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| **SUBJECT –** Institutional Review Board | **EFFECTIVE DATE –** September 2017 |
| **TITLE –** Initial Full Board Review of Research | **APPROVED BY –** IRB; Michael Manning, Associate Provost |

**SCOPE** - This policy applies to all faculty, staff, students and others conducting research involving human subjects within or under the auspices of SUNY POLYTECHNIC INSTITUTE, and to the SUNY POLYTECHNIC INSTITUTE Institutional Review Board (IRB) that reviews research.

**PURPOSE –** To define and establish guidelines and responsibilities for the initial full board review of human subject research proposals.

**POLICY** - SUNY POLYTECHNIC INSTITUTE Institutional Review Board (IRB) shall review all proposed non-exempt research, including the consent form, at convened meetings where a quorum of the IRB members are present, including at least one member whose primary concerns are in nonscientific areas, unless an expedited review procedure is used. The review shall be conducted in the presence of the Investigator, unless attendance is waived by the Board. Approval shall be by majority of the quorum present and only for research that satisfies approval criteria specified in federal regulations at 45 CFR 46.111, (and, where appropriate, 21 CFR 56.111 and 38 CFR 16.111). Members with a conflict of interest cannot participate in the review process except to provide additional information requested by the IRB.

## Guidance and Procedures

**Full Board Initial Review** - requires a convened meeting in which a quorum (fifty percent plus one) of the membership is present to discuss the human subject protection issues scheduled on the Agenda. A valid quorum requires the attendance of at least one member whose primary concerns are in non-scientific areas. If the quorum cannot be maintained (member leaves), discussion may continue, but there can be no votes taken. The IRB convenes the second Tuesday of each month during the academic year September – May, and other months as required.

Except where an expedited review procedure is authorized, all **non-exempt research** will be reviewed by the convened board, in the presence of the investigator or designated representative so clarification of information can take place, unless attendance is waived by the Chair. Further discussion of controverted issues and their resolutions, and all voting activities should take place after the investigator leaves the room. Members must participate in meaningful discussion of the research under review. Approval shall be by majority of the quorum.

***Non-exempt research*** – Research that has not been determined by the IRB to be exempt from the requirements of *45 CFR 46*, and requires IRB review.

## Conflict of Interest

HHS regulations at 45 CFR 46.107(e) specify that members who have a conflict of interest cannot participate in the IRB initial and continuing review except to provide information requested by the IRB. IRB members with a conflict of interest will absent themselves from discussion unless their presence is requested by the Board; however, may not vote on research in which a conflict of interest exists.

## Distribution of Materials

Each member of the IRB must receive information in sufficient detail to make the determinations required by HHS regulations at 45 CFR 46.111. The IRB uses an electronic system to distribute documents for IRB use. Documents listed below, as appropriate, must be submitted to the membership so as to receive them within seven calendar days of the scheduled meeting. Documents submitted by the PI that are received after the agenda has been distributed may be distributed electronically to the Board in the form of an Addendum, or deferred to the next scheduled meeting. The IRB membership will review all documents received.

1. Investigator's signed, completed *Application for Initial Full Board Review*
2. Detailed protocol summary
3. Copy of the proposed informed consent document
4. Copy of the current *Investigator's Brochure* (if available)
5. Copy of the HIPAA form, if required
6. Copy of any surveys, questionnaires, or other documents that subjects or patients will be required to complete as part of study participation
7. Any other documents pertinent to the study, such as letters from sponsors, pamphlets and advertisements
8. IRB Checklists and other forms to assist members in the review of research
9. Multi-center trials (HHS-supported) – At least one member will receive a complete copy of the protocol, and all members will receive the consent document. The protocol will be available to any other member upon request.

**Primary Reviewer System**

SUNY POLYTECHNIC INSTITUTE IRB may use a Primary Reviewer System in which one or more members with the appropriate
subject matter expertise and IRB reviewer experience is/are assigned, by the Chair, to review distributed materials. In this case:

1. The Primary Reviewer will review all of the distributed research documents and be able to facilitate discussion with the convened board, identify areas of the research that might require more information from the PI, and make a recommendation of the appropriate approval category. The reviewer will also complete the *IRB Checklist: Criteria for Approval of Research* form to ensure that the research meets all applicability criteria and represents one or more of the approvable categories of research.
2. The membership will review the following documents, at a minimum, (but may review all available documents) prior to the meeting and be able to engage in discussion:
   a. Investigator's signed, completed *Application for Initial Full Board Review*
   b. Checklists and other forms to assist review of research
   c. Protocol summary
   d. Recruit materials
   e. Informed consent document

**Criteria for Approval of Research**

For research to be approved, the IRB shall determine that all of the requirements listed below are satisfied. These criteria are listed on the *IRB Checklist: Criteria for Approval*, which is distributed to all members to use when conducting initial (and continuing review) of research.

1. Risks to subjects are minimized.
   (a) Procedures consistent with sound research design and do not unnecessarily expose subjects to risk; and

(b) Whenever appropriate, investigators use procedures already being performed on subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may reasonably be expected to result.
   (a) 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).
   (b) The IRB should NOT consider possible long-range effects of applying knowledge gained in the research (example: effects of research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Equitable selection of subjects.
   (a) Consider the purposes and the setting of the research.
   (b) Be cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, and documented to the extent required by federal regulations. Each consent form must address the basic elements of informed consent as specified in HHS regulations at 46.116. Additional elements of informed consent shall be included, when appropriate.
5. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
6. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
7. Whenever enrollment includes subjects likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

**Range of Possible Actions**

After review and discussion of the research proposal, the IRB Chair or designated representative will recommend the board vote one of the following possible actions:

**APPROVED** – The proposed research is approved as submitted and does not require modification. An approval letter will be sent to the Principal Investigator along with a copy of the IRB date-approved consent form.

**APPROVED PENDING MODIFICATIONS** – The proposed research requires minor modifications regarding the protocol or informed consent documents and / or process. The requested modifications are directly relevant to the determinations required by the IRB as specified by HHS regulations at 45 CFR 46.111 and documented above in paragraph *Criteria for Approval of Research.* The IRB Chair may conduct review and approval of submitted modifications using the expedited review procedure, if appropriate.

**TABLED/DEFERRED** – The proposed research requires substantive clarifications or modifications regarding the protocol or informed consent documents and / or process. The requested clarifications and modifications are directly relevant to the determinations required by the IRB as specified by HHS regulations at 45 CFR 46.111 and documented above in paragraph *Criteria for Approval of Research.* These protocols will need to be resubmitted for full board review.

**DISAPPROVED** – Questions about the proposed research are so significant that approval is not possible. The study may be rewritten and resubmitted for full board review. In this case, a new application must be completed.

Once a research project is approved, there can be no amendments to the protocol or consent form without review and approval by the SUNY POLYTECHNIC INSTITUTE IRB **EXCEPT** to avoid an immediate hazardous situation.

**Determine Frequency of IRB Review**

For each approved study, the convened board determines the frequency of continuing review appropriate to the degree of risk, as specified by HHS regulations at 45 CFR 46.103(b)(4)(ii) and, where required, FDA regulations at 21 CFR 50.25(b)(5)). In no case can the review interval exceed 365 days; however, more frequent review may be required. For example,

- An interval of one year is appropriate for research that poses no greater than minimal risk.
- For research that poses greater than minimal risk and no direct benefit to the subject, but may provide generalizable knowledge, a six month interval may be appropriate.

(a) The start date of the interval begins on the date the study was approved by the convened board (or expedited reviewer) for approved research, or research approved pending modifications.
(b) The start date for research that was tabled, deferred or resubmitted at a later date begins on the succeeding date of review in which the study is actually approved.

**Communicating Decisions and Actions to Investigators**

Investigators and, where appropriate, the Institutional Official (IO) will be notified promptly (usually within five business days) by official letter of all board decisions and actions. The IO will also receive a copy of the board-approved IRB minutes which includes documentation of board decisions. Other entities will be notified as requested by the PI, IRB Chair or other regulating agencies.

1. Where research is ***approved*** as submitted, the certification letter will include the approval period /expiration date, as well as any instructions or other information the Board requires. The letter must also include statements requiring the PI to advise the IRB of any:
   (a) Changes or modifications to the study prior to implementation;
   (b) Unanticipated problems or adverse events that occur as a result of participation in the research.
2. For ***approvals pending modifications***, the letter must discuss the modifications required.
3. For ***tabled or disapproved*** studies, the reason, including the applicable federal regulations and criteria, as well as any appeals process, must be specified.

**Additional Procedures and Responsibilities**

**IRB Responsibilities**

1. Review all materials submitted as an Agenda prior to the designated meeting.
2. Advise the Chair if a personal conflict of interest exists at the beginning of the meeting.
3. During the meeting, participate in meaningful discussion of the research under review.
4. Evaluate each study and determine if the criteria for approval are satisfied as required in this policy and according to HHS regulations at 45 CFR 46.111, utilizing the appropriate, distributed checklists.
5. Evaluate the consent document and determine if the required basic and additional elements are addressed as specified at 45 CFR 46.116 utilizing the appropriate, distributed checklists.

6. Conduct a risk/benefit assessment of the research. Determine whether the risks are reasonable in relation to the benefits to the subject and to the importance of knowledge to be gained.
7. Ensure adequate additional protections are specified for the protection of subjects of vulnerable populations.
8. Determine potential conflicts to ensure subjects are protected from bias in the enrollment process, the study or the interpretation of the data to be collected.
9. Resolve any questionable issues and determine acceptable corrective actions, if necessary, prior to advising the PI of the approval decision.
10. Determine frequency of continuing review based upon risk assessment.

**IRB CHAIR Responsibilities**

1. Review all protocols prior to the meeting and facilitate the IRB discussion, unless a Primary Reviewer is assigned.
2. Assist the IRB Coordinator, as necessary, in drafting letters to researchers regarding IRB decisions.
3. Conduct timely review and decisions about responses to conditions for IRB approval of research.
4. Determine if additional expertise, cultural or ad hoc consultants are needed.
5. Consult with the IRB Coordinator to assign a primary reviewer (when used) based upon the member's educational background and expertise.

**IRB Coordinator Responsibilities**

1. Screen the Application to ensure completeness. Coordinate with the Investigator to obtain missing documents or information. Additional screening may include a determination whether the:
   (a) Research involves vulnerable subjects or sensitive research topics or procedures
   (b) Review requires additional expertise, cultural or ad hoc consultants (for example: research involving prisoners is not authorized, unless a prisoner representative is appointed). This determination will be made in consultation with the IRB Chair. If so, the ad hoc receives the same information as voting IRB members.
2. Assist the IRB Chair in the assignment of a primary reviewer (when utilized).
3. Schedule the Application on the Agenda for the next appropriate IRB meeting and distribute it to the membership. Coordinate a request for the PI or representative to attend the meeting, unless waived by the Chair or IRB.
4. Document, distribute and maintain meeting minutes.
5. Issue the IRB decision letter to the investigator. Certification letters must include the approval period. If the study is approved pending modifications, include the requirements. For disapproved or tabled studies, specify the reason and the appeals process.

**6. Principal Investigator Responsibilities**

1. Submit the completed *Application for Initial Full Board Review* electronically to the IRB according to directions on the form, along with the consent form and all other appropriate documents pertaining to the study. Documents requiring investigator signature may be scanned electronically, or submitted to *H. Jones, Room B234/Kunsela.*
2. When notified by letter, attend the appropriately scheduled convened meeting to present the study to the Board.
3. Obtain IRB approval prior to initiating human subject research activities, and prior to implementing any changes to previously approved research.

4. Comply with all requests and requirements of the Board pertaining to approved research.
5. Supervise and ensure that all research activities are conducted ethically and in a manner that protects the rights and welfare of the participants.
6. Ensure staff members who will conduct research activities complete the required Human Subject Protections Training as specified in the training policy.
7. Immediately report any unexpected problems or serious adverse events to the IRB.

## References


Bankert, E. A. & Amdur, R. J. (2006) *Institutional Review Board Management and Function, 2nd ed.* Jones & Bartlett Publishers, Sudbury MA.

Code of Federal Regulations: Title 45, Part 46

Code of Federal Regulations: Title 21, Part 56

Code of Federal Regulations: Title 21, Part 50

Federal-Wide Assurance

Institutional Review Board Guidebook

Northshore Long Island Jewish IRB (http://www.northshorelij.com/NSLIJ/irb)

OHRP Guidance Document – 2011 Guidance on Written Procedures

OHRP Guidance Document – Informed Consent FAQs

Public Responsibility in Medicine and Research (PRIM&R) training resources - www.primr.org

SUNY Upstate Medical IRB - http://www.upstate.edu/researchadmin/compliance/irb/

SUNY Binghamton IRB – (http://research.binghamton.edu/compliance/humansubjects)

University of Kentucky IRB - (http://www.research.uky.edu/ori/