Suffolk University Institutional Review Board Policies and Procedures

Suffolk University
73 Tremont Street
Boston, MA 02108
617-725-4169

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This document describes the policies and procedures that the Institutional Review Board (IRB) at Suffolk University will follow when reviewing research with human subjects in compliance with federal requirements for the protection of research subjects.

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I. THE INSTITUTIONAL REVIEW BOARD (IRB)

The Institutional Review Board (IRB) is an independent ethical review committee mandated by the U.S. Department of Health and Human Services (DHHS). Federal regulations require each institution to implement human subject research regulations at its institution whenever its agents conduct research with human subjects. The IRB and Suffolk University research activities are subject to review by a variety of agencies, chief among them is the Office for Human Research Protections (OHRP). The Office of Research and Sponsored Programs (ORSP), under the direction of the Provost is the administrative office responsible for the University's system of protections for research participants.

Suffolk University maintains a single Federal Wide Assurance (FWA) with OHRP that commits the institution to complying with federal regulations related to human research protection. This assurance (FWA00007700) is applicable to all funded and non-funded research that is conducted or supported by Suffolk University agents such as faculty, staff and students. It stipulates that research conducted under the auspices of Suffolk University will be guided by the ethical principles established by the *Belmont Report* and appropriate ethical standards recognized by federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects, known as the *Common Rule (45 CFR 46, Subpart A)*. Suffolk University has committed to uphold other subparts of 45 CFR 46 that require additional protections for specified vulnerable populations: prisoners, children, and fetuses.

II. GUIDING DOCUMENTS AND PRINCIPLES

In establishing its procedures, Suffolk University is guided by the ethical principles outlined in two key historical source documents, the *Nuremberg Code* and the *Belmont Report.*

The ethical principles outlined in the *Nuremberg Code* and the *Belmont Report* influenced the Code of Federal Regulations 45 CFR 46 or the *Common Rule*. Together, these three documents serve as essential references for the IRB that reviews all Suffolk University research proposals involving human subjects. These policies and procedures have been updated to be consistent with the final rule update that was published in the Federal Register on January 19, 2017 and required to be put into effect by January 19, 2019.

Important Definitions

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed NOT to be research:

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is

collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those

associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

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

NOTE: If an investigator is unsure of whether or not a project meets the definition of human subjects research and requires IRB oversight s/he should strongly consider seeking consultation from the IRB Chair. It is helpful to send a 1-2 page description of the project to the Chair. The IRB Chair, with or without consulting the Board, will assist in determining whether or not the project requires IRB oversight. It may be prudent for the investigator to obtain a letter from the IRB Chair indicating that the project has been deemed as not meeting the federal regulations of research and does not require IRB oversight.

REGULATORY REQUIREMENTS FOR POLICIES, PROCEDURES AND DOCUMENTS

HHS regulations at 45 CFR 46.103(b)(4) and (5) require that institutions have written IRB procedures for each of the following:

1. The procedures which the IRB will follow for conducting its initial review of research;
2. The procedures which the IRB will follow for conducting its continuing review of research;

3. The procedures which the IRB will follow for reporting its findings and actions to investigators and the institution;
4. The procedures which the IRB will follow for determining which projects require review more often than annually;
5. The procedures which the IRB will follow for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review;
6. The procedures which the IRB will follow for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject; and
7. The procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, any Department or Agency head, and OHRP of:
   a. Any unanticipated problems involving risks to subjects or others (hereinafter referred to as *unanticipated problems*);
   b. Any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and
   c. Any suspension or termination of IRB approval.

GUIDANCE ON OPERATIONAL DETAILS

Written IRB procedures should provide a step-by-step description with key operational details for each of the above procedures. Important operational details for the above procedures should include:

1. A description of any primary reviewer system used for initial review, continuing review, review of protocol changes, and/or review of reports of unanticipated problems or of serious or continuing noncompliance;
2. Lists of specific documents distributed to primary reviewers (if applicable) and to all other IRB members for initial review, continuing review, review of protocol changes, and review of reports of unanticipated problems or of serious or continuing noncompliance;
3. Details of any process (e.g., a subcommittee procedure) that may be used to supplement the IRB's initial review, continuing review, review of protocol changes, and/or review of reports of unanticipated problems or of serious or continuing noncompliance;
4. The timing of document distribution prior to IRB meetings;
5. The range of possible actions taken by the IRB for protocols undergoing initial or continuing review and protocol changes undergoing review;
6. A description of how expedited review is conducted and how expedited approval actions are communicated to all IRB members;
7. A description of the procedures for:
   a. Communicating to investigators IRB action regarding proposed research and any modifications or clarifications required by the IRB as a condition for IRB approval of proposed research; and
   b. Reviewing and acting upon investigators' responses;
8. A description of which institutional office(s) and official(s) are notified of IRB findings and actions and how notification to each is accomplished;

9. A description, if applicable, of which institutional office(s) or official(s) is responsible for further review and approval or disapproval of research that is approved by the IRB; please note that, in accordance with HHS regulations at 45 CFR 46.112, no other institutional office or official may approve research that has not been approved by the IRB;
10. A specific procedure for how the IRB determines which protocols require review more often than annually, including specific criteria used to make these determinations (e.g., an IRB may set a shorter approval period for high-risk protocols or protocols with a high risk:potential benefit ratio);
11. A specific procedure for how the IRB determines which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review, including specific criteria used to make these determinations (e.g., such criteria could include some or all of the following:

    a. Randomly selected projects;
    b. Complex projects involving unusual levels or types of risk to subjects;
    c. Projects conducted by investigators who previously have failed to comply with the requirements of the HHS regulations or the requirements or determinations of the IRB; and
    d. Projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources);
12. A description of what steps are taken to ensure that investigators do not implement any protocol changes without prior IRB review and approval, except when necessary to eliminate apparent immediate hazards to subjects (e.g., this might be addressed through training programs and materials for investigators, specific directives included in approval letters to investigators, and random audits of research records);
13. A description of which office(s) or institutional official(s) is responsible for promptly reporting to the IRB, appropriate institutional officials, any supporting Agency or Department heads, and OHRP any:

    a. Unanticipated problems;
    b. Any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and
    c. Any suspension or termination of IRB approval;
14. A description of the required time frame for accomplishing the reporting requirements in the preceding paragraph; and
15. The range of possible actions taken by the IRB in response to reports of unanticipated problems or of serious or continuing noncompliance.

The Chair or his/her designee may occasionally evaluate the operational procedures of the IRB using the OHRP Q&A Self-Assessment Tool http://www.hhs.gov/ohrp/education/qip/ohrp_ded_qatool.html.

III. ROLE AND AUTHORITY OF THE IRB

The role of the IRB is to protect the rights and welfare of human research participants involved in research activities conducted under the auspices of Suffolk University. The IRB conducts prospective review of proposed research and monitors continuing research in order to safeguard the rights and welfare of participants. In carrying out its role and responsibilities Suffolk and the IRB serves two primary functions:

1. To determine and certify that all projects approved by the IRB conform to the regulations and policies regarding the health, welfare, safety, rights and privileges of human research participants; and
2. To assist Principal Investigators (PIs) in conducting ethical research that complies with federal regulations in a way that permits the safe accomplishment of the research activity.

The IRB has the authority to:

1. **approve** a study**,**
2. **require modifications to secure approval** of a study**,**
3. **disapprove** all research activities that fall within its jurisdiction as specified by both federal regulations and local institutional policy**,**
4. **suspend** a study due to noncompliance,
5. **terminate** a study due to noncompliance, or
6. **observe research,** have a third party observe and monitor research activities to protect human participants. In so doing, the IRB also has the authority to require progress reports and oversee the conduct of studies.

Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of the institution. However, those officials may not approve research if it has been disapproved by the
IRB. Research that has been reviewed and approved by the IRB may be subject to continuing IRB review at least annually or more frequently if specified by the IRB.

IV. COMPOSITION AND MANAGEMENT OF THE IRB

Suffolk University's single FWA from OHRP covers the operation of one institution-wide IRB. Members shall be appointed to the IRB in accordance with the requirements as set forth at 45 CFR §46.107. The IRB will be comprised of a minimum of five regular voting members, of which one must be unaffiliated with the University.

The IRB shall be sufficiently qualified through the experience and expertise of its members but will not consist entirely of members of one profession. The IRB shall be diverse in its composition and consideration will be given to the race, gender, and cultural background of each member. In addition, the IRB composition will be sensitive to such issues as community attitudes, promoting respect for its advice

and counsel in safeguarding the rights and welfare of human subjects.

At least one member of the IRB must have primary concerns in scientific areas and at least one must have primary concerns in non-scientific areas. Members whose training, background and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist, while members whose training, background and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist. When an IRB encounters studies involving science beyond the expertise of the members, the IRB will use a consultant to assist in the review.

It is possible for a member to fill two roles; for example, a member could be otherwise unaffiliated with the institution and have a primary concern in a non-scientific area. This individual would satisfy two of the membership requirements of the regulations.

In addition to possessing the professional competence necessary to review specific research activities, the IRB shallbe able to ascertain the acceptability of proposed research in terms of regulations, applicable law and standards ofprofessional conduct and practice. The IRB will therefore include persons knowledgeable in these areas. If the IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, or handicapped or mentally disabled persons, then consideration will be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these populations.

4.1 Other Review Committees and Discretionary Use of Outside Experts

Research subject to review by other, additional oversight committees or authorities who share responsibility related to protection of research participants (e.g., Dissertation Committee, Risk Management, and General Counsel)should occur prior to IRB review. The IRB will not review studies that are required to obtain approval fromadditional oversight bodies until documentation of approval from the additional committee is provided to the IRB.

Consultants are not members of the IRB and may not vote on protocols. The IRB may invite individuals with special expertise external to the IRB to assist in the evaluation of complex issues on specific protocols. These experts are considered non-voting consultants to the IRB and do not affect the determination of a quorum.

4.2 Term of Appointments

In general, IRB membership is a two-year commitment. The terms of regular voting IRB members will, to the extent possible, be staggered with three to four members completing their terms each academic year.

4.3 Meeting Attendance and Determination of Quorum

A quorum will be constituted by more than half of the number of the active regular voting membership, including one member whose primary focus is in a non-scientific area. IRB members currently on inactive status will not count toward the determination of quorum. When a quorum of regular members is not present an alternate member may incur full responsibilities of membership including voting privileges. If a quorum is lost during a meeting, then the Board may not take further official action or vote until the quorum is restored. When a quorum is not present an IRB meeting can proceed; however, no official action or vote can be taken without a quorum present.

4.4 Placing IRB Members on Inactive Status

Periodically IRB members need to take an extended leave of absence (e.g., maternity/paternity leave, sabbaticals, health leaves, etc.) from IRB service. The purpose of this policy is to specify a procedure of placing an IRB member on inactive status. Inactive status means that the member is still a member of the IRB, but their absence will not affect quorum. They will be noted on meeting minutes as inactive status, rather than merely absent.

1. Criteria for Inactive Status:
   Current active regular voting members of the IRB can petition the IRB Chair to be placed on inactive status if they anticipate an upcoming period of time lasting at least four months but no more than 12 months during which they will not be able to attend IRB meetings or complete regular duties of an active voting member (e.g., complete reviews in a timely manner).

2. Petitioning to be Placed on Inactive Status
   Current active voting members who wish to be placed on inactive status should make this request in writing to the IRB Chair (an email request will suffice). The request should be made as soon as possible, preferably at least six weeks before the placement on inactive status will begin. The request should include the start and end date of the period that the member would like to be placed on inactive status. It should also include a brief description of the reason for the inactive status request.

3. Decisions About Placing Members on Inactive Status
   The IRB Chair has the authority to approve a request to place a member on inactive status on her/his own but is required to consult with the Vice Chair of the IRB, the Assistant Vice Provost of The Office of Research and Sponsored Programs, and/or the department chair (or equivalent) of the member making the request (if necessary) prior to disapproving a request. The IRB Chair will inform the member of the decision in writing (email is sufficient) or during a regularly convened IRB meeting.

V. INITIAL REVIEW OF RESEARCH

5.1 Submission and Review of Research Protocols

The IRB must review all non-exempt human subjects research at a convened meeting, unless the research qualifies for the expedited review process. The IRB Chair or his/her designee will make the determination for the appropriate category of review.

All Human Subjects Research Applications (HRSA) must be endorsed by the PIs and appropriate administrators (e.g., Department Chair for College of Arts and Sciences and Sawyer Business School, Research Dean for Law School, Provost). HRSAs not properly endorsed will be returned without review.

In addition to proper endorsements, PIs must complete the CITI Human Subjects Training (CITI) prior to submitting a protocol for review by the IRB.

Human Subjects Research Applications are processed using IRBNet. Researchers need to register with IRBNet to access forms and submit applications. Information about IRBNet can be found at http://www.suffolk.edu/explore/16529.php

CITI training information can be found here http://www.suffolk.edu/explore/16532.php

If assistance is required to navigate either IRBNet or CITI researchers should contact ORSP staff at http://www.suffolk.edu/explore/16520.php

5.2 Administrative Requirements for the Submission of a Protocol

To ensure the most timely and efficient review of a protocol, the following administrative guidelines should be followed with respect to protocol submission:

1. Applications must be typed and submitted on the appropriate form (Human Research Subject Application).
2. All requisite PIs and appropriate administrators should endorse applications.
3. Applications must be complete and accurate, thoroughly addressing the items listed on the application.
4. Training in the Protection of Human Subjects in Research through CITI must be completed. Documentation of completion of the CITI training and dates must be submitted with the application. In those instances where a group of students are being used as research assistants for which human subjects are involved, a list of the students and the completion dates of their training must be included on the IRB application. Initial training is valid for a three-year period after which time refresher training must be completed.
5. All applicable supporting documents must be included with the application (informed consent, request for waiver of elements of informed consent, or request for waiver of written informed consent; parental

   permission; test or survey instruments; child assent scripts; letters from school principals or school district superintendents; certificates of confidentiality, recruitment materials such as flyers, etc.)
6. Application should clearly address issues of anonymity and confidentiality.
7. Application should clearly address the security and retention of data. The storage of research data at an off-campus location, such as at home, is NOT authorized.
8. All documents must be submitted using IRBNet.

5.3 Required Documents

To ensure the most efficient review of a protocol the following documents should be included with each protocol submission:

- Human Subjects Research Application (HSRA)
- Recruitment materials (letters, advertisements, posting, e-mail announcements, etc.)
- Informed Consent Form(s), Assent Forms or Waiver of Requirements of Informed Consent Forms
- Test or survey instruments, if applicable
- Letters from school principals or school district superintendents, if applicable
- Certificates of Confidentiality, if applicable
- Sponsor's Protocol, if applicable
- Grant application, if applicable
- Optional: Detailed Research Proposal or Protocol All information necessary for the IRB to sufficiently review the project should be contained in the HRSA and other materials. A detailed proposal or protocol can be submitted if other materials (such as a dissertation proposal or other project proposal) provides information that will help the IRB. The HRSA form can reference the research proposal (e.g., see proposal for a more comprehensive literature review), but this should be done prudently and sparingly so that most of the relevant information is contained in the HRSA or other submitted materials.

5.4 Protocol Review Timeline

Upon submission via IRBNet, all IRB applications will be first processed to ensure that the application is complete and in order. Processing typically takes no more than 3 business days. Once the processing is complete, the application will be assigned for review. Once assigned for review, IRB members will have 10 business days to complete all exempt and expedited reviews. After IRB members complete a review, the IRB Chair (or designee) will summarize the reviews and notify the investigators of the outcome (approve, modifications requested, referred to the full board). The time that it will take for final IRB approval will vary considerably depending on the quality of the application (i.e., the degree to which it is complete, clear, and organized) and any issues that need to be resolved.

Applications not meeting criteria for exempt or expedited reviews (i.e., full board reviews) must be discussed at a regularly convened IRB meeting with a quorum present. For consideration of a full board review, the protocol must be received four weeks prior to the scheduled IRB meeting. See the University's IRB website for a posting of the meetings.

5.5 IRB Determinations

All applications reviewed by the IRB will result in one of the four following determinations. The IRB Chair or his/her designee will notify the PI in writing of the IRB determination.

5.5.1 Approved

The PI shall be informed in writing by the IRB Chair or ORSP staff that the research was approved. A research project is approved only if all the criteria for IRB approval are satisfied and no additional changes are required. Study records must be retained for at least three years.

For IRB approval of expedited or full board reviews, the regulations specify that the following requirements are satisfied:

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

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, §ll.116.

(5) Informed consent will be appropriately documented or appropriately waived in accordance with §ll.117.

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

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

(i) The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.

(8) [Note: This eighth requirement pertains to research involving secondary analysis of data collected for other purposes, which can receive a limited review (i.e., 1-7 above do not

necessarily need to apply. Essentially, this is the criteria for Exemption Category 7.] For purposes of conducting the limited IRB review required by §ll.104(d)(7)), the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section, and shall make the following determinations:

(i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of §ll.116(a)(1)–(4), (a)(6), and (d);

(ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with §ll.117;

(iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

IMPORTANT NOTE: When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

5.5.2 Conditionally Approved

The PI shall be informed by IRB Chair or ORSP staff of any specific action(s) required of the PI in order to secure approval. The IRB may ask the PI to (a) confirm specific assumptions or understandings on the part of the IRB regarding how the research will be conducted; (b) make specified changes to the research protocol and informed consent form and/or (c) submit additional documents. A study may be conditionally approved only if, based on the assumptions or specified changes requested, the IRB is able to make all of the determinations required for approval and applicable subparts. The IRB may designate the IRB chairperson or other individuals with appropriate expertise or qualifications to review responsive materials from the PI and determine that the conditions have been satisfied. There must be full compliance with the required revisions or clarifications before the research can be approved.

5.5.3 Tabled or Deferred

The PI shall be informed by IRB Chair or ORSP staff of the motion to table or defer the research to a subsequent convened meeting. This motion shall result if the IRB is unable to review or vote on an application. This may occur if the quorum is lost, pertinent documents are unavailable, additional information is required to make the necessary determinations for approval and/or the scope of IRB expertise is not considered sufficient for appropriate decision-making.

5.5.4 Disapproved

The application is not approved by the IRB for reasons specified in a letter of disapproval to the PI from IRB Chair or ORSP staff. A study is not approved if the IRB has enough information to make the necessary determinations of approval but believes the research protocol does not meet

these requirements and is unable to provide suggested changes. The PI may respond to the IRB with written justification for a reversal of the decision or a proposal to change the conditions underlying the determination to disapprove the research, which may be a basis for IRB reconsideration.

Upon receipt of final approval from the IRB, ORSP staff will stamp approved Informed Consent Document(s) and other materials (e.g., letters to subjects, ads) with the IRB approval stamp that includes the date of approval and the date of expiration (if applicable). These documents are sent to the PIs along with the final approval letter that includes pertinent information. The letter reminds PIs that changes in research activity may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to subjects.

5.6 Preliminary Review of Protocols

A designated ORSP staff member with appropriate expertise or qualification will conduct a preliminary screening of the Human Subjects Research Application (HRSA). The HRSA is reviewed for completion and accuracy of the basic application and for the inclusion of all requisite supporting documents. Suggestions may be made to PIs for administrative revisions involving points of clarification or elaboration on items that may be viewed as problematic during IRB review.

The type of review that a study receives is commensurate with the level and type of risk to participants involved. These risks include the probability and severity of possible harm to the participants' physical, psychological, social, or economic welfare.

Federal regulations define minimal risk as risk that is *"…the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."*

This definition of minimal risk serves as a benchmark to determine whether proposed studies require review by a convened IRB. Other factors may be considered in determining the type of review.

5.7 Fully Convened Board Review

The IRB must review research protocols at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. A primary reviewer system will be used for new applications reviewed by the convened IRB.

The review of research must be substantive and meaningful with a recorded vote for, against, abstentions and recusals from each study. The minutes of IRB meetings should document with sufficient detail the separate deliberations, actions, and votes for each protocol undergoing review by the convened IRB in addition to a written summary of the discussion of controverted issues and their resolution.

The ORSP staff initially screen all HRSAs for convened review and documents are uploaded to IRBNet for all IRB members for review and action at the next regularly scheduled meeting. There are a number of conditions in which a convened review by the full Board is warranted. Review by the full Board at a convened meeting is required but not limited to:

- A protocol that involves more than minimal risk of harm to subjects (which includes physical, emotional, social, psychological, or financial risk)
- A certificate of confidentiality is requested
- Research involves recruitment of vulnerable populations
- A conflict of interest or potential conflict of interest exists with an assigned expedited reviewer or reviewers

5.7.1 Primary/Secondary Reviewer System

The IRB Chair or his/her designee assigns a primary and secondary reviewer for all expedited and full-board reviews of new protocol submissions. All members, including the IRB Chair, may serve as a primary reviewer. In selecting the primary reviewer, consideration is given to the individual's knowledge of the subject area embodied in the proposal. If no IRB member has adequate knowledge or experience to review a given protocol, a consultant with appropriate expertise and experience may be engaged to conduct the review.

The primary and secondary reviewers conduct in-depth review of all items required for IRB submission of a new application, including the Informed Consent Document(s), and all supplemental materials (including, if applicable, the grant application).

The primary and secondary reviewers are strongly encouraged to contact the IRB Chair or designated ORSP staff member in advance of the board meeting to request any additional information or clarification. The IRB Chair or designated ORSP staff member is responsible for contacting the PI to make the request and obtain any necessary additional information. The primary reviewer leads the discussion of the project. No IRB member, including the primary and secondary reviewers, may participate in the review of any project in which the member has a conflict of interest.

Primary and secondary reviewers are provided checklists to ensure that all criteria for approval of research have been fulfilled. Each reviewer is expected to upload the appropriate checklist to IRBNet so it can become part of the complete project file.

5.7.2 Timing of Document Distribution prior to IRB Meetings

All attending IRB members will receive all documents necessary to conduct a thorough review one week prior to the meeting date. All documents are made available on IRBNet. Members can use their username and password to access all documents for review on IRBNet. Any nonaffiliated member can create a username and password to access IRBNet.

Paper copies of relevant materials will not be provided.

Additional materials uploaded to IRBNet or included in the meeting packets include a copy of the previous month's meeting minutes, a list of all exempt and expedited actions taken since the previous month's meeting and a copy of the meeting agenda.

5.8 Expedited Review

Expedited review is a procedure through which certain kinds of research may be reviewed and approved without convening a meeting of the IRB. Federal regulations make provisions for certain categories of research to be reviewed through an expedited procedure if the research involves no more than minimal risk. Expedited review is intended to enable the institution to conserve administrative resources, provide timely reviews and focus the convened meetings of the IRB on those research activities involving greater risks or ethical complexities.

The IRB may also use the expedited review procedure to review minor changes in previously approved research during the period covered by the original approval. Under an expedited review procedure, review of research may be carried out by the IRB Chairperson or by one or more experienced members of the IRB designated by the Chairperson.

When an expedited review procedure is used, a list of research protocols approved under the expedited review procedure and a summary of the project and expedited action taken is provided to the IRB prior to or during the next regularly scheduled convened meeting. The IRB is free to request additional information from the Chair or designated ORSP staff member regarding the expedited determination of a particular protocol.

Research protocols that qualify for expedited review must meet two conditions: the research must be determined to be minimal risk; and all proposed research activities must be included in the list of eligible categories of expedited research as established by the DHHS for this purpose.

The expedited review procedure may be carried out by the IRB Chair, or by one or more IRB members designated by the Chair. Expedited reviewers possess all the same authorities as the full IRB to approve, modify, or conditionally approve the proposed research activities, except the authority to disapprove a research activity. An expedited reviewer always has the option of referring the protocol for full IRB review if they think that: 1) more than minimal risk is present, 2) the project does not meet one of the categories for expedited review, 3) the presence of other issues related to the well-being and rights of participants necessitate a full board discussion/review, 4) and/or the project warrants a decision of disapproval. A research activity may be disapproved only after review in accordance with the ordinary, non-expedited procedure (i.e., full board review) set forth in 45 CFR 46.108(b). Regarding the distinction between a recommendation of modifications to a submission or a request for further information versus a recommendation of conditional approval for expedited actions, if an IRB member recommends a modification or requests for information the reviewer is indicating that s/he would like to review and approve the investigators' response prior to recommending approval. A recommendation of conditional approval by the reviewers indicates that so long as the IRB Chair or a designee of the IRB Chair reviews the investigator's responses to the conditions stated and determines that the investigator has adequately addressed these conditions, then full-approval can be granted by the IRB Chair without the reviewers' reviewing the investigators response. Expedited reviews are done on an ongoing basis,

meaning that the review is accomplished independently of the IRB meeting schedule.

Protocols that qualify for expedited review undergo a preliminary review by an ORSP staff member with appropriate expertise or qualification upon receipt, and if found to be accurate and complete, they are then processed for review by the designated reviewer. Expedited reviewers may, after review, refer applications for convened review.

Consultants may assist the IRB Chair in making decisions in expedited review, but expedited review cannot be performed solely by persons who are not voting members of the IRB.

5.8.1 Applicability

To be eligible for expedited review, a research activity must be determined to be no more than "minimal risk" (See above definition of minimal risk).

Reviewers should take into account any protective measures included in the research design as part of the process of determining if the proposed research involves no more than minimal risk.
However, some social and behavioral studies involve more than minimal risk, even though they include such protective measures.

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

Research activities that present no more than minimal risk to human subjects, and involve only procedures listed in one or more of the nine categories presented below, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects. The categories in this list apply regardless of the age of subjects, except as noted, and pertain to both initial and continuing IRB review.

5.8.2 Categories of Research for Which Expedited Review Procedure Can Be Used

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
    a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. [Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.]
    b. Research on medical devices for which: an investigational device exemption application (21 CFR Part 812) is not required; or 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 subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples include:
   a. Hair and nail clippings in a non-disfiguring manner;
   b. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
   c. Permanent teeth if routine patient care indicates a need for extraction;
   d. Excreta and external secretions (including sweat);
   e. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
   f. Placenta removed at delivery;
   g. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
   h. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
   i. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
   j. Sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:
   a. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects' privacy;
   b. Weighing or testing sensory acuity;
   c. Magnetic resonance imaging;
   d. Electrocardiography, electroencephalography, thermography, detection of naturally

   e. occurring radioactivity, electroretinography, ultrasound, diagnostic infrared

imaging, doppler blood flow, and echocardiography;

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

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). [NOTE: Some research in this category may be exempt from the DHHS regulations for the protection of human 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 or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. [NOTE: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. 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 the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; or
   b. Where no subjects have been enrolled and no additional risks have been identified; or
   c. Where the remaining research activities are limited to data analysis.

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

5.9 Exempt from IRB Review

The Common Rule exempts some biomedical and many social and behavioral research studies from its regulatory requirements, including the requirement of IRB review. Research that is thought to be exempt from IRB review is to be submitted via IRBNet on an Human Subjects Research Application. It is the responsibility of the Institutional Review Board (IRB) or other designated institutional official(s), not the PI, to determine whether research activities qualify for exemption. The IRB Chair (or designee) initially screens all requests for exemption from IRB review and has the authority to make these determinations. Although research under exemption categories do not need to be reviewed and approved by the IRB, the *Belmont Principles* of respect for persons, beneficence and justice still apply. Unless otherwise required by department or agency heads, research activities in which the only involvement of human participants will be in one or more of the following eight categories are exempt

from the policies outlined in the federal regulations regarding the protection of human subjects and review by the IRB:

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

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
    i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
    ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
    iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § ll.111(a)(7).

3. (3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
    a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
    b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
    c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § ll.111(a)(7).

    (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

    (iii) If the research involves deceiving the subjects regarding the nature or purposes of the

research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

    i. The identifiable private information or identifiable biospecimens are publicly available;
    ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
    iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of ''health care operations'' or ''research'' as those terms are defined at 45 CFR 164.501 or for ''public health activities and purposes'' as described under 45 CFR 164.512(b); or
    iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

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

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

i. If wholesome foods without additives are consumed, or
ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

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

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

Any research pertaining to survey or interview procedures or observations of public behavior in which the investigator participates that involves children and that would normally be exempt under category 2 cannot be exempt from IRB review.

The regulations define children as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. Massachusetts's law considers any person under 18 years old to be a child.

5.9.1 Determination of Exemption

A request for exemption means that the researcher believes that a proposed research activity does not require IRB review and approval. The university, however, is still able to choose to review all such activities, whether funded or not, and certify that the research meets the federal, state, local and Suffolk University requirements for exemption and that risks to participants have been minimized and proper protections have been implemented (when applicable). To fulfill requirements for the proper review of research, PIs cannot "self-exempt" from IRB review. Evaluation and certification of a protocol for exemption status will be performed by IRB Chair or another designated member.

The IRB Chair or designee will not consider any research exempt that involves children (see children's exempt section below), prisoners (see prisoners exempt section below), sensitive aspects of subject's behavior, or sensitive surveys.

1. The IRB Chair or designee will not consider any research exempt that involves a test article regulated by the FDA unless the research meets the criteria for exemption described in 45 CFR 46.101(b)(6).

2. Although research under exemption categories do not need to be reviewed and approved by the IRB, the *Belmont Principles* of respect for persons, beneficence and justice still apply. The IRB Chair, or designee, has the authority to and will review the proposed research and will validate or decline the PI's request for exemption, ensure that risks to individuals are minimized, and confirm that the research meets ethical standards. The IRB will document the review and action of the Research Compliance Coordinator or IRB Chair, or designee, including the category specified in 45 CFR 46.101(b)(1-6).Exempt research does not need to fulfill all of the required conditions of IRB approval (see section 5.5.1 above). However, projects that meet exempt criteria will be reviewed to assure: 1) The risk level is appropriate, 2) If necessary, proper informed consent procedures are adopted, and 3) proper procedures have been put in place to protect the confidentiality of the data, particularly with regards to any identifiable information.

3. The IRB Chair or ORSP staff will promptly notify the PI in writing or via email of its decision regarding the research. If it is determined that the research is not exempt or if modifications are required the IRB Chair or ORSP staff will include in its written notification a statement of the reason for its decision and give the PI an opportunity to respond in writing.

4. If the IRB Chair, or designee, determines that an application does not qualify for exemption, the application will be processed either through Expedited Review or by full IRB review.

5. At the time the protocols are deemed to be exempt, PIs are reminded of the responsibility to report all modifications and unanticipated problems involving risks to subjects or others in accordance with IRB written procedures.

5.9.2 Exemption of Research Involving Children

Research that involves children and falls into categories 1 - 7 described previously may be found to be exempt by the IRB. However, the exemption category 2 (45 CFR 46.101(b)(2)) above, pertaining to survey or interview procedures or observations of public behavior, does not apply to research involving children, except for minimal risk research involving the observation of public behavior in a situation where privacy is not expected and no identifying information is collected.

5.9.3 Exemption of Research Involving Prisoners

Research under categories 1-7 described previously is not exempt if it involves prisoners.

Research involving prisoners typically must be reviewed by the convened IRB. In some instances, research involving prisoners might be appropriate for an expedited reviews; however, an expedited review of research involving prisoners must involve a prisoner representative.

5.10. Issues Considered by the IRB during the Review Process

5.10.1 Study Design

The IRB will examine the soundness of the study design insofar as it impacts the rights and welfare of the human subjects. The responsible conduct of research dictates that if a research study is so methodologically flawed that little or no reliable information will result, it is unethical to put subjects at risk or even inconvenience them through participation in such a study. The IRB may request an expert consultant review or defer to scientific review committees, including the PI's departmental review, in order to determine whether a study design places subjects at unnecessary risk. The IRB may approve a study design that involves deception or withholding of information, if the strategies are justified and the protocol provides for a post-study debriefing of the subjects.

5.10.2 Risks and Benefits

The IRB will assess whether the risks to subjects are reasonable in relation to the anticipated benefits, if any, to the subjects, and the importance of the knowledge reasonably expected to result from the research. The IRB will consider only those risks and benefits that may result from the research as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research. The federal regulations do not allow the IRB to evaluate the possible long-range effect of applying the knowledge gained through the research. For example, the possible effects of the research on public policy. The IRB is required to review any possible benefits a subject may derive from participation in research, or the benefits of new knowledge that may justify asking a person to undertake the risks of the study.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. In the prison population minimal risk is *"the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or the routine medical, dental, or psychological examination of healthy persons."* This definition should be considered when determining which level of IRB review might apply to a particular research protocol.

5.10.3 Equitable Selection of Subjects

The selection of subjects should be equitable and free of any coercion, both explicit and implied. The IRB will consider the purpose of the research and the setting of the research. The IRB will closely examine research involving vulnerable subject populations, such as children, prisoners, subjects with cognitive disorders, or economically or educationally

disadvantaged subjects. PIs should detail any extra precautions taken to safeguard the rights and welfare of subject populations.

5.10.4 Identification of Subjects and Confidentiality

The IRB is required to review the method for prospective identification and recruitment of subjects. They will examine the means of identifying and contacting potential subjects and the methods for ensuring the subjects' privacy and confidentiality. PIs are required to submit plans for ensuring the privacy and confidentiality of subjects.

5.10.5 The Informed Consent and Assent Process

The IRB will carefully review informed consent and assent processes; when, where and how consent or assent is obtained, and any provisions for the on-going consent or assent of subjects. Informed consent shall be obtained only under circumstances that provide the prospective subjects or the subject's legally authorized representative with sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion and undue influence. Generally, the IRB will not dictate the procedure to be used to obtain informed consent or assent, but reserves the right to do so if deemed necessary.

The following describes the federal regulations regarding informed consent:

General requirements for informed consent:

(1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.

(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

(3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.

(4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

(5) Except for broad consent (i.e., for storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens):
(i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that

facilitates comprehension.

(ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

(6) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Basic elements of informed consent.
(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others that may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be
advantageous to the subject;

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

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research

studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional elements of informed consent.
(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;

(3) Any additional costs to the subject that may result from participation in the research;

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

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

(6) The approximate number of subjects involved in the study;

(7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.

Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted as an alternative to the informed consent requirements described above. Researchers who desire to obtain broad consent are encouraged to consult the federal regulations on obtaining broad consent.

5.10.6 Subject Safety

Whenever appropriate, the IRB will require a research plan make adequate provisions for monitoring the data collected to ensure the safety of subjects. The IRB will review who has

been identified as having the primary responsibility for analyzing individual events to determine whether the study should be modified to minimize risk to current or future research subjects.

5.10.7 Frequency of Review

Projects that are deemed exempted research do not require continuing review. As of July 19, 2018, expedited reviews no longer require continuing review. We are still performing continuing reviews on approved expedited reviews prior to this date. Project receiving approval via full board procedures require an annual review. The IRB may determine that a project requires more than annual review and may require an appropriate monitoring procedure that could include monitoring of the consent process, observation of the research procedures, formulation of a data and safety monitoring plan, and review of research related records.
Reasons for requiring IRB review more frequent than annually may include but are not limited to:

- Risk level of study procedures
- Securing the confidentiality of sensitive information
- Monitoring the safety of subjects
- Ensuring participants are free from undue influence or coercion

5.10.8 Surveys, Questionnaires, Interview Materials, or other Testing Instruments

These materials should be reviewed to ensure that they adequately reflect the purpose and procedures in the study and handle sensitive issues appropriately. If the materials ask for information that, according to local law, would require reporting (e.g., elder, spouse or child abuse), the consent form should explain this exception to the promise of subject confidentiality. There are, however, a variety of psychological and other measures which are considered "standard" and, while they cannot be modified, reviewers should still indicate if use of a given measure is appropriate for a particular study. In particular, reviewers should consider if survey answers, if known, would impact a subject's reputation, insurability, etc.

5.10.9 Coercion and Undue Influence

Coercion occurs when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance. For example, a PI might tell a prospective subject that he or she will lose access to needed health services if he or she does not participate in the research.

Undue influence, by contrast, often occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance. For example, a PI might promise psychology students extra credit if they participate in the research. If that is the only way a student can earn extra credit, then the PI is unduly influencing potential subjects. If, however, she offers comparable non-research alternatives for earning extra credit, the possibility of undue influence is minimized.

Undue influence also can be subtle. For example, patients might feel obligated to participate in research if their physician is also the PI, or students might feel pressure to participate in research if everyone else in the class is doing so. Because influence is contextual, and undue influence is likely to depend on an individual's situation, it is often difficult for IRBs to distinguish undue influence. It is up to the IRB to use its discretion in determining which circumstances give rise to undue influence. For example, an IRB might consider whether the informed consent process will take place at an appropriate time and in an appropriate setting, and whether the prospective subject may feel pressured into acting quickly or be discouraged from seeking advice from others.

Because of their relative nature and lack of clear-cut standards on the boundaries of inappropriate and appropriate forms of influence, PIs and IRBs must be vigilant about minimizing the possibility for coercion and undue influence. Reasonable assessments can be made to minimize the likelihood of undue influence or coercion occurring. For example, IRBs may restrict levels of financial or nonfinancial incentives for participation and should carefully review the information to be disclosed to potential subjects to ensure that the incentives and how they will be provided are clearly described. Known benefits should be stated accurately but not exaggerated, and potential or uncertain benefits should be stated as such, with clear language indicating how much is known about the uncertainty or likelihood of these potential benefits.

The IRB should be especially attentive to reviewing research protocols when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, mentally disabled persons, or economically or educationally disadvantaged persons. In these instances additional safeguards are to be included in the study to protect the rights and welfare of these subjects. Thus, inducements that would ordinarily be acceptable in some populations may become undue influences for these vulnerable subject groups.

5.10.10 Payment to Research Subjects

It is not uncommon for subjects to be paid for their participation in research, especially in early phases of investigational drug, biologic or device development. Payment to research subjects for participation in studies must not be considered a benefit. Financial incentives are often used when health benefits to a subject are remote or non-existent. The amount and schedule of payment must be presented to the IRB at the time of the initial review. The IRB will review both the amount of the payment and the proposed method and timing of disbursement to assure that neither are coercive nor present undue influence.

Difficult questions must be addressed by the IRB when considering payment to research subjects. For example, how much money should research subjects receive, and for what should subjects receive payment, their time, the inconvenience, discomfort or some other consideration? The IRB must consider whether any aspect of the proposed remuneration will be an undue influence, thus interfering with the potential subject's ability to give voluntary informed consent. In no case should remuneration be viewed as a way of offsetting risks; that is, it should not be considered a benefit to be weighed against study risks. The level of remuneration should not be so high as to cause a prospective subject to accept risks that he

or she would not accept in the absence of the remuneration. The same principle would apply to remuneration offered to parents whose children are prospective subjects.

5.10.11 Deception

As a rule, deception of subjects is not considered ethical in human subject research and especially in relation to the idea of informed consent. In certain circumstances, the IRB may approve the use of deception when it is absolutely necessary for the outcome of the study and does not put the subjects at inappropriate risk. In such instances, PIs may be asked to debrief subjects upon completion of their participation and this debriefing should disclose the deception used and why the use of deception was necessary.

5.10.12 Financial Conflict of Interest in Research

Financial conflict of interest in research is the existence of a significant financial interest that an independent observer might reasonably determine could affect or compromise, or appears to affect or compromise, the design, conduct, reporting or management of research. The effect or compromise contemplated might relate to the collection, analysis, and interpretation of data, the hiring of staff, the procurement of materials, the sharing of results, the choice of protocol, the involvement or consenting of human participants, or the use of statistical methods.

The IRB must be concerned about potential for biased judgment or other abuse when IRB members, PIs or study staff have a financial obligation or interest that may pose a conflict of interest which competes with the obligation to protect the rights and welfare of human subjects. The IRB will refer to Suffolk's policy for financial conflict of interest in research when reviewing projects. The IRB may request additional information regarding the management plan put into place when a financial conflict of interest exists.

5.11 Protocol Revisions Prior to IRB Approval

Revisions to new human subject applications may be required prior to obtaining final IRB approval. Correspondence is sent to the PI detailing requests for revisions, clarification, or additional information as well as information regarding the conditions for approval.

When specific changes are requested in the protocol or consent document(s) the IRB Chair or designee reviews these for compliance. The application receives final approval when all required changes have been submitted and approved.

Upon receipt of final approval, ORSP staff stamps approved Informed Consent Document(s) and other materials (e.g., letters to subjects, ads) with the IRB approval stamp, the date of approval, and the date of expiration (if applicable). These documents are sent to the PIs along with the final approval letter. The letter reminds PIs that changes in research activity may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to subjects.

5.11.1 Required Documentation for Protocol Revisions Prior to IRB Approval

- Revised protocol in "track changes" format, or other document describing where in the protocol the change has been applied, as applicable
- Revised consent forms in both "track changes" and clean copy format, as applicable
- Any other document requested by the IRB at its prior review.

5.12 Review of IRB Decisions

PIs may request a review of the IRB's determination for specific changes to the protocol or consent document(s). The PI may make such a request in writing to the IRB.

If the IRB decides to disapprove a research activity, it will include in its written notification a statement of the reasons for its decision, and give the PI an opportunity to respond in person or in writing. A review of a disapproved research project must be done at a full board meeting. In the case of a decision by the IRB to disapprove, no administrative official or agent of Suffolk University may overturn the decision.

5.13 Urgent Review of Applications

Urgent review procedures may be invoked only under unusual circumstances. This does not include urgency that is a result of negligence or delay on the part of the PI or project staff to submit human subject applications in a timely fashion.

On occasion, however, a PI may be faced with an immediate deadline beyond his or her control. If the IRB Chair permits urgent review of a protocol and it is administratively feasible, the materials are distributed as soon as possible to IRB members to allow sufficient time for review prior to the meeting. The PI may be required to attend the meeting to answer any questions that arise.

5.14 Suspension or Termination of IRB Approval

The IRB has the authority to suspend or terminate approval of human subject research that is not being conducted in accordance with the IRB's requirements, or research that has been associated with unexpected serious harm to subjects. In general, these may include any incident, experience, or outcome, which has been associated with an unexpected event(s), related or possibly related to participation in the research, and suggests that the research places subjects or others at a greater risk of harm than was previously known or suspected.
Unanticipated events may or may not require suspension of the research. Each incident is evaluated on a case by case basis to make this determination.

Any suspension or termination of approval includes a statement of the reasons for the IRB's action and is reported promptly to the Institutional Official (IO), PI, the PI's department chair and Office of Research and Sponsored Programs staff. The IRB may require corrective action or education as deemed necessary for the PI or any other key personnel. Administrative officials from Suffolk, as required by federal regulation and University policy, will notify federal regulatory agencies where applicable.

Suspension involves temporarily discontinuing a PI's privilege to conduct a specific human subject

research project. The suspension may be partial, in that certain activities may continue while others may stop, or it may be complete in that no activity related to the research may proceed. The IRB will make this determination.

Termination is the ending of all activities related to a specific human research project or may involve revocation of a PI's privilege to conduct human subject research except for the continuation of follow-up activities necessary to protect subject safety.

5.15 Determining Initial Approval and Expiration Dates

IRB Approval of Research without Conditions

When the IRB conducts the initial review of a research project at a convened meeting and approves the research for one year *without* requiring changes to the protocol or informed consent documents, or submission of clarifications or additional documents the effective date of initial approval is the date of that IRB meeting. The expiration date of the initial approval period and the date by which the first continuing review must occur is 364 days after the date of the IRB meeting at which the project was initially reviewed and approved. For example, if the IRB meeting at which a research project was reviewed and approved without conditions was October 1, 2018 the expiration of such IRB approval would be September 30, 2019.

IRB Conditional Approval of Research

When the IRB asks the PI to (a) confirm specific assumptions or understandings on the part of the IRB regarding how the research will be conducted; (b) make specified changes to the research protocol and informed consent form and/or (c) submit additional documents as a condition of approval the initial approval date is the date the IRB Chair or designee reviews and determines that the responsive materials subsequently submitted satisfy the conditions set forth by the Board. The expiration date of the initial approval period and the date by which the first continuing review must occur is 364 days from the date of the IRB meeting at which the project was initially reviewed and conditionally approved.

VI. CONDUCTING CONTINUING REVIEW OF RESEARCH

The updated IRB regulations (effective as of January 19, 2019) have made substantial revisions to regulations regarding continuing review. Most notably, the updated regulations have removed the requirement to conduct continuing review of ongoing research for studies that undergo expedited review and for studies that have completed study interventions and are merely analyzing study data or involve only observational follow up in conjunction with standard clinical care. There are two important things to note regarding these changes to regulations to continuing review:

1. The updated regulations grant the IRB authority to require continuing review for any type of protocol.
2. Investigators still have the current obligations to report various developments (such as unanticipated problems or proposed changes to the study) to the IRB.

6.1 Submission and Review of Continuing Review Protocols

Except when an expedited review procedure is used, the IRB must review the continuation of research protocols at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. A primary reviewer system will be used for continuing review of protocols by the convened IRB.

All Human Subjects Research Renewal Request Forms (RRF) must be endorsed by the PI and uploaded to IRBNet. RRFs not properly endorsed will be returned without review.

6.2 Administrative Requirements for the Submission of Continuing Review Protocol

To ensure the most efficient review of a protocol the following documents should be included with each continuing review submission:

1. Applications must be submitted on the appropriate form (Human Subjects Research Renewal Request Form). Applications must be complete and accurate, thoroughly addressing the items listed on the application.

2. All requisite PIs endorse applications.

3. Training in the Protection of Human Subjects in Research through CITI must be completed. Documentation of completion of the CITI training and dates must be submitted with the application. In those instances where a group of students are being used as research assistants for which human subjects are involved, the names of the students and the completion dates of their training must accompany the IRB application. Initial training is valid for a three-year period after which time refresher training must be completed.

4. All applicable supporting documents must be included with the application and uploaded to IRBNet (informed consent, request for waiver of elements of informed consent, or request for waiver of written informed consent; parental permission; test or survey instruments; child assent scripts; letters from school principals or school district superintendents; certificates of confidentiality, recruitment materials such as flyers, etc.)

5. Procedures should clearly address the security and retention of data. The storage of research data at an off-campus location, such as at home, is not authorized.

6.3 Continuing Review Timeline

Applications for continuing review requiring a fully convened IRB must be submitted according to the IRB submission deadlines posted on Suffolk's website. Applications for continuing reviews that are expedited should be submitted at least 30 calendar days prior to the protocol expiration date.

Applications for continuing review received after the continuation review date will result in the protocol's expiration on the continuation review date. An expired protocol means that the project does not have approval and any additional work or use of existing data requires the submission of a new protocol application for IRB review.

6.4 IRB Determinations

All continuing reviews will result in one of the four determinations described above in section 5.5 (IRB Determinations) and include: Approved, Conditionally Approved, Tabled or Deferred, Disapproved.

6.5 Preliminary Review of Protocols

The IRB Chair or a designated ORSP staff member with appropriate expertise or qualifications will conduct a preliminary screening of all Human Subjects Renewal Request Forms (RFF). The RRF is reviewed for completion and accuracy of the basic application and for the inclusion of all requisite supporting documents. Suggestions may be made to the PIs for administrative revisions involving points of clarification or elaboration on items that may be viewed as problematic during IRB review.

6.6 Continuing Review by a Fully Convened Board

The IRB must review all research protocols at a convened meeting at intervals appropriate to the degree of risk, but no less frequently than once per year. A primary and secondary review system as described in section 5.7 of this policy will be followed for continuing reviews.
In addition to the relevant documents listed in section 5.7.2 of this policy, the attending IRB members will have access to the follow up documents through IRBNet:

- Request for Continuing Review Form, which includes:
  - A summary of the protocol and any amendments
  - A status report on the progress of the research, including:
    - The number of participants accrued and description of participants;
    - A summary of anticipated adverse events that have occurred;
    - A description of any unanticipated problems involving risks to participants or others and of any serious, unanticipated adverse events; and
    - The number of subjects who discontinued their participation; and
    - A summary of the reasons for the withdrawals, if known.

  - Requested modifications that are being made as part of the continuing review process. A summary of any recent literature, findings, or other relevant information, especially information about risks associated with the research.
  - Current human subjects training certificates for all study personnel.
  - Any materials that are going to be modified (i.e., consent document, protocol, recruitment flyers, etc.)

All IRB members will have access to the complete protocol including the Human Subjects Research Application, Detailed Protocol Summary and other relevant materials through IRBNet.

6.7 Use of Expedited Review Procedures for Continuing Review

When reviewing research under an expedited review procedure, the IRB Chair or designated IRB member(s) should receive and review all of the above-referenced documentation, including the complete protocol.

Generally, if research did not qualify for expedited review at the time of initial review, it does not qualify for expedited review at the time of continuing review, except in limited circumstances described by expedited review categories 8 and 9 (see section 5.8.2). It is also possible that research activities that previously qualified for expedited review have changed or will change, such that expedited IRB review would no longer be permitted for continuing review, for example, a modification to the protocol in which the previous risk to subjects was minimal but as a result of the modification, now places them at more than minimal risk.

6.7.1. Applicability and Expedited Review Categories

The IRB Chair or designated IRB member will use the same applicability standards and categories of research for which expedited review procedures as described in sections 5.8.1 and 5.8.2.

6.8 Issues Considered by the IRB during the Continuing Review Process

Continuing review of research must be substantive and meaningful with a recorded vote on each study, unless the research is otherwise appropriate for expedited review. The same criteria exist for the IRB to approve the continuation of a protocol as those that must be satisfied for the initial approval of research as described in section 5.10 of this policy. These criteria include, among other things, determinations by the IRB regarding:

- Risks to human subjects;
- Potential benefits;
- Informed consent; and
- Safeguards for human subjects

In particular, when conducting continuing review, the IRB needs to determine whether any new information has emerged either from the research itself or from other sources that could alter the IRB's previous determinations, particularly with respect to risk to subjects. In addition to the considerations outlined in section 5.10 of this policy, the IRB's continuing review procedures should consider relevant information received since the date of the last IRB review and approval of the research project from the investigator and any monitoring entity (e.g., the research sponsor, a coordinating or statistical center, an independent medical monitor, a data and safety monitoring board, or a data monitoring committee, or any other source). Information regarding any unanticipated problems that have occurred since the previous IRB review in most cases will be pertinent to the IRB's determinations at the time of continuing review regarding the risk:benefit relationship of the research.

It also may be appropriate for the IRB at the time of continuing review to confirm that any provisions under the previously approved protocol for monitoring the research data to ensure safety

of subjects have been implemented and are working as intended (e.g., the IRB could require that the investigator provide a report from the monitoring entity described in the IRB-approved protocol).

The IRB also should assess whether there is any new information presented by the investigator or others (for example, subjects or other individuals who have observed the investigator obtaining subjects' informed consent) that raises concerns about the circumstances under which informed consent is being obtained. For example, the IRB should assess whether there is any new information indicating that the investigator may not be obtaining informed consent under circumstances that provide subjects with sufficient opportunity to consider whether or not to participate or that minimize the possibility of coercion or undue influence.

Continuing review provides the IRB with an opportunity to determine whether there is any new information that should be considered to represent such a significant new finding and therefore be communicated to subjects who have already enrolled in the research (e.g., important new toxicity information or new adverse event information related to the research interventions that are identified during analysis of the research data; or new information regarding alternative treatments).

6.8.1 Evaluating Investigator and Institutional Issues

When appropriate, the reviewing IRB should consider issues regarding the investigator and the institution(s) where the research is being conducted during its continuing review, such as the following:

- Changes in the investigator's situation or qualifications
- Evaluation, investigation, and resolution of any complaints related to the investigator's conduct of the research;
- Changes in the acceptability of the proposed research in terms of institutional commitments (e.g., personnel and financial resources, adequacy of facilities) and applicable regulations, state and local laws, or standards of professional conduct or practice; and
- Reports from any third party observations of the research

6.9 Evaluation of Research Progress

When evaluating the research progress the IRB should consider the consistency of information submitted at the time of continuing review with that of the IRB-approved protocol, the total subject enrollment and subject withdrawal.

The IRB should confirm that the information provided by the investigator at the time of continuing review is consistent with the research protocol previously approved by the IRB. If this information suggests that the investigator is not conducting the research in accordance with either the IRB-approved protocol or the requirements or determinations of the IRB, the IRB should defer re-approving the research or re-approve the research for a limited period of time (e.g., one month) and seek an explanation from the investigator regarding the apparent discrepancies.

The IRB should pay special attention to the total number of subjects enrolled. If enrollment in a research project is occurring at a much slower rate than expected and there are concerns about

enrolling enough subjects to provide sufficient data to answer the scientific question(s) being addressed, it may not be ethical to continue exposing subjects to the risks of the research. The IRB may request the PI to explore the reasons for low enrollment and take appropriate steps to remedy the situation. If no such remedy exists, the IRB should not re-approve the study because the risks to subjects are not reasonable in relation to the anticipated benefits to the subjects and the importance of the knowledge that may reasonably be expected. On the other hand, if the investigator has enrolled more subjects than the maximum number allowed under the IRB-approved protocol, this would represent a violation of the constraints of the IRB approval and of the requirement that all changes in research not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subjects.
If over enrollment occurs, the research must address why additional subjects were enrolled. The IRB will determine how data obtained from over enrollment may be used.

IRB review of this information may shed light on problems related to the conduct of the research. For example, a high rate of subject withdrawal secondary to serious adverse events may indicate that the risks of the research are greater than expected and may lead the IRB to conclude that the research should not be approved for continuation. In addition, as with a lower than expected enrollment rate, if there is a higher than expected rate of subject withdrawal, it may not be ethical to continue exposing subjects to the risks of the research because the project may not provide sufficient data to answer the scientific question. An IRB may recommend that the reasons behind the high withdrawal rate be explored by the investigator and appropriate steps taken to remedy the situation. In the absence of an adequate plan to remediate the high withdrawal rate, the IRB may determine that the research should not be re-approved.

6.10 Verification from Outside Sources

Investigators are expected to provide the IRB with all relevant information regarding the conduct of the research. In order to ensure that no material changes occurred during the IRB designated approval period, the IRB may require verification of information from sources other than the investigator. Such independent verification may be considered in the following instances:

- Complex protocols involving unusual levels or types of risks to subjects;
- Protocols conducted by PIs who previously have failed to comply with federal regulations or the requirements or determinations of the IRB;
- Protocols where concern about possible material changes occurring without IRB approval have been raised based on information provided in continuing review reports or from other sources.

The IRB will determine which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review on a case-by-case basis. When the IRB finds the need for independently verified information, it will notify the investigator in writing of any outstanding issues or requests. The IRB will not give final approval for a protocol until it has received and reviewed the independently verified information and found it to be satisfactory.

6.11 Lapse in IRB Approval

As previously noted, continuing review of research must occur at intervals appropriate to the degree

of risk, but not less frequently than once per year. A lapse in IRB approval of research occurs whenever an investigator has failed to provide continuing review information to the IRB or the IRB has not conducted continuing review and re-approved the research – with or without conditions – by the expiration date of IRB approval. The investigator and IRB should plan ahead to ensure that continuing review and re-approval of research occurs prior to the end of the approval period specified by the IRB. However, it is the responsibility of investigators to provide in a timely manner the information needed by the IRB to perform its continuing review functions, and any reminder notices regarding the need to do so from the IRB to investigators are a courtesy. IRB support staff, through the use of IRBNet ensure investigators receive notices 90, 60 and 30 days prior to expiration.

Continued Research Activities after Lapse in IRB Approval

If IRB approval lapses, all activities involving human subjects **must stop** after IRB approval expired, *unless* it is determined to be in the best interests of already enrolled subjects to continue participating in the research. The determination regarding whether it is in the best interests of already enrolled subjects to continue to participate in the research after IRB approval has expired may be made initially by the investigator, possibly in consultation with the subjects' treating physicians, psychologists or psychiatrist (if the investigator is not the subjects' treating physician, psychologists or psychiatrist), but the investigator as soon as possible should submit a request for confirmation that the IRB agrees with this determination. The determination by the IRB may be made by the IRB chairperson, by another IRB member or group of IRB members designated by the IRB chairperson, or at a convened meeting of the IRB.

Enrollment of new subjects cannot occur after the expiration of IRB approval. Continuing participation of already enrolled subjects in a research project during the period when IRB approval has lapsed may be appropriate, for example, when the research interventions hold out the prospect of direct benefit to the subjects or when withholding those interventions poses increased risk to the subjects. This determination may be made for all enrolled subjects as a group or for each individual subject. If the investigator or IRB determines that it is not in the best interests of already enrolled subjects to continue to participate, investigators must stop all human subjects research activities, including intervening or interacting with subjects and obtaining or analyzing identifiable private information about human subjects.

6.11.1 IRB Review of Lapsed Human Subjects Research Applications

When IRB approval of an ongoing research project lapses and the investigator wants to continue the project, the IRB should complete continuing review for the project as soon as possible. Investigators may resume the human subjects research activity once continuing review and approval by the IRB has occurred. The IRB should document why the lapse in IRB approval occurred, and, if appropriate, any corrective actions that the investigator, institution, or IRB is taking to prevent any such lapse of approval of the project from occurring again in the future

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When IRB approval of an ongoing research project lapses and the IRB subsequently re-approves the project, the IRB may approve the project for one year and establish a new anniversary date for the expiration date of subsequent approval periods, or the IRB may re-approve the project for a period of less than one year so as to retain the original anniversary date on which prior approval periods expired.

6.11.2 Lapse in IRB Approval versus Suspension or Termination of Approval

When continuing review of a research project does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically. Such expiration of IRB approval is not considered to be a suspension or termination of IRB approval. Therefore, such expirations of IRB approval do not need to be reported as described in section 9.6 of this policy. However, if the IRB notes a pattern of non-compliance with the requirements for continuing review (e.g., an investigator repeatedly or deliberately neglects to submit materials for continuing review in a timely fashion or the IRB itself is frequently not meeting the continuing noncompliance that needs to be reported to appropriate institutional officials, the HHS agency that supported the research, and OHRP.

VII. MODIFICATIONS TO CURRENTLY APPROVED RESEARCH

The terminology used to describe a change to a protocol may vary, including terms such as modification, amendment or revision. Typically, outside sponsors may call any change to the protocol an amendment.

7.1 Submission and Review of Modification Requests

The IRB must review and approve all modifications to currently approved research prior to implementation except when necessary to eliminate apparent immediate hazards to the subject. All modifications will be reviewed by a convened Board except where the modification is minor and qualifies for expedited review. The IRB Chair will make the final determination of whether a modification is considered minor or major taking into account the totality of the circumstances. The IRB will follow the same procedures as described in section 5.7 of this policy when reviewing modifications at convened meetings.

In addition to relevant materials described in section 5.7.2 of this policy, the following should be included with each protocol submission and these materials will be made available to all attending IRB members through IRBNet:

- Request for Modification to Existing Research Form
- Revised Human Subjects Research Application with tracked-changes and without, if applicable
- Revised Detailed Protocol Summary with tracked- changes and without, if applicable
- Revised Informed Consent Form Documents with track changes and without, if applicable
- Revised Test or Survey Instruments with tracked-changes and without, if applicable
- Any other relevant materials such as CITI training for new research staff, support letters from research sites, recruitment materials, etc.

The essence of the study should be summarized by the reviewers for IRB members and the reviewers should state what the proposed modification is and how it will affect the conduct of the study, the risk/benefit ratio, and whether or not the modification should be approved as written. If the modification requires a change in the informed consent document, then the reviewer must

review that change and recommend appropriate board action. Modifications submitted to the IRB, along with supporting correspondence, are entered into IRBNet.

7.2 Definitions and Examples of Minor and Major Modifications

Regulations permit the use of expedited procedures for review of minor changes to previously approved research during the period for which the approval is authorized. Modifications that alter the risk/benefit ratio so that risks are increased or benefits are decreased shall be reviewed at a convened meeting.

7.2.1 Minor Modifications

Minor changes have no substantive effect upon an approved protocol or reduce the risk to the subject. Examples of minor changes are:

- Changes in research personnel that do not alter the competence of the research team to conduct the research;
- Scientific or therapeutic changes that leave the research population at the same or lower risk than risk(s) already approved;
- Changes in research procedures that have a minor impact on risks of harm
- An increase in the number of study visits for the purpose of increased safety monitoring;
- Changes to improve the clarity of statements, enhance comprehension, to correct typographical errors, or updating to current templates, without altering the content or intent of the statement; or
- Clarification of discrepancies within the IRB review materials (e.g., application form, protocol, consent) such as numbers of subjects, number and identity of research sites, timing, nature, and duration of research procedures.

7.2.2 Major Modifications

Major changes are changes that may increase the research population's risk or are of questionable risk. Examples of major changes that are considered to increase the risk to the subject

- Knowledge of a new risk, which might affect the risk/ benefit ratio;
- Increasing the length of time a subject is exposed to experimental aspects of the study;
- Changing the originally targeted population to include a more at-risk population (e.g., adding children to the study);
- Adding additional procedures where the risk of the additional procedure is greater than minimal risk;
- Adding an element that may breech the confidentiality of the subject such as tissue banking or genetic testing; or
- Increasing the number of participants to be "treated" more that 25%, which may affect the statistical plan for the study.

7.3 Submission of Materials and Timelines

Approval of a modification does not extend or otherwise change the project's expiration date. IRB

review of modification requests does not constitute a continuing review of the research application. All PIs are still required to submit research projects for IRB review and approval on an annual basis, at minimum, irrespective of any modifications submitted.

Deadlines for submissions only apply to full board reviews. Full board reviews must be submitted four weeks prior to the convened meeting. Refer to the meeting dates schedule on the IRB website http://www.suffolk.edu/explore/16531.php.

Expedited modifications can be reviewed at any time and will be, typically, reviewed within 5 business days after which the PI will receive feedback from the review.

7.4 IRB Determinations

The IRB may approve, conditionally approve, table or defer or disapprove modification requests. (see section 5.5). PIs are notified in writing of the decision of the IRB and of any changes required. Modification approval is not granted until all required changes have been made and submitted for review and approval. Once approved, the PI is sent a modification approval letter. The IRB may only approve modifications through the current approval expiration period, unless considered at the time of continuation review. Upon receipt of the approval for the modification, the PI may initiate the modification.

If approved research is changed to eliminate an apparent immediate hazard(s) to the subject, the PI is required to notify the IRB of the change(s) within 48 hours. The IRB will review at the next convened meeting to determine if the change(s) instituted was consistent with the subject's continued welfare.

7.5 Changing Principal Investigators

When changing principal investigators, a protocol modification must be submitted to explain who the PI was and who is being appointed the new PI. The original PI completes the Request for Modification to Existing Research Form. Changes in principal investigators may qualify for expedited review of the modification.

VIII. ADVERSE EVENTS AND UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS

Federal regulations require the prompt reporting by PIs of "any adverse event or unanticipated problems involving risk to subjects or others." All serious or unanticipated problems must be reported to the IRB, within 48 hours, in a written report with a detailed description of the problems and must be signed by the PI.

8.1 Definitions and Examples

8.1.1 Unanticipated Problems

Unanticipated problems involving risks to subjects or others are any incident, experience

or outcome that was unanticipated or unexpected, suggests that the research places subjects or others at a greater risk of harm than was previously anticipated and is at least possibly related to the research procedures.

Problems or events that are unanticipated and suggest an increase in risks to subjects or others should be reported to the IRB if in the opinion of the PI they are possibly, probably or definitely *related* to the research procedures. Those unanticipated problems or events that the PI deems unlikely or *not related* do not meet this definition of unanticipated events. All problems or events that do NOT meet this definition of unanticipated problems should be reported to the IRB in summary form at the time of annual continuing review.

8.1.2 Anticipated Problems

Anticipated (expected) problems are those that are already described as potential risks in the protocol and consent form. These do not meet the definition of unanticipated problems and should be reported in summary form only at the time of IRB continuing review, regardless of whether serious or related.

8.1.3 Adverse Events

Adverse events are defined as any event meeting the following:

- Any untoward or unfavorable medical occurrence in a human subject, including abnormal sign, symptom, or disease, temporally associated with the subjects participation in the research, whether or not considered related to the subject's participation in the research;

- Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social behavioral research.

- Adverse events can either be internal or external. Internal adverse events are experienced by subjects enrolled by the investigator at his/her institution. An external adverse event are those events experienced by subjects enrolled by investigators at other institutions.

Examples include death, hospitalization, disability as well as breach of confidentiality**.**

8.1.4 Examples of Unanticipated Problems

The following events may meet OHRP's definition of unanticipated problems involving risks to subjects or others and should be reported:

- Any serious event (including injuries, side effects, deaths or other problems), which in the opinion of the PI was unanticipated, involved risk to subjects or others, and was possibly related to the research procedures;

- Any serious accidental or unintentional change to the IRB-approved protocol that involves risk or has the potential to recur;
- Any deviation from the protocol taken without prior IRB review to eliminate apparent immediate hazard to a research subject;
- Any publication in the literature, safety monitoring report (including Data and Safety Monitoring Reports), interim result or other finding that indicates an unexpected change to the risk/benefit ratio of the research;
- Any breach in confidentiality that may involve risk to the subject or others;
- Any complaint of a subject that indicates an unanticipated risk; or
- Any other serious and possibly related event, which in the opinion of the PI constitutes an unanticipated risk.

8.2 Reporting Adverse Events and Unanticipated Problems

When the IRB receives a report of an adverse event that is an unanticipated problem involving risk to subjects or others, the IRB Chair or other qualified designee will evaluate the reported event and make a final determination as to whether further corrective action(s) or notice to subjects is required. The IRB will provide the PI with notification of its evaluation in writing.

The IRB Chair or other qualified designee is responsible for initially assessing whether or not the adverse event is an unanticipated problem that involves, or has the potential to involve, risk of harm to subjects or others. The IRB Chair may recommend that the unanticipated problem be reviewed by a convened meeting. The IRB chair will provide a report to the Institutional Official when it has identified such an event related to research participation, or when a serious event exceeds the frequency of occurrence initially anticipated in the research. The sponsor is defined as the funding agency.

The IO, following consultation with the IRB, will report to the sponsor and OHRP (if applicable) any incident that the IRB has determined to constitute an adverse event related to research participation that qualifies as an unanticipated problem involving risks to subjects or others.

The IO may also provide a preliminary report to the sponsor and OHRP (if applicable) of any incident that upon completion of the IRB's initial review is considered likely to constitute an unanticipated adverse event related to research participation that qualifies as an unanticipated problem involving risks to subjects or others.

IX. NON-COMPLIANCE

All Principal Investigators, and any other individuals involved in research at Suffolk University, should forward any allegations or concerns about noncompliance to the IRB. Notification should be sent within five business days. Contact information and reporting forms can be found on the ORSP website and in IRBNet. ORSP and the IRB are responsible for determining the validity of all allegations of noncompliance with respect to human subjects research activities conducted under the auspices of Suffolk University and, if found to be non-compliant, determining whether it constitutes non-compliance that is serious or continuing in nature. If it is determined that a research protocol is not in compliance with regulations, regardless of whether it received prior review and approval by the IRB, it may direct one or more corrective actions be taken.

9.1 Investigating Allegations of Non-Compliance

Federal regulations require that any serious or continuing non-compliance with DHHS human subjects' regulations or the determinations of the IRB must be promptly reported to the Office of Human Research Protections (OHRP).

Noncompliance consists of any action or activity associated with the conduct or oversight of research involving human subjects that fails to comply with either the research plan as approved by the IRB, federal regulations, or institutional policies governing such research. Noncompliance may range from minor to serious, be unintentional or willful, and may occur once or several times. Noncompliance may result from the action of the participant, PI, or staff and may or may not impact the rights and welfare of research participants or others or the integrity of the study. Complaints or reports of noncompliance from someone other than the research PI are handled as allegations of noncompliance until such time that the report is validated or dismissed.

9.2 Definitions of Noncompliance

9.2.1 Serious Noncompliance:

Serious noncompliance may include any behavior, action or omission in the conduct or oversight of human research that has been determined to:

- Affect the rights and welfare of participants and others;
- Increase risks to participants and others, decrease potential benefits or otherwise unfavorably alter the risk/benefit ratio;
- Compromise the integrity or validity of the research; or
- Result from the willful or knowing misconduct on the part of the PI(s) or study staff. Examples include, but are not limited to:
  - Conducting non-exempt research that requires direct interaction or interventions with human subjects without first obtaining IRB approval;
  - Enrolling subjects who fail to meet the inclusion or exclusion criteria in a protocol that involves greater than minimal risk and that in the opinion of the IRB Chair, designee, or convened IRB, places the participant(s) at greater risk; or
  - Failure to report serious events, unanticipated problems, or substantive changes to the proposed protocol to IRB.

9.2.2 Continuous Noncompliance:

A pattern of noncompliance that, in the judgment of the IRB Chair, designee, or a convened IRB:

- Indicates a lack of understanding or disregard for the regulations or institutional requirements that protect the rights and welfare of participants and others;
- Compromises the scientific integrity of a study such that important conclusions can no longer be reached;

- Suggests a likelihood that noncompliance will continue without intervention; or
- Involves frequent instances of minor noncompliance.

Continuing noncompliance may also include failure to respond to a request from the IRB to resolve an episode of noncompliance or a pattern of minor noncompliance.

9.3 IRB Review of Noncompliance

Suffolk University and IRB have the authority to conduct a for cause investigation or to request any information it desires necessary from any source, including the PI, other PIs on the research protocol, or the sponsor at any time. Within 7 working days of alleged noncompliance being reported to the IRB, the IRB Chair in conjunction with the ORSP staff will appoint an ad-hoc subcommittee to perform an inquiry into the matter. The ad hoc subcommittee will consist of a minimum of three voting IRB members. The PI will be notified in writing of the allegation and have an opportunity to respond to the allegation(s) during this initial inquiry. The results of the inquiry will be shared with the Chair of the IRB and the PIs and others as described below.

- Dismissal of the allegation or complaint as unjustified: If the allegation or complaint is found to be unjustified following the inquiry and review by the Chair or designee, then the findings will be noted in the IRB records and, where appropriate, written notice will be provided to the PIs.
- Minor noncompliance: If the noncompliance is determined by the IRB Chair to be minor, then the issue may be resolved between any combination of the IRB Chair, or designee, and PIs. Possible recommendations may include:
    - Resolution through corrective actions;
    - Resolution through educational measures appropriate to the nature and degree of the noncompliance.
- If resolution through corrective or educational measures is required, then the PI must provide written documentation of completion of the measures to the IRB within 30 days of the PI being notified.

The PI will be notified in writing whether the corrective action plan is adequate and whether the matter has been resolved.

- Serious or Continuing Noncompliance: If the inquiry suggests that the incident may constitute serious or continuing noncompliance, then the matter will be considered by the fully convened IRB Committee. The Chair or designee will notify the PI and the Institutional Officer (IO) of the incident and its possibility of constituting serious or continuing noncompliance. If research participants are at immediate risk of harm or have the potential to be placed at further risk while awaiting the outcome of a convened IRB meeting, then the IRB Chair may place one or all aspects of the study on suspension pending the decision of the full IRB.

9.3.1 Review of Serious or Continuing Noncompliance by a Fully Convened IRB

The fully convened IRB will review the incident and make its own determination. The IRB may determine that:

- The incident does not meet the criteria for serious or continuing noncompliance and recommend that it be handled as minor noncompliance; or

- More information is required and may request that an ad-hoc subcommittee of at least three members undertake further investigation. This ad-hoc subcommittee will consist of IRB members whose areas of expertise are suited to reviewing the complaint and area of study. The ad-hoc subcommittee may also include the IRB members who conducted the initial inquiry. The ad-hoc subcommittee may conduct further interviews or other methods of information gathering. The researcher under investigation will be given an opportunity to submit written comments and to appear before the ad-hoc subcommittee on at least one occasion prior to an investigative report being issued. The ad-hoc subcommittee will provide a written report to the fully convened IRB following their inquiry, including a summary of the information gathered, conclusions and recommendations. The fully convened IRB will review the report in the same manner as the initial report; or
- The incident constitutes serious and/or continuing noncompliance.

If the IRB determines that the incident constitutes serious and/or continuing noncompliance, it may take any action it deems necessary to protect the rights or welfare of the participants involved, including, but not limited to:

- Remediation or educational measures required of the research team
- Monitoring of research activities by appropriate person(s).
- Monitoring of the informed consent process by appropriate person(s).
- Notification of past or current research participants.
- Requiring re-consenting of participants.
- Modification of the research protocol.
- Increased reporting by the researcher of his or her human subject research activities to the IRB.
- Requiring a more frequent continuing review schedule.
- Requiring periodic audits by the Research Compliance Coordinator or other quality assurance or quality improvement auditors.
- Restrictions of the PI's research practice, such as limiting the privilege to minimal risk or supervised projects.
- Suspension of approval for one or more of the researcher's studies.
- Termination of approval for one or more of the researcher's studies.
- Referral to other University authorities or committees for possible further review and resolution by those bodies including possible disciplinary action up to and including termination in accordance with the appropriate disciplinary procedures for faculty, staff, and students.

9.4 Suspension or Termination

The IRB may suspend a protocol when it is believed to be in the best interest of participants to stop some or all protocol related activities temporarily. Studies may be suspended, put on hold during an investigation of noncompliance or following a protocol deviation, adverse event or unanticipated problem involving risks to participants or others. These protocols are still considered to be active studies and hence require continuing review by the IRB.

Only a fully convened IRB may terminate a protocol when it is believed to be in the best interest of participants to stop protocol related activities permanently. Studies may be terminated

following an investigation of noncompliance, protocol deviation, adverse event or unanticipated problem involving risks to participants or others.

The IRB will notify the PIs in writing of the reason for the suspension or termination. The IRB also will notify ORSP staff and the IO. The IO may notify the OHRP agency supporting the research of protocols formally terminated by the IRB.

9.4.1 Continuity of Research Procedures when a Study is Suspended

If a study is suspended or terminated, new participants may not be enrolled and no study procedures may take place unless the IRB or IRB Chair determines that continuation of study procedures is in the best interest of currently enrolled participants.

9.5 Studies Conducted Without IRB Approval

Federal regulations and guidelines do not allow for review and post hoc approval of studies that have already been conducted involving human participants, human biological materials, or identifiable data that can be connected to any living individual. Suffolk's Federalwide Assurance (FWA) with the federal government states that the IRB must review and approve data collection procedures and protocols before the study begins. The FWA is a legally binding contract that the university has signed with the U.S. Office of Human Research Protections (OHRP), and it obligates Suffolk to comply with the ethical principles of The Belmont Report and the federal regulations for the protection of human participants.

The IRB has adopted the following procedures regarding studies conducted without prior IRB approval:

The IRB and ORSP will investigate why the investigator did not have the project reviewed by the IRB. Depending upon the circumstances leading to the lack of compliance as well as the type of study conducted, ORSP and/or the IRB may require the following corrective actions. These will apply only to research that requires formal approval by the IRB (i.e., non- exempt research).

- If the data are intended for publication, the investigator must disclose to the publication editor(s) that the data were collected without the approval of the Suffolk University's Institutional Review Board. Some journals and disciplinary fields now require such disclosure as a condition of publication.
- If the study is on-going, interaction with human participants must cease until the IRB has reviewed and approved all study procedures.
- In some cases, the IRB may require that investigators inform participants of the investigator's lack of compliance with the IRB procedures, and solicit permission from the participants to use the data or biological materials collected.
- When there are multiple instances of lack of compliance in a unit, the IRB will ask the unit to take extra steps to assure that its investigations comply with human participant regulations.
- When the lack of compliance has resulted in risk of harm to participants, the IRB will report the situation to OHRP and appropriate university officials, as required by the FWA. In addition, the IRB may forbid publication of the results of the study.
- If, after the IRB has intervened to take corrective action, the investigator undertakes a second study without human participant review and approval further corrective/disciplinary action will

be explored including suspension and termination of all of the investigators research involving human participants.

9.6 Reporting Serious or Continuing Noncompliance:

For all incidents determined by the IRB to be serious or continuing noncompliance, the IRB will notify the following individuals within 3 business days:

- The PI;
- The PI's Department Chair;
- The PI's Dean;
- ORSP staff; and
- The IO.

Where applicable, the IO will also notify within 30 days:

- The Provost;
- University authorities;
- OHRP;
- The funding agency, when applicable; and
- For other institutions participating in the research, the IRB Administrator(s) and the IRB Chair(s) of those institutions.

The IRB's determination and required actions will be communicated to the PI in writing. The PI must provide written documentation of completion of any required actions to the IRB within 30 days. Once the appropriate corrective actions are complete the matter will be considered resolved. A final report detailing resolution of the matter will be communicated, in writing, to the PI and others as appropriate. A copy of all correspondence and the final report will be maintained in the IRBNet.

9.7 Reporting Suspension or Termination of IRB Approval

For all suspensions or terminations by the IRB, the IRB will notify the following individuals within 3 business days:

- The PI;
- The PI's Department Chair;
- The PI's Dean;
- ORSP staff; and
- The IO.

The IO will also notify within 30 days:

- ORSP;
- The Provost;
- University authorities;
- OHRP;
- The funding agency, when applicable; and

- For other institutions participating in the research, the IRB Administrator(s) and the IRB Chair(s) of those institutions, when applicable.

9.8 Noncompliance Due to Instances of Research Misconduct

Research misconduct is fabrication, falsification and plagiarism in biomedical or behavioral research. Research misconduct in human subjects research commonly occurs in the proposal, conduct or reviewing of research or reporting of research results. Examples of falsification and/or fabrication in human research may include:

- Substituting one subject's record for another's
- Altering eligibility dates and eligibility tests results
- Changing dates on patient screening logs
- Creating records of interviews that did not occur
- Creating records of patient visits that did not occur and inserting false records into medical charts
- Creating records of follow-up visits with deceased patients

Research misconduct may constitute serious or continuing noncompliance and may need to be reported to the regulatory agencies as described in section 9.5 of this policy in addition to the Office of Research Integrity (ORI). ORI is the federal agency that is responsible for the administration and oversight of Public Health Service (PHS) policies and funds. A condition for PHS support is assessing, investigating, and reporting research misconduct allegations to OIR.

9.8.1 Noncompliance versus Research Misconduct

Not all instances of noncompliance fall within the definition of research misconduct. Examples may include:

- Failure to report unanticipated problems
- Protocol deviations without IRB approval
- Failing to obtain or properly document informed consent
- Breaching confidentiality of subject data
- Falsifying informed consent signatures or documents

Similarly, not all instances of research misconduct constitute noncompliance. Examples may include:

- Falsely reporting clinical trial results in publications
- False statements in an application for PHS funding for human subjects research
- Intentionally eliminating outlying data points, when analyzing the data after all research interventions have ceased.

There are instances where research misconduct can have implications for human subject protections. Examples may include:

- Backdating enrollment form to make subject eligible. This means researchers enrolled subjects outside the time window stated in the IRB-approved protocol.
- Falsifying a lab report required for admission to a clinical trial. This means researchers failed to order lab tests required to confirm subject eligibility and

deviated from the IRB- approved protocol.

- Intentionally reversing end point results between treatment and control subjects to improve the statistics. This means researchers deliberately unblended treatment and control subjects, contrary to the protocol, to reverse end point results and compromised the integrity of the research therefore impacting the risks/benefit ratio.

9.8.2 Investigations of Research Misconduct

In cases where noncompliance is due to suspected research misconduct, Suffolk University's policy for research misconduct will be followed. A final report of the inquiry or investigation into the allegation of research misconduct will be provided to the IRB. If the IRB determines such incident constitutes noncompliance, the reporting procedures as described in section 9.6 will be followed.

The IRB retains the authority to suspend the research in cases when it believes is in the best interest of subjects while the research misconduct investigation is ongoing. The above described procedures for suspension and termination of research will be followed.

X . IRB Committee Activity Management

10.1 Procedures for Developing, Approving, Documenting and Implementing Changes to Current Policies and Procedures of Suffolk University's Institutional Review Board

1. Purpose:
   This policy specifies the process of developing, approving, documenting, and implementing changes to the current policies and procedures of Suffolk University's Institutional Review Board (IRB).

2. Recognizing a Need for Changes and Initiating the Change Process:
   When an IRB policy or procedure needs modification, the IRB Chair or designee will draft a written proposal. Such proposal will include a statement of the need for the change, and a draft of the new policy or procedure, and how it will be implemented. This proposal will be posted as described below, for comment and voting by IRB members. Minor policy and procedural changes may not warrant this formal process, and may be more appropriately termed "IRB guidance or clarification." The IRB Chair will have discretion to determine what triggers a formal policy or procedure change versus "IRB guidance or clarification." Minor changes that the Chair determines fall into the "IRB guidance or clarification" category will be communicated to the board at regularly scheduled IRB meetings, via e-mail and/or via IRBNet.

3. Review Process:
   Once the draft proposal has been reviewed by the IRB Chair and the Assistant Vice Provost for The Office of Research and Sponsored Programs, who may need to seek counsel from other Suffolk University staff/administrators to assure that the proposed policy and/or procedural change is consistent with Suffolk University's policies and all relevant laws and regulations, it will be presented to the board for review and comments.

The draft proposal will be uploaded as PDF file onto IRBNet into a project titled "Proposals for Changes to Policies and Procedures" with all board members given reviewer access. The board will be given one week to provide any comments regarding the proposed policy. IRB members should insert a comment either indicating that they are okay with the proposal as written or offer any suggested changes. This review period can be shortened if all active board members (i.e., current board members that are not on any type of leave from the IRB) have indicated that they have reviewed the proposed policy and either have no comments or offer a comment.

4. Voting on the Final Policy Change:
After the review period, the Chair or designee will compile a final version of the policy or procedure. This version will be presented to the board either at a meeting or announced as posted on IRBNet, at the discretion of the Chair. In either case, a final draft will be uploaded to IRBNet. All active board members will be asked to vote to approve, disapprove or note an abstention through the reviewer comment section.
Members will be given one week (7 days) exclusive of holidays, to review and vote on the final proposal. The voting period will last a minimum of 7 days, but can be extended if necessary by the IRB Chair. A policy or procedure change will be adopted if more than 50 percent of active IRB members vote to approve the proposed change.

Once a policy or procedural change is approved by the IRB through this process, it will be added to an appendix to the currently approved policy and procedures manual. This entry will include the date the policy was adopted, and include reference to the earlier sections of the policy and procedures which have been modified. When complete revision is made to the policies and procedures manual, the amendments in this appendix will be incorporated in the updated manual.

All approved policy and procedure changes will be summarized at the next IRB meeting so that these are also documented in the meeting minutes.

XI. IRB Committee Education and Evaluation

XII. IRB Committee Records and Documentation

12.1 IRB Records and Documentation

1. **IRB Protocol Records.** IRB protocol records must include all the information stipulated by HHS regulations at 45 CFR 46.115(a)(1), (3), (4), and (7).
2. **Minutes of IRB Meetings**. The minutes of IRB meetings must include all the information stipulated by HHS regulations at 45 CFR 46.115(a)(2). IRB minutes will be developed using the IRBNet minute maker. The minutes of IRB meetings should document, among other things:

    a. Separate deliberations, actions, and votes for each protocol undergoing initial or continuing review by the convened IRB.
    b. The vote on all IRB actions including the number of members voting for, against,

and abstaining; the basis for requiring changes in or disapproving the research; and a summary of the discussion of controverted issues and their resolution. OHRP recommends that the recusal of IRB members because of a conflicting interest also be documented when recording votes on IRB actions. In order to document the continued existence of a quorum, the following examples demonstrate one acceptable format for documenting in the minutes the votes on actions taken by the IRB on research projects undergoing initial or continuing review:

- Total = 15; Vote: For-14, Opposed-0, Abstained-1.
- Total = 14 (1 member recused and did not vote); Vote: For-12, Opposed-2, Abstained-0.

c. IRB meeting minutes will be developed in draft form within three working days following an IRB meeting. Draft minutes will be sent to the IRB Chair and Vice Chair for initial review. After initial review, the minutes will be distributed via e-mail to all IRB members for review and approval. Once minutes are approved, the document is uploaded to IRBNet as the approved copy. All meeting documentation resides within IRBNet. IRB meetings are recorded. Meeting recordings are utilized for the primary purpose of developing the minutes. Once meeting minutes are approved, meeting recordings may be erased. The Chair or his/her designee may periodically utilize the OHRP self assessment tool (questions 58-83) to evaluate the quality of meeting minutes. http://www.hhs.gov/ohrp/education/qip/ohrp_ded_qatool.html

3. **Documentation of Findings.** HHS regulations at 45 CFR 46.116(d) require that the IRB make and document four findings when approving a consent procedure which does not include, or which alters, some or all of the required elements of informed consent or when waiving the requirement to obtain informed consent. OHRP recommends that when approving such a waiver for research reviewed by the convened IRB, these findings be documented in the minutes of the IRB meeting, including *protocol-specific* information justifying each IRB finding. Similarly, where HHS regulations require specific findings on the part of the IRB, such as:

   a. Approving a procedure which waives the requirement for obtaining a signed consent form [see 45 CFR 46.117(c)];
   b. Approving research involving pregnant women, human fetuses, or neonates (see 45 CFR 46.204-207);
   c. Approving research involving prisoners (see 45 CFR 46.305-306); or
   d. Approving research involving children (see 45 CFR 46.404-407), the IRB should document such findings.

   OHRP recommends that for research approved by the convened IRB, all required findings be fully documented in the minutes of the IRB meeting, including *protocol-specific* information justifying each IRB finding. For research reviewed under an expedited review procedure, these findings should be documented by the IRB Chairperson or other designated reviewer elsewhere in the IRB record.

4. **Documentation of Risk and Approval Period.** IRBs must determine which protocols require continuing review more often than annually, as appropriate to the degree of risk [see 45 CFR 46.103(b)(4) and 46.109(e)]. OHRP recommends that the minutes of IRB meetings clearly reflect these determinations regarding risk and approval period (review

interval).

5. **Retention of IRB Records.** HHS regulations at 45 CFR 46.115(b) require that IRB records be retained for at least 3 years, and records relating to research which is conducted be retained for at least 3 years after completion of the research. All records must be accessible for inspection and copying by authorized representatives of HHS at reasonable times and in a reasonable manner.

12.2 Guidance Relevant to Review of Protocol Changes

1. **Requirement for Review of Proposed Protocol Changes by the IRB at Convened Meetings.** In accordance with HHS regulations at 45 CFR 46.108(b), review of proposed protocol changes must be conducted by the IRB at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas, except where expedited review is appropriate under HHS regulations at 45 CFR 46.110(b)(2).
2. **Expedited Review of Minor Changes.** OHRP recommends that institutions adopt policies describing the types of minor changes in previously approved research which can be approved under an expedited review procedure in accordance with HHS regulations at 45 CFR 46.110(b)(2).
3. **Protocol Revisions.** OHRP recommends that each revision to a research protocol be incorporated into the written protocol. This practice ensures that there is only one complete protocol with the revision dates noted on each revised page and the first page of the protocol itself. This procedure is consistent with the procedure used for revised and approved informed consent documents which then supersede the previous one(s).

XIII. Students

13.1 Use of Students as Research Participants

Projects that propose to use students as research subjects will be carefully reviewed to ensure that:
1) students do not feel undue influence to participate, and
2) classroom time is not appropriately used for research purposes.

As described in the Exempt Research section of this document, it is sometimes appropriate to use data collected in the classroom for research purposes. The following issues will be taken into consideration when reviewing research conducted in the classroom:

1) Will students be asked to complete any additional activities (e.g., completion of surveys) that they would not have to complete if the research was not being conducted. In other words, will the students be asked to complete additional activities above and beyond what they would have to do if the research was not being conducted.
2) If yes to 1, then informed consent is likely necessary to make it clear that student participation in the research component of course activities is voluntary.
3) If a principle investigator plans on using students from a course that s/he teaches, special procedures must be implemented to reduce the risk of participants feeling undue influence to participate, such as having a third party administer the consent and course instructors remaining unaware of who and who did not consent to the study until after grades have been submitted.

4) Investigators should keep in mind that students attend classes to receive an education. It is inappropriate to use significant amount of class time for research purposes unless these activities are for educational purposes that are normally part of the class (i.e., students would complete these activities whether or not research was being conducted).

13.2 Research Conducted by Students

For all research conducted by Suffolk students, for the purpose of IRB oversight, a faculty supervisor must be the principle investigator; thus, the faculty supervisor is responsible for ensuring that all proper IRB procedures are followed.

13.2.1 Student Research Project for Didactic Purposes Only

Many undergraduate and graduate courses (e.g., Research Methods, Statistics) require students to conduct a research project. If the project is being conducted for didactic purposes only (i.e., with no expectation to "contribute to generalizable knowledge", as per the above definition of research) then the project does not require IRB oversight. However, the faculty instructor/supervisor has an obligation instruct students about the ethical conduct of research using human subjects and provide oversight of the project to make sure it is conducted in a manner consistent with the protection of human subjects.

13.2.2 Independent Student Research

Many student research projects, such as senior honors projects, master's theses, and doctoral dissertations, are conducted with the expectation that the project will "contribute to generalizable knowledge" (as per the federal regulations' definition of research). Regular IRB oversight is required for these types of student research projects. As noted above, for all research conducted by Suffolk students, for the purpose of IRB oversight, a faculty supervisor must be the principle investigator; thus, the faculty supervisor is responsible for ensuring that all proper IRB procedures are followed.

XIV. Hotline and Compliance Concerns Email Management

The IRB Hotline and Compliance Concerns email box will be monitored by ORSP. Any issues reported via these channels will be evaluated by ORSP in conjunction with the IRB Chair and will be managed according to the appropriate protocols as defined in the Suffolk IRB Policies & Procedures.