1) Full disclosure of the nature of the research and the subject's participation. This involves 8 basic elements:
  - (a) Description of the research (purpose, duration, procedures);
  - (b) Risks;
  - (c) Benefits;
  - (d) Alternatives;
  - (e) Confidentiality;
  - (f) Compensation for injury;
  - (g) Whom to contact;
  - (h) Right to withdraw or refuse.
- (2) Additional elements include:
  - (a) Risks related to pregnancy;
  - (b) Anticipated reasons for termination from the study;
  - (c) Costs;
  - (d) Consequences of withdrawal;
  - (e) New findings;
  - (f) Number of subjects.
- (3) Adequate comprehension on the part of the potential subjects:
  - (a) Informed consent is not valid unless the consentor understands the information that has been provided. The investigator must consider the nature of the proposed subject population, the type of information to be conveyed, and the circumstances under which the consent process will take place in determining the appropriate way to present the information.
- (4) The subject's voluntary choice to participate:
  - (a) In order to be valid, consent must be freely given, without any form of coercion. In addition to overt forms of coercion, the investigator needs to be sensitive to more subtle forms of coercion, such as social pressure, requests from authority figures, and undue incentive for participation.
- ii) Documentation of "legally effective informed consent" usually involves the use of a written consent form signed by the subject or the subject's legal representative. Again, the consent form is merely the documentation of informed consent, and does not, in itself, constitute informed consent. The fact that a subject signed a consent form does not mean that s/he understood what was being agreed to or truly gave his/her voluntary consent. It must be emphasized that the consent document does not substitute for discussion with the potential subjects/participants.
- iii) OHRP recommends that consent forms meet the following four criteria:
  - (1) Be brief, but have complete basic information
  - (2) Be readable and understandable to most people
  - (3) Be in a format that helps people comprehend and remember the information

- (4) Serve as a script for the face to face discussions with the potential subjects/participants.
  - iv) An Informed Consent template is available on NYCC online and through the Research Department.
  - v) Documentation of Informed Consent is required for each subject enrolled in the study. If informed consent cannot be obtained, the investigator must apply for a waiver of informed consent. See [Section 5\(d\)](#) below for more detailed information on this process.
- b) Methods of Monitoring the Informed Consent Process
- i) The wording from the provided Informed Consent template should not be changed but the investigator can add to the language where appropriate.
  - ii) The investigator needs to delete all sections of the Informed Consent template that do not apply to the research.
  - iii) Informed Consent forms should be written at a 6<sup>th</sup> grade reading level with an easy to follow format (i.e. plenty of white space, appropriate font size, lists of information, etc.)
  - iv) Informed Consent form must be provided to subjects at least 24 hours prior to their participation in the study.
    - (1) If obtaining Informed Consent in less than 24 hours will not produce an increased risk to the subjects, than the 24 hour requirement can be waived by the IRB.
    - (2) However, the subject must have the freedom to read the Informed Consent at their leisure.
  - v) The IRB requires that the approval and expiration dates be affixed to all approved Informed Consent documents and stipulate that copies of these dated documents must be used in obtaining consent. This procedure is recommended by OHRP because it helps ensure that only the current, IRB-approved informed consent documents are presented to subjects and serves as a reminder to the investigators of the need for continuation review.
  - vi) The investigator is responsible for reviewing the Informed Consent form with the subject.
    - (1) Before participation, the subject must have the opportunity for a discussion with the investigator or his/her representative regarding the subject's participation.
    - (2) The investigator is responsible for the process of ensuring subjects understand what will happen during the study and the risks and benefits that they may receive.
    - (3) The investigator is responsible for the documentation of Informed Consent – the ability to produce the signed copy of the Informed Consent form.
  - vii) The IRB's role in monitoring Informed Consent process:
    - (1) The IRB will initially review and approve the Informed Consent form
    - (2) The IRB Administrative Assistant will continually review approved research with respect to their expiration date and provide the investigator with the continuing review application ([See Section 10](#)) prior to the expiration date.
    - (3) At each Continuation Review, the Investigator must supply the two most recently signed Informed Consent documents. The IRB will review to ensure there have been no changes to the Informed Consent since the last approval.
    - (4) Members of the IRB, the IRB Administrator and Administrative Assistant must have access to the Investigator's files related to their protocol for audit at any time.

- (5) At any time, members of the IRB, the IRB Administrator, the IRB Administrative Assistant and other representative officials may request to participate in the Informed Consent process with the Investigator and the subjects.
- viii) If the RESEARCH ACTIVITIES ARE DIRECTED TOWARD PREGNANT WOMEN, the IRB will follow [subpart B](#) of the federal guidelines for rules as to whether the mother and/or father must give consent after having been fully informed regarding the impact on the fetus. For children as defined in [45 CFR 46.402\(a\)](#) who are pregnant, assent and permission are obtained in accord with the provisions of [subpart D](#). The IRB will follow subpart B of the federal regulations for the additional protections for research involving pregnant women.
- ix) If the RESEARCH ACTIVITIES ARE DIRECTED TOWARD PRISONERS, the IRB will follow [subpart C](#) of the federal regulations for the additional protections for research involving prisoners as subjects.
- c) Description of Requirements for Research Involving Children.
- i) Federal regulations ([15 CFR 45, Subpart D](#)) require additional protections for research involving children because they are considered a vulnerable research population as persons who have not attained the legal age for consent in the jurisdiction in which the research will be conducted ([45 CFR 46.402\(d\)](#)).
- ii) Whenever feasible, appropriate studies should be conducted on adults and older children before young children are involved as research subjects.
- iii) The IRB is required to consider the degree of risk inherent in the proposed research and the methods for obtaining the assent of the children as well as the permission of parents or legal guardians. The IRB must find that the activity represents one of four permissible categories of research ([45 CFR 46.404-407](#)), and that adequate provisions are made for soliciting the assent of the children and the permission of each child's parents or guardian. ([45 CFR 46.408](#)).
- iv) The IRB's policy with respect to obtaining consent from the parents or legal guardians and assent from minors is specified below:
- (1) Parental consent must be obtained if the research involves minors under the age of 18.
- (2) Minor subjects/participants 6 years of age or older should be involved in the decision to participate in a research project.
- (3) Documentation of assent is required for subjects aged 7-17.
- (a) In most cases, a written Assent Form should be used to document assent.
- (b) A copy of the assent form must be submitted to the IRB for review.
- (c) The form should include a simplified version of the elements of informed consent with a template available from the Research Department.
- (d) Note that the child should be given an explanation, at a level appropriate to the child's age, maturity and condition, of the procedures to be used, their meaning to the child in terms of discomfort and inconvenience, and the general purpose of the research.
- (e) Refer to General Guidelines for Developing Assent forms – available through the Research Department.
- (4) [Section 15\(d\)](#) contains the specific procedures for conducting research with children involved as subjects.

d) Waiver of Informed Consent

- i) Under the federal guidelines ([45 CFR 46.116](#)), the IRB can approve study procedures that involve the waiver of informed consent if the following conditions are satisfied:
  - (1) The research involves no more than minimal risk to the subjects;
  - (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
  - (3) The research could not practicably be carried out without the waiver or alteration; and
  - (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- ii) There is no such process as “implied consent”. If written informed consent is not possible, an investigator must apply to the IRB for a waiver of this requirement.
- iii) Under [45 CFR 46.117](#), an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
  - (1) 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. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; or
  - (2) 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.
  - (3) In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

**6) Procedures for ensuring prompt reporting to the IRB of proposed changes in a research activity and ensuring that such changes in approved research may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject. (OHRP Required Element 6)**

a) Steps to ensure approval of all changes in research activities by IRB review

- i) Each investigator will receive the Researcher’s Responsibilities Form upon initial approval of their IRB application.
- ii) The Principal Investigator must sign two copies, retain one copy for their records, and return a copy to the IRB as written record of their understanding of Researchers’ Responsibilities.
  - (1) Signed copies will be kept with the IRB file in the Research Department Main Office.
- iii) Researchers’ Responsibilities include the prompt reporting of all proposed changes in research activities for IRB review and approval before initiating any proposed changes.
  - (1) Part of the Researchers’ Responsibilities and training is the knowledge that investigators must submit requested changes to the IRB via an Amendment Form prior to initiating any proposed changes.
- iv) The IRB will rely on after-the-fact reporting from study personnel, subjects, representatives of the subject, the continuing review process and/or the institution to randomly audit research protocols to ensure that all research activities are being conducted in accordance with IRB approval.

b) Process for filing the Amendment form

- i) The Investigator may request the Amendment form from the IRB Administrative Assistant. The form is also available on NYCC online.
  - ii) Submit the completed form to the IRB Administrative Assistant to initiate the expedited review process ([See Section 4\(d\)\(ii\)](#))
  - iii) The HHS protection of human subjects regulations allow for expedited review and approval of requests for minor changes in previously approved studies. ([45 CFR 46.110\(b\)\(2\)](#)).
  - iv) Approval of the Amendment request will follow the guidelines in [Section 4\(d\)\(ii\)](#) on Expedited Review.
  - v) Disapproval of the Amendment request will result in a Convened IRB Review. Review and notification guidelines are outlined in [Section 4\(d\)](#).
- c) Research conducted without IRB Approval of Proposed Changes
- i) Changes in protocol that are not approved or occur prior to approval through the Amendment Process are noncompliant with 45 CFR 46.
  - ii) Refer to [Section 8](#) for handling allegations of noncompliance by the IRB with OHRP.
- d) Exception: eliminate apparent immediate hazards to subjects
- i) If the investigators change the research in order to eliminate apparent immediate hazards to subjects without prior IRB approval, they should report those changes promptly to the IRB using the [Adverse Event Form](#)
  - ii) Refer to [Section 7](#) for reporting Adverse Events.

**7) Procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, the Department or Agency head, and OHRP of any unanticipated problems involving risks to subjects or others. (OHRP Required Element 7)**

- a) Guidance for [OHRP - Adverse Event Reporting](#)
- b) Definitions
  - i) **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.
  - ii) **Serious adverse event:** Any event temporally associated with the subject's participation in research that meets any of the following criteria:
    - (1) results in death;
    - (2) is life threatening (places the subject at immediate risk of death from the event as it occurred);
    - (3) requires inpatient hospitalization or prolongation of existing hospitalization;
    - (4) results in a persistent or significant disability/incapacity;
    - (5) results in a congenital anomaly/birth defect; or
    - (6) any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the outcomes listed above (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).

- iii) Non-serious adverse event: Any event that does not meet the definition of a serious adverse event
  - iv) Anticipated adverse event: These are risks or events reported in the Investigator's Brochure and listed in the informed consent form. The IRB will consider an adverse event as "anticipated" or "expected" only if it is discussed in the protocol and included in the Informed Consent document.
  - v) Unanticipated 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:
    - (1) 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
    - (2) 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.
  - vi) Possibly related to the research: There is a *reasonable possibility* that the adverse event, incident, experience or outcome may have been caused by the procedures involved in the research. A *reasonable possibility* is defined as more likely than not related to the research procedures or, in other words, there is a > 50% likelihood of the event having been caused by the procedures involved in the research.
  - vii) Internal adverse event: From the perspective of one particular institution engaged in a multicenter clinical trial, *internal adverse events* are those adverse events experienced by subjects enrolled by the investigator(s) at that institution. In the context of a single-center clinical trial, all adverse events would be considered *internal adverse events*
  - viii) External adverse event: From the perspective of one particular institution engaged in a multicenter clinical trial, *external adverse events* are those adverse events experienced by subjects enrolled by investigator(s) at other institutions engaged in the clinical trial.
- c) Data Safety Monitoring Plan (DSMP)
- i) Before research is approved and the first subject enrolled, the Investigator(s) and the IRB should give appropriate consideration to the spectrum of adverse events that might occur in subjects.
  - ii) In particular, in order to make the determinations required for approval of research under HHS regulations at [45 CFR 46.111\(a\)\(1\), \(2\), and \(6\)](#), the IRB needs to receive and review sufficient information regarding the risk profile of the proposed research study, including the type, probability, and expected level of severity of the adverse events that may be caused by the procedures involved in the research.
  - iii) The investigator also should describe how the risks of the research will be minimized.

- iv) In addition, depending upon the risks of the research and the likelihood that the research could involve risks to subjects that are unforeseeable, the IRB must ensure, if appropriate, that the research includes adequate provisions for monitoring the data collected to ensure the safety of the subjects [\(45 CFR 46.111\(a\)\(6\)\)](#).
- v) The monitoring provisions should be tailored to the expected risks of the research; the type of subject population being studied; and the nature, size (in terms of projected subject enrollment and the number of institutions enrolling subjects), and complexity of the research protocol.
  - (1) For research involving no more than minimal risk to subjects, it may be appropriate for the principal investigator to be responsible for any monitoring provisions.
  - (2) For a multicenter clinical trial involving a high level of risk to subjects, frequent monitoring by a Data and Safety Monitoring Board may be appropriate.
  - (3) Data and Safety Monitoring Plans may fall anywhere along a continuum from monitoring by the Principal Investigator or group of Investigators to the establishment of an independent Data and Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC). When a DSMB is utilized, the IRB considers the DSMB's findings in its determination regarding continuing approval of research.
- vi) The IRB will consider the Investigator's plan for collecting, monitoring, storage, and analysis of data. The level of monitoring required is related to the degree of risk posed by the research.
  - (1) The IRB shall determine that the protocol (or other documentation) includes adequate plans for monitoring the data collected, i.e., for analyzing the data during the collection process to enable the identification of problems regarding data integrity and reevaluation of risks to subjects to assure that they are no greater than initially predicted.
  - (2) The IRB will determine whether the DSMP is adequate for the nature, size, and complexity of the research protocol, the expected risks of the research and the type of population being studied.
  - (3) When a reviewer considers a DSMP to be inadequate, he/she shall indicate this concern either in writing or as a part of his/her review or during the board's discussion of the project at a Convened IRB meeting.
- vii) OHRP notes that adequate monitoring provisions for research, if deemed appropriate by the IRB, might include one or more of the following elements, among others:
  - (1) The type of data or events that are to be captured under the monitoring provisions.
  - (2) The entity responsible for monitoring the data collected, including data related to unanticipated problems and adverse events, and their respective roles (e.g., the Investigators, the research sponsor, a coordinating or statistical center, an independent medical monitor, a DSMB/DMC, and/or some other entity). (OHRP notes that the IRB has authority to observe or have a third party observe the research [\(45 CFR 46.109\(e\)\)](#).)
  - (3) The time frames for reporting adverse events and unanticipated problems to the monitoring entity
  - (4) The frequency of assessments of data or events captured by the monitoring provisions.

- (5) Definition of specific triggers or stopping rules that will dictate when some action is required.
  - (6) As appropriate, procedures for communicating to the IRB(s), the study sponsor, the Investigator(s), and other appropriate officials the outcome of the reviews by the monitoring entity.
- viii) The IRB at the time of continuing review will confirm that any provisions under the previously approved protocol for monitoring study data to ensure safety of subjects have been implemented and are working as intended.
- (1) IRB will require that the Investigator provide a report from the monitoring entity described in the IRB-approved protocol.
  - (2) In many cases, such a summary could be a simple brief statement that there have been no unanticipated problems and that adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document, and any investigator brochure.
  - (3) In some cases, a summary of any unanticipated problems and available information regarding adverse events and any recent literature that may be relevant to the research should be included in continuing review reports submitted to the IRB by investigators.
  - (4) In circumstances, when the clinical trial is subject to oversight by a monitoring entity (e.g., the research sponsor, a coordinating or statistical center, or a DSMB/DMC), a current report from the monitoring entity must be submitted to the IRB at the time of continuing review. The summary report should include the following:
    - (a) A statement indicating what information (e.g., study-wide adverse events, interim findings, and any recent literature that may be relevant to the research) was reviewed by the monitoring entity;
    - (b) The date of review; and
    - (c) The monitoring entity's assessment of the information reviewed.
- d) Unanticipated Problems and Adverse Events
- i) Federal regulations require prompt reporting to the IRB of any unanticipated problems involving risks to subjects or others.
  - ii) OHRP considers unanticipated problems, in general, to include any incident, experience, or outcome that meets all of the following criteria:
    - (1) 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.
    - (2) related or possibly related to participation in the research (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
    - (3) 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.
      - (a) If the adverse event is serious, the answer is always yes to this criterion.

- e) Determination of which Adverse Events are Unanticipated Problems
  - i) Some of the adverse events experienced by subjects enrolled in research studies will meet the criteria for unanticipated problems involving risks to subjects or others and so must be reported promptly to the IRB and OHRP ([Refer to section 7\(m\)](#))
  - ii) The vast majority of adverse events, both serious and non-serious, occurring in the context of research are expected.
    - (1) in light of the known toxicities and side effects of the research procedures or
    - (2) are expected due to the natural history of subjects' underlying diseases and conditions
  - iii) Thus, most individual adverse events do not represent unanticipated problems subject to the reporting requirements outlined in the [45 CFR 46.103\(b\)\(5\)](#) and [21 CFR 56.108\(b\)\(1\)](#).
  - iv) Questions to ask:
    - (1) Is the adverse event unexpected?
    - (2) Is the adverse event related or possibly related to participation in research?
    - (3) Does the adverse event suggest 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?
  - v) If the answer to **all three questions** is yes, then the adverse event is an unanticipated problem and must be reported to appropriate entities under the HHS regulations at [45 CFR 46.103\(a\)](#) and [46.103\(b\)\(5\)](#).
  - vi) The next three sub sections (f, g, and h) discuss the assessment of those three questions
- f) Assessing whether an adverse event is unexpected
  - i) 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:
    - (1) 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
    - (2) 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.
  - ii) OHRP recognizes that it may be difficult to determine whether a particular adverse event is unexpected.
  - iii) OHRP notes that for many studies, determining whether a particular adverse event is unexpected by virtue of an unexpectedly higher frequency can only be done through an analysis of appropriate data on all subjects enrolled in the research.
  - iv) In OHRP's experience the vast majority of adverse events occurring in the context of research are expected in light of (1) the known toxicities and side effects of the research

procedures; (2) the expected natural progression of subjects' underlying diseases, disorders, and conditions; and (3) subjects' predisposing risk factor profiles for the adverse events.

(1) Thus, most individual adverse events do not meet the first criterion for an unanticipated problem and do not need to be reported under the HHS regulations [45 CFR 46.103\(a\) and \(b\)\(5\)](#) (OHRP Adverse Event Reporting: see examples (1)-(4) in [Appendix C](#)).

- g) Assessing whether an adverse event is related or possibly related to participation in research
  - i) Adverse events may be caused by one or more of the following:
    - (1) the procedures involved in the research;
    - (2) an underlying disease, disorder, or condition of the subject; or
    - (3) other circumstances unrelated to either the research or any underlying disease, disorder, or condition of the subject
  - ii) In general, 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, whereas;
  - iii) Adverse events determined to be solely caused by an underlying disease, disorder, or condition of the subject; or other circumstances unrelated to either the research or any underlying disease, disorder, or condition of the subject would be considered unrelated to participation in the research.
  - iv) Determinations about the relatedness of adverse events to participation in research commonly result in probability statements that fall along a continuum between definitely related to the research and definitely unrelated to participation in the research.
  - v) OHRP considers possibly related to participation in the research to be an important threshold for determining whether a particular adverse event represents an unanticipated problem.
  - vi) OHRP recognizes that it may be difficult to determine whether a particular adverse event is related or possibly related to participation in the research
  - vii) Many individual adverse events occurring in the context of research are not related to participation in the research and, therefore, do not meet the second criterion for an unanticipated problem and do not need to be reported under the HHS regulations [45 CFR 46.103\(a\) and \(b\)\(5\)](#) (OHRP Adverse Event Reporting: see examples (5) and (6) in [Appendix C](#)).
- h) Assessing whether an adverse event 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
  - i) OHRP considers adverse events that are unexpected, related or possibly related to participation in research, and *serious* to be the most important subset of adverse events representing unanticipated problems, because such events always suggest that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized and routinely warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of subjects (OHRP Adverse Event Reporting: see examples (1)-(4) in [Appendix D](#)).

- ii) Other adverse events that are unexpected and related or possibly related to participation in the research, but not serious, would also be unanticipated problems if they suggest that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized. (OHRP Adverse Event Reporting: see examples (5) and (6) in [Appendix D](#)).
  - iii) Examples of unanticipated problems that do not involve adverse events and need to be reported under the HHS Regulations at 45 CFR 46 (OHRP Adverse Event Reporting: see [Appendix B](#) for examples).
- i) Reporting of Adverse Events/Unanticipated Problems to IRB
- i) Principal Investigator typically becomes aware of the adverse event directly from the subject or subject's representatives, another collaborating investigator, or the subject's healthcare provider.
  - ii) If the Principal Investigator determines that the adverse event represents an unanticipated problem, the Investigator must report it promptly to the IRB ([45 CFR 46.103\(b\)\(5\)](#)).
  - iii) Regardless of whether the adverse event is determined to be an unanticipated problem, the Investigator also must ensure that the adverse event is reported to a monitoring entity (e.g. the research sponsor, a coordinating or statistical center, an independent medical monitor, or DSMB/DMC) or the IRB *as described in the IRB approved protocol with respect to the data safety and monitoring plan*.
  - iv) If the monitoring entity subsequently determines that the adverse event does in fact represent an unanticipated problem (for example, due to an unexpectedly high frequency of the event), the monitoring entity should report this determination to the Investigator, and such reports must be promptly submitted by the investigator to the IRB ([45 CFR 46.103\(b\)\(5\)](#)).
  - v) Investigators submit the Adverse Event Form to the IRB for review (via the IRB Administrative Assistant), which addresses the following criteria related to the content of reports:
    - (1) appropriate identifying information for the research protocol, such as the title, Investigator's name, and the IRB project number;
    - (2) a detailed description of the adverse event, incident, experience, or outcome;
    - (3) an explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem; and
    - (4) a description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.
  - vi) At the time of continuing review, Investigators will be asked to summarize unexpected and related or possibly related adverse events that occurred since the last continuing review. (Refer to Continuing Review form)
- j) IRB review of Adverse Events/Unanticipated Problems
- i) The IRB Administrator and the IRB Chairperson using the expedited review process will review the adverse events form to assess the three criteria for unanticipated problems.
  - ii) When reviewing a report of an unanticipated problem, the IRB should consider whether the affected research protocol still satisfies the requirements for IRB approval under HHS regulations at [45 CFR 46.111](#).

- iii) In particular, the IRB should consider whether risks to subjects are still minimized and reasonable in relation to the anticipated benefits, if any, to the subjects and the importance of the knowledge that may reasonably be expected to be gained.
- iv) The IRB has authority, under HHS regulations at [45 CFR 46.109\(a\)](#), to require, as a condition of continued approval by the IRB, submission of more detailed information by the Investigator(s), the sponsor, the study coordinating center, or DSMB about any adverse event or unanticipated problem occurring in a research protocol.
- v) Any proposed changes to a research study in response to an unanticipated problem must be reviewed and approved by the IRB before being implemented, except when necessary to eliminate apparent immediate hazards to subjects.
- vi) If the changes are more than minor, the changes must be reviewed and approved by the Convened IRB ([45 CFR 46.103\(b\)\(4\)](#) and [110\(a\)](#)).
- vii) When reviewing a particular incident, experience, or outcome reported as an unanticipated problem by the Investigator, the IRB may determine that the incident, experience, or outcome does not meet all three criteria for an unanticipated problem.
  - (1) In such cases, further reporting to appropriate institutional officials, the department or agency head (or designee), and OHRP would not be required under HHS regulations at [45 CFR 46.103\(a\) and \(b\)\(5\)](#).
- k) The range of the IRB's possible actions in response to reports of unanticipated problems:
  - i) Changes to the research protocol initiated by the investigator prior to obtaining IRB approval to eliminate apparent immediate hazards to subjects;
  - ii) Implementation of additional changes to the research protocol to minimize newly recognized risks;
  - iii) Modification of inclusion or exclusion criteria to mitigate the newly identified risks;
  - iv) Implementation of additional procedures for monitoring subjects;
  - v) Suspension of enrollment of new subjects;
  - vi) Suspension of research procedures in currently enrolled subjects;
  - vii) Modification of Informed Consent documents to include a description of newly recognized risks; and
  - viii) Provision of additional information about newly recognized risks to previously enrolled subjects.
- l) Reporting of Adverse Events/Unanticipated Problems to appropriate institutional officials:
  - i) The Executive Vice President for Academic Affairs is the only additional appropriate institutional official to whom internal adverse events that are unanticipated problems will be reported by the IRB Administrator, who is the Dean of Research.
  - ii) The incident report submitted to OHRP will be sent to the Executive Vice President of Academic Affairs by the IRB Administrator.
  - iii) The IRB Administrator, IRB Chairperson, and IRB members are the only appropriate institutional officials to whom external adverse events that are unanticipated problems are to be reported.
- m) Reporting unanticipated problems to OHRP and supporting agency heads (or designees):

- i) 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) and OHRP ([45 CFR 46.103\(b\)\(5\)](#)).
  - ii) The IRB Administrator is responsible for reporting unanticipated problems to the supporting HHS agency head (or designee) and OHRP.
  - iii) On reporting information to OHRP, the IRB Administrator will follow the guidelines in the Guidance on Reporting Incidents to OHRP at [http://www.hhs.gov/ohrp/policy/incidreport\\_ohrp.html](http://www.hhs.gov/ohrp/policy/incidreport_ohrp.html).
  - iv) For multicenter research projects, only the institution at which the subject(s) experienced an adverse event determined to be an unanticipated problem (or the institution at which any other type of unanticipated problem occurred) must report the event to the supporting agency head (or designee) and OHRP
- n) Reporting Time Frame
- i) Unanticipated problems that are serious adverse events should be reported to the IRB within 24 hours of the principal investigator becoming aware of the event.
  - ii) Any other unanticipated problem should be reported to the IRB within one (1) week of the investigator becoming aware of the problem.
  - iii) All unanticipated problems should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and OHRP within one (1) month of the IRB's receipt of the report of the problem from the investigator.

<b>ADVERSE EVENT REPORTING REQUIREMENTS</b>			
<b>Seriousness</b>	<b>Expectedness</b>	<b>Relationship</b>	<b>Time Frame</b>
Serious	Unexpected	Possibly, Probably, or Definitely Related	As soon as possible, but no later than one (1) working day / 7 calendar days after the investigator is notified of the event.
Non-Serious	Unexpected	Possibly, Probably, or Definitely Related	As soon as possible, but no later than 5 working days / 14 calendar days after the investigator is notified of the event.
<p><b>Possibly related</b> means that the event is more likely than not related to participation in the research or, in other words, there is a &gt;50% likelihood that the event is related to the research procedures.</p>			
<p><b>NOTE: At the time of continuing review, investigators will be asked to summarize unexpected and related or possibly related adverse events that occurred since the last continuing review.</b></p>			

- o) Reporting of External Adverse Events to IRBs

- i) Only when a particular adverse event or series of adverse events is determined to meet the criteria for an unanticipated problems should a report of the external adverse event(s) be submitted to the IRB at each institution under the HHS regulations at 45 CFR 46.
- ii) Typically, such reports to the IRBs are submitted by investigators.
- iii) OHRP recommends that any distributed reports include:
  - (1) a clear explanation of why the adverse event or series of adverse events has been determined to be an unanticipated problem; and
  - (2) a description of any proposed protocol changes or other corrective actions to be taken by the investigators in response to the unanticipated problem.
- iv) OHRP recommends that for multicenter 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 IRB 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 IRB.

**8) Procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, the Department or Agency head, and OHRP of any serious or continuing noncompliance (OHRP Required Element 7)**

a) Definitions

- i) Noncompliance is defined as any violation of any regulation that governs human subject research, any deviation from the study protocol approved by the IRB; or any violation of any conditions imposed by the IRB on the approved study or conduct of the research.
- ii) Minor noncompliance is a noncompliant event that does not impact the subject safety, compromise the integrity of study/data, violate a subject's rights or welfare or affect the subjects willingness to participate in the research. Minor noncompliance may be reported through the policies governing exceptions and deviations or by contacting the Research Department if there are questions as to how it should be reported.
- iii) Serious noncompliance is a noncompliant event that may impact the subject safety, increase risks to the subjects, affect the integrity of the data, violate a subject's rights or welfare or affect the subject's willingness to participate in the study.
- iv) Continuous noncompliance is defined as a series of more than one noncompliant event, in reasonably close proximity, that indicates the need for evaluation of the methods and systems used to protect human subjects. Continuous noncompliance need not involve a sequence of similar events if the events, taken as a whole, indicate that examination of the methods and systems used is warranted.

b) Policy

- i) Noncompliance with the regulations or policies applicable to human research or noncompliance with the requirements or determinations of the IRB must be promptly reported to the IRB.
- ii) Issues or events that are reported are considered *possible* noncompliance until a final determination is made by the IRB or designated IRB reviewer.
- iii) Noncompliance that is determined to be serious or continuing must be promptly reported to the appropriate institutional officials, OHRP and the Food and Drug Administration (FDA) (if applicable).

- iv) For the purpose of this policy, all sources of possible noncompliance will be referred to as allegations until the issue is determined to be noncompliance by the IRB or designated IRB reviewer.
- c) Identification of Noncompliance
  - i) Investigators and research staff are responsible for promptly reporting possible noncompliance to the IRB using the Noncompliance Report Form.
    - (1) Minor or administrative protocol deviations are defined as those which do not affect the scientific soundness of the research or adversely affect the rights, safety, or welfare of human subjects.
    - (2) A minor or administrative protocol deviation is limited to minor departures from the protocol for a single subject.
    - (3) Minor or administrative protocol deviations are not considered noncompliance and prompt reporting to the IRB is not required.
    - (4) A summary of minor or administrative deviations is provided in the progress report reviewed during the continuing review.
  - ii) A report by an individual can be made directly to the IRB.
    - (1) Complaints from subjects, members of the research team or others could contain allegations of noncompliance.
    - (2) Comments, concerns or complaints from research participants or family members of research participants, members of the research team, or individuals not otherwise affiliated with the institution that may also be noncompliance are accepted as verbal reports; however persons recording a complaint are encouraged to provide their concerns in writing.
    - (3) Allegations of noncompliance from other members of the institution may be initially provided as verbal reports but must later be submitted in writing.
  - iii) The IRB may learn of noncompliance through its continuing review of ongoing research.
  - iv) A report by another committee, department or official could contain instances of possible noncompliance.
  - v) A report from the study sponsor or sponsor's monitoring entity could contain instances of possible noncompliance.
- d) Prompt reporting timeframe by the Principal Investigator/Research Staff to the IRB:
  - i) The Principal Investigator must report noncompliance to the IRB within seven (7) days of discovery of the noncompliance issue.
  - ii) The IRB Administrator is designated as the IRB Reviewer for this process.
  - iii) Given his/her position in the IRB Office, the IRB Administrator is readily available to promptly review allegations of noncompliance.
  - iv) The IRB Administrator is expected to communicate with the IRB Chair and Administrative Assistant and initiate a review process to determine if an allegation constitutes noncompliance.
- e) Inquiry Process to Evaluate an Allegation/Report of Noncompliance

- i) If the allegation suggests that subjects are at immediate risk, the IRB Chair or IRB Administrator may immediately suspend IRB approval or take other action as appropriate to protect the safety and welfare of subjects or protect the integrity of the research.
- ii) The IRB Chair may appoint one or more voting member(s) based on the seriousness and/or the frequency of violations and/or disregard for the federal regulations or the institutional policies and procedures applicable to human research to gather information pertaining to the nature of the allegation, the procedures approved in the IRB protocol, and the procedures followed in conducting the study.
  - (1) The IRB Chair, as a member of the IRB, may conduct the inquiry alone. With allegations involving less serious issues, the IRB Chair may gather the facts without the involvement of the additional members.
  - (2) In more serious cases, the IRB Chair and designated IRB members (subcommittee) work together to gather the information.
- iii) The IRB Chair or subcommittee (collectively referred to as IRB inquiry members) may elect to interview the complainant(s) if applicable, or in cases where the complainant requests anonymity, the individual who received the original allegation may interview the complainant.
  - (1) A summary of the interview is prepared, given to complainant, who may comment on the summary.
  - (2) In some cases, the complainant may have already submitted a written complaint, which the IRB inquiry member(s) then verify.
  - (3) The IRB inquiry member(s) may request additional information from the complainant.
- iv) The IRB inquiry member(s) may interview the subject of the allegation (respondent) or PI from whom the report was received and provide the opportunity to comment on the allegation and provide information.
  - (1) A summary of the interview is prepared, given to the respondent, who may comment on the summary.
  - (2) In some cases, the respondent may have submitted a written rebuttal to the complaint or report of noncompliance, which the IRB inquiry members verify.
  - (3) The IRB inquiry member(s) may request additional information from the respondent.
- v) Depending on the nature of the allegation or report and the information collected during the interviews, the IRB inquiry member(s) may:
  - (1) Interview other individuals;
  - (2) Examine research data, both published and unpublished;
  - (3) Examine informed consent/assent forms;
  - (4) Examine medical records;
  - (5) Examine inclusion/exclusion criteria;
  - (6) Examine the applicable approved IRB protocol; and
  - (7) Any other pertinent information
- vi) The inquiry process is complete when the IRB inquiry member(s) conclude that there is sufficient information related to the event to determine whether noncompliance occurred.

- vii) The IRB inquiry member(s) prepare a summary report:
  - (1) The report consists of a summary of the allegations or report of noncompliance, interview summaries, and copies of pertinent information (correspondence such as emails)
  - (2) The report may or may not include recommendations for IRB action depending on the outcome of the inquiry process.
  - (3) The report is filed with the applicable approved IRB protocol.
- f) Possible Outcomes of the Inquiry Process
  - i) If the IRB inquiry member(s) determine that the event was NOT noncompliance (dismissal of the allegations), then:
    - (1) The IRB inquiry member(s) may dismiss the allegation as unjustified and; may decide to take no action
      - (a) If the IRB inquiry member(s) finds that the allegation is unjustified and takes no action, then the decision will be communicated in writing to the complainant (if the identity of the person is known) and to the PI against whom the allegation was raised (respondent) or from whom the report was received.
      - (b) Communications are filed with the applicable approved IRB protocol.
    - (2) The IRB inquiry member(s) may continue to review the complaint as an unanticipated problem involving risks to subjects or others (following guidelines in [Section \(7\)\(j\)](#)).
  - ii) If the IRB inquiry member(s) determine that the event was noncompliance (finding of noncompliance), and the noncompliance is not serious or continuing, then:
    - (1) The IRB Chair may manage the concern through communications with the Principal Investigator. Management decisions and recommendations are based on the Principal Investigator's stated plan to correct issues and prevent a future occurrence.
    - (2) Upon resolution of the issue with the Principal Investigator, the IRB Chair provides a written summary of the determination and actions taken on the Noncompliance Report Form to complete the process, which is filed with the applicable approved IRB protocol.
    - (3) The IRB inquiry member(s) may continue to review the complaint as an unanticipated problem involving risks to subjects or others (following guidelines in [Section \(7\)\(j\)](#)).
  - iii) If the IRB inquiry member(s) determine that the event was noncompliance (finding of noncompliance) and the event is possibly serious or continuing noncompliance, the issue is forwarded to the convened IRB for review (See [Section \(4\)\(d\)](#) on convened IRB reviews).
  - iv) Refer to [Section \(8\)\(j\)](#) on noncompliance involving scientific misconduct.
- g) Convened IRB Review Procedures for Noncompliance that is Possibly Serious or Continuing
  - i) The IRB Administrator advises the convened IRB regarding the applicable institutional policy and federal regulations, assists the IRB in documenting the review, answers questions about the review process, maintains the records as required by state and federal laws, and serves as a liaison with the funding agency or agencies.
  - ii) The IRB reviews the material presented by the IRB inquiry member(s) at a convened meeting at which a quorum is present.

- (1) The convened IRB is provided with the summary report from the inquiry process and any other documents deemed important.
- iii) The convened IRB determines whether to request additional information or whether to interview additional persons of interest.
- iv) The IRB may give the Principal Investigator the opportunity to meet with the convened IRB before it takes final action.
- h) Possible Outcomes of the Convened IRB
  - i) The convened IRB makes the final determination whether the noncompliance is serious or continuing based on the materials compiled during the inquiry.
  - ii) The convened IRB approves a management plan that may include a variety of actions, depending on the outcomes of the review, including, but not limited to, the following:
    - (1) No action;
    - (2) Approve continuation of research without changes with a cautionary reminder to the PI;
    - (3) Require formal educational intervention;
    - (4) Require minor or major changes in the research procedures and/or consent documents;
    - (5) Modify the current approval period
    - (6) Require monitoring of research;
    - (7) Require monitoring of the consent process
    - (8) Suspend IRB approval (see [Section\(9\)\(d-e\)](#))
    - (9) Terminate IRB approval (see [Section 9\(f-g\)](#))
    - (10)Require audits of other active protocols of the investigator;
    - (11)Disqualify the investigator from conducting research involving human subjects at the institution;
    - (12)Determine that the data collected cannot be used for publication;
    - (13)Require that subjects previously enrolled in the study be contacted and provided with additional information and/or re-consented;
    - (14)Request that publishers and editors be informed of manuscripts emanating from the research have been submitted or published;
    - (15)Recommend to the appropriate officials of the intuitions engaged in the research that further administrative or disciplinary action be taken
- i) Notifications
  - i) The IRB Administrator communicates in writing the IRB's decision to the person raising the allegations (if the identity of the person is known) or person making the report of noncompliance.
  - ii) The IRB Administrator communicates in writing the IRB's decision to the Principal Investigator.
    - (1) The PI submits a response to IRB concerns in writing within thirty days of the date the IRB issues the final decision

- (2) The IRB limits concerns to a review of the procedures employed to reach the decision (i.e. claims that the process was faulty in a way that creates a considerable risk that the outcome was incorrect) or grievances of sanctions imposed as a result of a finding of noncompliance.
  - (3) The PI specifies the nature of any claimed procedural error or the perceived unfairness of sanctions issued.
  - (4) The IRB resolves questions or concerns raised by a Principal Investigator regarding the outcome of a specific IRB noncompliance review through direct communication with the Principal Investigator.
- iii) The IRB informs the following individuals of the allegation, the review process, and the findings of the review, if appropriate, depending on the outcome of the review:
    - (1) Executive Vice President of Academic Affairs
    - (2) The external sponsor
    - (3) The applicable regulatory agency
  - j) Reporting of any Serious or Continuing Noncompliance to OHRP
    - i) If the noncompliance is serious or continuing, the IRB, with the assistance of the IRB Administrator, reports the incident(s) to the applicable funding agencies and OHRP following procedures outlined in [Section 1\(f\)](#).
    - ii) The IRB must report noncompliance within seven (7) working days or twenty-one (21) calendar days of the completion of the IRB process for reviewing allegations of non-compliance with actual determinations of serious continuing non-compliance. ([Section 8 a-i](#))
  - k) Noncompliance and Scientific Misconduct
    - i) If the noncompliance event possibly involves research misconduct defined as fabrication, falsification, plagiarism in proposing, performing, or reviewing research, or in reporting research results, the IRB inquiry member(s) notifies the Research Director.
    - ii) Refer to the NYCC [Policy for Responding to Allegations of Scientific Misconduct](#).
- 9) Procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, the Department or Agency head, and OHRP of any suspension or termination of IRB approval (OHRP Required Element 7).**
- a) Policy
    - i) The convened IRB or Institutional Official may suspend or terminate approval of research that is not being conducted in accordance with the IRB requirements or that has been associated with unexpected serious harm to participants.
    - ii) The IRB Chair or IRB Administrator may suspend approval of research that is not being conducted in accordance with the IRB requirements or that has been associated with unexpected serious harm to participants.
    - iii) Any suspension or termination of approval shall include a statement of the reason for the IRB action with the statement of the reason being filed with the applicable IRB protocol.
  - b) The process of considering suspension or termination of research may be prompted for several reasons, for example:

- i) During the IRB review of reports of unanticipated problems (link to Adverse Event Form ) or noncompliance (link to noncompliance form)
  - ii) During the IRB review of progress reports submitted for continuing review
  - iii) Based on results of compliance reviews, audits, or other institutional processes
  - iv) Based on complaints from participants, family members or others
- c) Initiating the process of considering suspension or termination of research
- i) The IRB Administrator is designated the reviewer for this process.
  - ii) Given his/her position in the IRB Office, the IRB Administrator is readily available to promptly review issues such as allegations of noncompliance, unanticipated problems, progress reports, compliance reviews and complaints that may indicate research is not conducted in accordance with IRB requirements or associated with unexpected serious harm to participants requiring consideration of suspension.
  - iii) The IRB Administrator is expected to communicate with the IRB Chair and Administrative Assistant and initiate a review process to determine if suspension or termination of research is necessary.
  - iv) The IRB Chair or IRB Administrator may suspend approval of research that is not being conducted in accordance with the IRB requirements or that has been associated with unexpected serious harm to participants.
    - (1) The IRB Chair or IRB Administrator may only suspend the research; authority to terminate the research is limited to the convened IRB or Institutional Official.
    - (2) The IRB Chair or IRB Administrator will suspend approval of some or all of the research when the continuation of the research may adversely affect the rights and welfare of research subjects or when continuation may represent an immediate threat of harm to the subjects.
    - (3) The issue resulting in suspension is taken to the next scheduled meeting for consideration by the convened IRB.
    - (4) For issues of a more serious nature, if there is insufficient time to have the next scheduled convened IRB review the situation the IRB Chair or IRB Administrator may call a special meeting of the IRB to review the issue.
- d) Suspension of IRB Approval
- i) The IRB Chair or IRB Administrator will consider suspension as an action pending review of the issue by the convened IRB
    - (1) The procedure ends when the convened IRB determines: 1) suspension is not an appropriate action, or 2) the convened IRB makes a final determination whether to continue or alter the suspension or terminate the research.
  - ii) The convened IRB, IRB Chair, or IRB Administrator, when making the determination of suspension, **when a suspension involves the withdrawal of current subjects from a research protocol or interruption of research procedures**, considers alternative actions to protect subjects from harm that could result from withdrawal of research procedures that could affect their health or well-being, for example:
    - (1) Transfer of subjects to another investigator that would allow continuation of research (i.e. assign a new Principal Investigator)

- (2) Arrangement of clinical care outside the research
  - (3) Continuation of some research activities under the supervision of an independent monitor
  - (4) Permitting follow-up of subjects for safety reasons
  - (5) Require reporting of adverse events or outcomes to the IRB and the sponsor
  - (6) Re-consent participants
- iii) If the Institutional Official, IRB Chair, or IRB Administrator suspends IRB approval,
- (1) The Institutional Official, IRB Chair or IRB Administrator documents the reason for suspension and notifies the Principal Investigator in writing
  - (2) The IRB Administrative Assistant adds the issue to the agenda of the next scheduled meeting or arranges a special meeting and the IRB discusses the suspension at a convened meeting.
  - (3) IRB members are provided a copy of the protocol, informed consent form, information relevant to the suspension, and who ordered the suspension.
- e) Notification of Suspension
- i) Written correspondences of the suspension from the Institutional Official, IRB Chair or IRB Administrator to the Principal Investigator may include, but is not limited to, the following:
    - (1) An explanation of the extent of the suspension in terms of enrollment, recruitment, interventions, interactions, and data analysis;
    - (2) The reasons for the suspension, an explanation of the reasons for the decision
    - (3) An offer to the investigator to respond to the convened IRB in writing;
    - (4) A request for a description of any procedures needed to protect the rights and welfare of current subjects if the suspension involves currently enrolled subjects;
    - (5) A description of whether follow-up of subjects for safety reasons is permitted or required.
  - ii) The Principal Investigator notifies enrolled subjects (active and former) of any suspended research protocol, and the Principal Investigator considers the appropriate procedures for withdrawal of enrolled subjects, taking into account their rights and welfare.
  - iii) The IRB Administrator or IRB Chairperson informs the following individuals of the suspension of research approval:
    - (1) Executive Vice President of Academic Affairs
    - (2) The external sponsor
    - (3) The applicable regulatory agency
  - iv) Documentation of suspension is filed with the applicable IRB protocol.
- f) Termination of IRB Approval
- i) The authority to terminate an IRB approved research protocol is limited to the convened IRB or Institutional Official.
  - ii) The convened IRB **may consider alternatives to termination** as an approach to protect currently enrolled participants who may be harmed if the research is terminated.

- iii) As alternatives to termination, the IRB may require modification of the study to allow continuation including the following changes:
  - (1) Add, remove, or limit the responsibilities of investigator(s)
  - (2) Arrangement of clinical care outside the research
  - (3) Add or modify the local safety monitoring plan (e.g. addition of an independent monitor, addition of safety monitoring procedures or data)
  - (4) Re-consent participants
  - (5) Shortening the current approval period.
- iv) The convened IRB when making the determination of termination, **when a termination involves the withdrawal of current subjects from a research protocol**, considers alternatives to termination that will result in protection of subjects from harm that could result from withdrawal of research procedures that could affect their health or well-being, e.g.:
  - (1) Notification of currently enrolled participants that the study has been terminated by a written communication approved by the IRB.
    - (a) In this case, communication to participants will explain the rationale for termination, contact information to address subject questions and any action steps for the subjects.
    - (b) A list of current and/or former participants needs to be readily available for review by the IRB.
    - (c) The IRB Administrative Assistant will assist the PI with the mailing of the letters to ensure compliance with this IRB requirement.
  - (2) Possible transfer of subjects to another research study
  - (3) Arrangement of clinical care outside the research
  - (4) Permitting follow-up of subjects for safety reasons
- g) Notification of Termination
  - i) Written correspondences of the termination from the IRB Administrator, the IRB Chair, or institutional Official to the Principal Investigator may include, but is not limited to, the following:
    - (1) An explanation of the extent of the termination in terms of enrollment, recruitment, interventions, interactions, and data analysis;
    - (2) The reasons for the termination, an explanation of the reasons for the decision, and an offer to the investigator to respond to the convened IRB in writing;
    - (3) A request for a description of any procedures that need to be followed to protect the rights and welfare of current subjects if the termination involves currently enrolled subjects;
    - (4) A description of whether follow-up of subjects for safety reasons is permitted or required;
    - (5) An explanation that any request for the IRB to reconsider the termination must be made within 30 days from date of the notification.

- ii) The Principal Investigator notifies enrolled subjects (active and former) of any terminated research protocol, and the Principal Investigator considers the appropriate procedures for withdrawal of enrolled subjects, taking into account their rights and welfare.
- iii) The IRB informs the following individuals of the termination of research approval:
  - (1) Executive Vice President of Academic Affairs
  - (2) The external sponsor
  - (3) The applicable regulatory agency
- iv) Documentation of termination is filed with the applicable IRB protocol.
- h) Reporting any suspension or termination of IRB approval to OHRP:
  - i) The IRB, with the assistance of the IRB Administrator, reports any suspension or termination of IRB approval to the applicable funding agencies and OHRP following procedures outlined in [Section \(1\)\(f\)](#).
  - ii) The IRB must report any suspension or termination of IRB approval within seven (7) working days or twenty-one (21) calendar days of the determination to suspend or terminate the research.

**10) Procedures IRB will follow for conducting Continuing Review of research and Final Reporting of completed projects. (OHRP Required Element 2)**

- a) Method of Review
  - i) Continuing review of a study must be conducted at the level of the initial review and approval.
    - (1) Using the Convened IRB review process. Refer to Section 4(d)(i) for the Convened IRB Review process.
    - (2) Using the Expedited Review process. Refer to Section 4(d)(ii) for the Expedited Review process.
  - ii) However, under certain conditions, a study initially reviewed and approved at a Convened IRB meeting may be reviewed through expedited review procedures.
    - (1) Continuing review of research previously approved by the convened IRB as follows:
      - (a) Where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants
      - (b) Where no participants have been enrolled and no additional risks have been identified
      - (c) Where the remaining research activities are limited to data analysis
    - (2) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where [categories 2 through 8](#) as described in [Section 4\(d\)\(3\)](#) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
- b) Notification to Investigators
  - i) Refer to [Section 4\(d\)\(i\)\(8\)](#) for notification to the investigator, if Convened IRB Review process is necessary

- ii) Refer to [Section 4\(d\)\(ii\)\(7\)](#) for notification to the investigator related to the Expedited Review Process
- c) Required Documentation for Continuing Review
  - i) The IRB Administrative Assistant will distribute the Continuation Report form to the Investigator at least two months prior to the expiration of the protocol.
  - ii) The Investigator must complete and return the continuation form within 2 weeks of receiving the request from the IRB Administrative Assistant. A deadline date for the receipt of the Continuation Form will be specified on the Continuation Report by the IRB Administrative Assistant.
  - iii) In addition to completing the Continuation Form, the following materials may need to be submitted:
    - (1) Two complete copies of recent subject Informed Consent forms,
      - (a) If no data was collected during the previously approved study period, a written statement to this effect should be included with the Continuation Report in lieu of the consent forms.
    - (2) A description of any significant findings pertaining to subject risk or adverse reactions that may impact subject participation
    - (3) Any Serious/Adverse Event Form(s) as submitted to the IRB since the last review.
    - (4) Current report(s) from any Data Safety Monitoring Board/Committee, if applicable, since the last review.
  - iv) The IRB Administrative Assistant will then distribute the documents via email or postal mail for review. Refer to [Section 4\(a\)](#) and [Section 10\(a\)](#)
- d) Completion of IRB approved Research Project
  - i) Upon completion of the research project, or upon notification of a continuation report being due, the investigator must file a Final Report.
  - ii) IRB Administrator and IRB Chairperson will review the Final Report.
  - iii) A letter will be sent to the investigator requesting more information and/or informing the investigator that the IRB protocol will be closed.
- e) Further review by institution
  - i) Responsible party
    - (1) N/A
  - ii) Institutional policies relevant to review
    - (1) N/A
  - iii) Actions that may be taken by the institution
    - (1) N/A
- f) Notification of investigator of expiration of IRB approval
  - i) If the Investigator fails to submit the Continuation Report by the deadline, he or she will be notified in writing by the IRB Chair or Administrator of the expiration of the protocol.

- ii) The Investigator must submit a Final Report upon notification of expiration of the IRB protocol.
- iii) Failure to complete the Final Report within 2 weeks of notification will result in a determination of noncompliance with the IRB. Review of future IRB applications will not occur until all previous Final Reports have been filed.

### **11) Investigator Responsibilities**

- a) Follow the submission guidelines outlined in [Section 4\(b\)](#).
- b) It is recommended the Investigator, Co-Investigator, or representative attend the Convened IRB meeting in order to address questions or concerns about the protocol.
- c) The Investigator must conduct the research exactly as explained in his/her protocol and as approved by the IRB
- d) The Investigator must complete the Continuation Form and/or Final Report as described in [Section 10](#).
- e) Prompt notification of any change in research methods, procedures, and key personnel. This notification must be accompanied by an IRB Amendment Form.
- f) Prompt notification, in writing, using the available Adverse Event form, about subjects that reacted negatively to the research procedure. Not every adverse reaction needs to be reported immediately, only the severe or unexpected ones. See [Section 7](#) regarding Serious and Adverse Event reporting.
- g) Prompt notification of any serious or continuing noncompliance using the Noncompliance form (See [Section 8](#))
- h) The researcher must keep all consent forms on file and available for inspection for a period of at least three years from the date of acceptance of the final report.
- i) The researcher must make all research results, data collected, and informed consent documents available for inspection by the IRB or its appointed representatives, during the time the protocol has been approved by the IRB, and for 3 years from the date of termination or final report.
- j) The researcher must allow onsite inspection of the laboratory, data, and data collection procedures by the IRB or its appointed representatives.

### **12) Procedures the IRB will follow for reporting its findings and actions to the Investigator and the Institution. (OHRP Required Element 3)**

- a) To Investigator:
  - i) Initial Review of Protocols:
    - (1) Convened IRB Review, [Section 4\(d\)\(i\)\(8\)](#).
    - (2) Expedited IRB Review, [Section 4\(d\)\(ii\)\(7\)](#)
    - (3) Exemption Status, [Section 4\(d\)\(iii\)\(4\)](#).
  - ii) Continuing/Final Review of Protocols, [Section 10\(bc\)](#)
  - iii) Amendments to Protocols, [Section 6\(b\)](#) and [Section 4\(d\)\(ii\)\(6\)](#) or [Section 4\(d\)\(i\)\(7\)](#).
  - iv) Unanticipated Problems, [Section 7\(l\)](#).
  - v) Any serious or continuing noncompliance, [Section 8\(h\)](#).

- vi) Suspension of Research, [Section 9\(e\)](#).
  - vii) Termination of Research, [Section 9\(g\)](#).
  - viii) Protocols Requiring Review More Often than Annually, [Section 13\(b\)\(ii\)](#) and [Section 13\(c\)](#).
- b) To Institution:
- i) Written Communications to the Executive Vice President and Provost:
    - (1) IRB Meeting Minutes
    - (2) Each November, the Administrative Assistant compiles .pdf documents of all active IRB approved protocols.
      - (a) The compilation of all IRB approved protocols within the past year will be sent to NYCC's Insurance Company, NCMIC Group, Inc., 14001 University Ave, Clive, IA.
    - (3) Incident Reports of Unanticipated Problems, [Section 7\(l\)](#).
    - (4) Incident Reports of Serious or Continuing Noncompliance, [Section 8\(h\)\(iii\)](#).
    - (5) Incident Reports of Suspension of Research, [Section 9\(e\)\(iii\)](#).
    - (6) Incident Reports of Termination of Research, [Section 9\(g\)\(iii\)](#).

**13) Procedures the IRB will follow for determining which projects require review more often than annually. (Required Element 4)**

- a) Depending upon the nature of the research project, and its potential hazards or benefits, the IRB may require review on a more frequent basis than annually.
- b) Specific criteria used to make those determinations
  - i) Each protocol will be reviewed on a case-by-case basis, and will be asked to review more often than annually if required through majority vote during the initial IRB review.
  - ii) The Investigator will be made aware of the rationale of the IRB to review the application more often than annually, if applicable, in the Approval Letter.
- c) Document approval period
  - i) The Investigator will be made aware of the approval start and end dates through the Initial Approval Letter, as well as through the stamped dates on the Informed Consent (if applicable). The Investigator is responsible for submitting a Continuation Review form prior to the expiration date.
- d) Refer to [Section 10](#) for Continuing Review process.

**14) Procedures the IRB will follow for determining which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review. (OHRP Required Element 5)**

- a) Depending upon the nature of the research project, and its potential hazards or benefits, the IRB may require verification from sources other than the investigator that no material changes are occurring in the approved protocol.
  - i) Each protocol will be reviewed on a case-by-case basis.
  - ii) This determination may be made during initial review, continuing review, following a report of an adverse or unanticipated event, following a report of investigator noncompliance, or at random as part of the IRB's compliance oversight responsibilities.

- b) Examples of when the IRB may require verification from other sources including, but are not limited to the following:
  - i) *Pattern of Submitting Incorrect Versions of Required Documents*: The investigator or responsible study coordinator has a pattern of submitting the wrong version of documents that the IRB must review such as the protocol or consent document;
  - ii) *History of Late Reporting of Adverse Events*: The principal investigator has a history of late notification to the IRB of adverse events or unanticipated problems;
  - iii) *Previous Late Reporting of Changes in Research*: The IRB has knowledge that the principal investigator previously implemented changes to any human subject research (other than emergency changes solely for the protection of study subjects) without prior approval from the IRB; or
  - iv) *Report of Changes to Research*: The IRB receives a report from a third party that the research has deviated from the IRB approved protocol.
- c) Verification Process: Members of the IRB, the IRB Administrator, Administrative Assistant, and other representative officials will then randomly participate in the Informed Consent and data collection processes with the Investigators and the subjects for the duration of the current approval period and any subsequent approval periods through the Continuing Review process for the protocol in question.

**15) Procedures for Additional Protections for Special Classes of Subjects: Subparts B, C, D.**

- a) 45 CFR 46 Subparts:
  - i) [Subpart B](#): Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research
  - ii) [Subpart C](#): Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
  - iii) [Subpart D](#): Additional Protections for Children Involved as Subjects in Research
- b) General Procedures:
  - i) NYCC's IRB does not typically receive protocols involving pregnant women, human fetuses, neonates, prisoners or children. If a protocol is received including one of these special classes of subjects, the IRB will refer to 45 CFR 46 Subparts B, C, and D for guidance.
- c) Specific procedures for conducting research with pregnant women involved as subjects:
  - i) No pregnant women may be involved in a research activity unless:
    - (1) the purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs OR
    - (2) the risk to the fetus is minimal.
  - ii) An activity permitted under paragraph (c)(i) of this section (15) may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding the possible impact on the fetus, except that the father's informed consent need not be secured if:
    - (1) The purpose of the activity is to meet the health needs of the mother
    - (2) His identify or whereabouts cannot be reasonably ascertained
    - (3) He is not reasonably available

- (4) The pregnancy resulted from rape
- (5) He is deceased
- iii) The IRB will require that pregnancy or the possibility of being pregnant be listed under the exclusion criteria in all IRB applications and Informed Consent forms unless research addresses the activity permitted under paragraph 15(c)(i)(a) above.
- d) Specific procedures for conducting research with children involved as subjects
  - i) For research involving children under the age of 18 years old, the investigator must submit Assent Forms and Parental Permission forms.
    - (1) The guidelines and a sample template for the assent form and parental permission forms (modifying the Informed Consent form) are available from the IRB Administrative Assistant and NYCC online.
    - (2) Current regulations tend to avoid the term “consent” when one person grants approval for another to enroll in research. Parents or legal guardians therefore grant “permission” for children to participate in research ([45 CFR 46.408](#)). The “permission” form is in essence a consent document and should follow all applicable requirements for Informed Consent document.
    - (3) Investigators should modify the Informed Consent document to represent the parental permission for participation.
    - (4) Whenever possible, the permission of both parents should be obtained; however, current federal regulations do not require permission from both parents in all research situations.
      - (a) In general, the risk to the child and the prospect of direct benefit for the child as a research subject determine whether single parental/guardian permission may be permitted.
      - (b) If the research involves no greater than minimal risk, permission of only one parent is sufficient ([45 CFR 46.404](#)).
      - (c) If the research involves greater than minimal risk, consent of both parents must be obtained unless one parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has the legal responsibility for the care and custody of the child [[45 CFR 46.408\(b\)](#)].
      - (d) Investigators should obtain written permission from the parent prior to contacting children for participating in research.
  - ii) Assent forms for a Child
    - (1) If the child is under the age of 7, only a Parental Permission form is required.
    - (2) If the child is 7-12 years of age, a child assent form is required in addition to the Parental Permission form.
      - (a) The form should be brief and study specific, with subheadings or numerical paragraphs, and contain language that is both appropriate to the child’s maturity and age.
      - (b) The Assent form should have a simple format that is easy to read and when possible, limited to one page.

- (c) The use of larger type, simple schema, and pictures will facilitate the child's understanding of the text.
  - (d) The IRB understands that the writing of a good assent form is an art and that there is more than one correct approach to creating a document that is easily understood by the child and includes all of the pertinent information.
  - (e) With the template as a guide, the simplified form should contain the following elements and conclude with an assent statement:
    - (i) Why the child was chosen to participate
    - (ii) What is going to take place from the child's point of view
    - (iii) The risks and discomforts to the child
    - (iv) The possible benefit to the child
    - (v) Identification of the researcher by name and telephone number in case the child would like to call and ask questions
    - (vi) In non-therapeutic research, statement that child has a choice to participate or to withdraw at any time without consequences.
    - (vii) Statement that child may keep a copy of the Assent form.
    - (viii) Date and signature lines for the researcher and the child indicating assent.
- iii) Assent Forms for youth
- (1) If the child is 13-18 years of age, a Youth Assent Form is required in addition to a Parental Permission form.
  - (2) The Youth Assent form may follow the format provided for adult consent but is required to contain simple language written at the appropriate educational level of the youngest prospective subject in the youth age range.
  - (3) The Youth Assent form must contain all required elements of Informed Consent for participation of adults in research (use the Informed Consent template)
- iv) Assent Process
- (1) The assent form does not replace a thoughtful discussion with the child and youth regarding participation in research.
  - (2) Many researchers have suggested that the assent process, or discussion with the child or youth is more important than the document
  - (3) Investigators should remember that the assent process should take into account, in both oral and written communication, the child's or youth's experience and level of understanding.
  - (4) Ultimately, the assent process should illustrate respect for the child or youth and convey the essential information the child or youth requires, in a manner the child or youth can understand, in order to make a decision about participating in the research.
  - (5) In some research projects, it may be necessary to utilize two or more Assent forms written to accommodate subjects across the age range.

- (6) Assent forms and Parental Permission forms should be written in parallel fashion in order to maintain consistency between certain guaranteed elements of privacy or privilege to parent/teacher/guardian and the child.
- v) Conducting research in the school setting.
  - (1) For research conducted in a child's school the Parental Permission form should indicate, if applicable, that the study is conducted with the approval of but not under the auspices of the school.
  - (2) In addition, the Assent form and the Parental Permission form should clearly indicate that the study:
    - (a) is not part of the child's regular curriculum and therefore the child's grade is not affected by a decision whether or not to participate; and
    - (b) does not require the participation of the child and that the child need not participate if she/he chooses not to participate.
- e) Specific procedures for conducting research with human fetuses, neonates, and prisoners involved as subjects
  - i) Based upon the educational research mission of NYCC, the submissions of IRB applications for conducting research involving human fetuses, neonates, and prisoners are not anticipated.
    - (1) The IRB Administrator will seek guidance from OHRP if and when such IRB applications are submitted.

## **16) Institutional Education Requirements**

- a) Resources
  - i) The IRB Training Videos "Protecting Human Subjects; Three Instructional Films: Evolving Concerns, Balancing Society's Mandates, and the Belmont Report" are available through:
    - (1) the research main office on VHS tape; OR
    - (2) downloaded versions provided by the IRB Administrative Assistant; OR
    - (3) at the NYCC library on VHS tape, to be viewed onsite or checked out through the media desk.
  - ii) IRB policies, [IRB Guidebook](#), [45 CFR 46](#), and other resources are available for review by any IRB members or research individual in the Research Office. Electronic copies or links to online copies are available on NYCC Online.
    - (1) Items may not be removed from the Research Department; however, copies may be made.
  - iii) NYCC Online contains all IRB application documents and directions for Investigators.
- b) All IRB members must watch the IRB training videos to obtain IRB Educational Certification
  - i) IRB members must watch the videos prior to their initial assignment to the IRB and upon reassignment of each additional 3 year term.
- c) All research personnel, to include Principal Investigators, Co-Investigators, and all other persons with access to the data must watch the IRB training videos to obtain IRB Educational Certification.

- i) Each person associated with the research project must have current Educational Certification upon submission of the protocol.
  - ii) Educational Certification is valid for three years.
  - iii) Upon expiration of the 3 year Certification period, the research individual must again watch the IRB training videos to maintain or reestablish his/her Certification to conduct research.
- d) Documentation
- i) IRB Members, Research Investigators, and Research Assistants must provide a written statement (via email, letter, fax) attesting the date they have watched the training videos.
    - (1) Training from other sources (e.g. CITI – Collaborative Institutional Training Initiative) can be substituted providing written documentation is provided.
  - ii) All written documentation will be kept on file in the Research Office by the Administrative Assistant.
  - iii) The IRB Administrative Assistant will maintain a database detailing the Educational Certification of individual IRB members and research personnel and the expiration date of the training.
    - (1) The IRB Administrative Assistant will verify Educational Certification of all research individuals upon submission of full convened, continuation, expedited and/or exempt review applications
    - (2) The IRB Administrative Assistant will verify the Educational Certification of all IRB members upon reviewing/updating the FWA and IRB Registration through OHRP, and/or upon the initial or re-appointment of IRB members.
    - (3) The IRB Administrator at the beginning of every month, will verify Educational Certification of all Research Individuals on all active protocols by reviewing the database.
  - iv) Any individual who lacks current Educational Certification will be temporarily removed from all IRB duties/activities until Certification is renewed.

## **17) Important Definitions**

- a) Appendix A

## **18) IRB Fees**

- a) There are no IRB fees for the review of protocols for conducting research with human subjects.
- b) The IRB will only review protocols for conducting research with human subjects by faculty, administrators, staff or students with an affiliation with NYCC
  - i) The IRB will review protocols for conducting research with human subjects by individuals with part-time or adjunct affiliations with NYCC.

## **19) Maintenance of IRB documentation/Record Retention**

- a) Refer to [45 CFR 46.115](#)
- b) IRB Protocol files
  - i) Open/approved protocols
    - (1) All open/approved protocols will be kept on file in lockable cabinets in the Research Main Office.

- (a) Access to the locked files is granted to IRB members, Chairperson, Administrator and Administrative Assistant; Investigators (only for the investigator's own protocol files); OHRP representatives
- (2) Each Investigator is responsible for keeping his/her own files, Informed Consent documents, and data collection files in locked cabinets.
  - (a) Protocol applications and Informed Consent documents should outline who will have access to the locked files.
  - (b) Must be available for audit by IRB representatives/OHRP
- ii) Closed/expired/disapproved protocols
  - (1) Closed/expired/disapproved protocol files will be kept in the Research Main Office in a lockable cabinet for a period of 3 years past the closed/expired/disapproved date. Files will then be destroyed by shredding.
- iii) Electronic files
  - (1) Copies of documents will be kept electronically on the Research server. Once the paper versions of the files are destroyed, the electronic versions will be copied to a CD or storage device and stored in the Research Main Office in a lockable cabinet.
- c) IRB meeting minutes
  - i) The IRB Administrative Assistant writes the minutes from the Convened IRB meeting within 2 weeks of the meeting date.
  - ii) Approval and Maintenance of meeting minutes
    - (1) The minutes of convened IRB meetings are considered confidential, and access to them is restricted and secured.
      - (a) Within NYCC, the files are accessible by the IRB Chairperson, IRB members, IRB Administrator, and NYCC's Executive Vice President and Provost.
      - (b) IRB records are accessible for inspection and copying by representatives of the sponsor of the research, authorized representatives of federal agencies or departments, and by other authorized agents of regulatory or accrediting organizations, at reasonable times and in a reasonable manner.
    - (2) Minutes are officially approved on behalf of the IRB by the IRB Chairperson.
    - (3) Approved Meeting minutes will be kept in the IRB Minutes/Members binder in a locked cabinet in the Research Main Office by the Administrative Assistant.
    - (4) Approved Meeting Minutes will be kept on file for 3 years, then destroyed.
    - (5) Copies of Approved Meeting Minutes will be sent to the Executive Vice President and Provost.
    - (6) Approved Meeting Minutes cannot be altered by anyone, including a higher authority once the minutes are approved by the IRB.
  - iii) IRB Meeting Minutes must include the following (where applicable):
    - (1) Purpose of meeting (i.e. name and PI for protocol up for review)
    - (2) Names of members present/absent/recused. If an alternate member is present, the name of the member being represented should be noted. Any members attending by phone should be noted as such.

- (3) It should also be noted whether quorum was met. If quorum is broken during the meeting, the time should be noted and the minutes should reflect the suspension of any votes and/or decisions. Names of any guests in attendance and the reason for their attendance.
  - (4) The IRB Administrative Assistant is responsible for reporting to the convened IRB decisions that occur outside a convened meeting under the rules and regulations applicable to IRB review of human subjects research.
    - (a) Summary of administrative actions and discussions (e.g. membership, member training, modifications to SOP, etc.)
    - (b) The minutes should reflect that all IRB members received a list of IRB actions (continuation reviews, expedited reviews, exempt certificates, amendment reviews, etc.) since the last convened meeting.
  - (5) Summary of all questions/concerns discussed in regards to the meeting's purpose. The name of the member posing the question should not be recorded. Any explanation or rebuttal from the PI or protocol representative should also be summarized. Where applicable, the page number of the questioned information should be noted for future reference.
  - (6) The time the PI or protocol representative leaves the convened meeting.
  - (7) Summary of deliberations by IRB members prior to voting.
  - (8) Actions taken by the IRB. All votes should be recorded as:
    - (a) Number of voting members: \_\_\_\_\_
    - (b) Number voting to approve: \_\_\_\_\_
    - (c) Number voting to oppose: \_\_\_\_\_
    - (d) Number abstained: \_\_\_\_\_
    - (e) Result of Vote: (Approved, Denied, Approved Pending Changes)
  - (9) Recording of the Start and End times of the meeting.
- d) IRB membership
- i) Membership lists/credentials will be kept in the IRB Minutes/Members binder in the Research Main Office for a period of 10 years.
  - ii) The IRB Administrative Assistant will maintain the files. The files are accessible by the IRB Chairperson, Administrator, Administrative Assistant, and OHRP representatives.
- e) IRB forms/policies/procedures/training materials
- i) All IRB documentation will be kept in the Research Main Office
  - ii) IRB membership lists, meeting schedules, and all application materials will be available on NYCC online
  - iii) Forms will be updated/reviewed annually
  - iv) The campus community and regulating bodies may access the forms by contacting the IRB Administrative Assistant or visiting the Research Main Office.

## 20) Emergency Research

- a) IRBs are constituted to protect the welfare of human research participants through a prospective ethical and scientific review and approval process.
- b) A core ethical principal for the approval of routine proposed human subject research is ensuring that respect for persons is upheld through the voluntary Informed Consent process.
- c) For routine research, IRBs are required to ensure that Informed Consent will be sought from each prospective subject or the subject's legally authorized representative and that it will be appropriately documented.
- d) Only when a study was considered minimal risk did the regulations ([45 CFR 46](#)) make provisions for waiving and altering consent and the requirement to document consent.
  - i) Some scientific studies of critical conditions were performed under the argument that the supplemental risk of a proposed therapy was minimal
  - ii) However, the lack of ability to allow a waiver for greater than minimal risk research created an obstacle to scientific advances in the care of critical patients.
  - iii) Thus, in 1996, the FDA codified, in [21 CFR 50.24](#), the exception from Informed Consent requirements for emergency research
    - (1) The regulations allow for an exception to the requirement to obtain Informed Consent from each subject, or the subject's legally authorized representative, prior to enrollment in a clinical investigation.
    - (2) The exception applies to emergency research involving human subjects who cannot give Informed Consent because of their emerging, life-threatening medical condition, for which available treatments are unproved or unsatisfactory, and where the intervention must be administered before Informed Consent from the subjects' legally authorized representative is feasible.
- e) Based upon the educational research mission of NYCC and scope of practice for chiropractors and licensed acupuncturists, the emergency research scenario permitted under [21 CFR 50.24](#) involving a particularly vulnerable population: persons with life-threatening conditions who can neither give Informed Consent nor actively refuse enrollment will not be encountered.
- f) Any claim of emergency research at NYCC will be reported to OHRP as a serious noncompliance incident.

## **21) Description of FDA related responsibilities**

- a) The NYCC IRB does not, under normal circumstances, review applications that would require FDA participation/approval/guidance.
- b) However, if such an application were received, the IRB would need to register with the FDA prior to reviewing the research.
  - i) The IRB Administrator, Chairperson, and/or Administrative Assistant will need to use the new IRB registration submission page at <http://ohrp.cit.nih.gov/efile/lrbStart.aspx>. After obtaining a submission number from the system, the new registration process will begin. Since NYCC's IRB is registered with OHRP, only FDA-specific information will be required on the registration.

## **22) Institution-specific practices**

- a) N/A

## **23) Contingency plans if the IRB cannot function**

- a) Senior Administrators at NYCC will take the following actions:
  - i) New IRB protocols will not be reviewed
  - ii) All open protocols will be suspended immediately
  - iii) Report the reason as to why the IRB is no longer functioning and provide a list of suspended protocols to OHRP following the reporting guidelines in [Section 1\(f\)\(iii\)](#) and [9\(h\)](#).