SUNY Polytechnic Institute

SUBJECT – Institutional Review Board	**EFFECTIVE DATE –** September 2017
TITLE – Expedited Review of Research	**APPROVED BY -** IRB Committee; Michael Manning, Associate Provost

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

PURPOSE – To establish guidelines and procedures for the use of the expedited review procedure by researchers and the IRB, in compliance with federal regulations.

POLICY - The SUNY Polytechnic Institute Institutional Review Board (IRB), in accordance with *45 CFR 46.110*, may use the expedited review procedure to review:

1. Research activities that present no more than minimal risk *and* involve only the categories of research listed in the Federal Register and adopted by the Department of HHS (and, where applicable, by the FDA); and
2. Minor changes in previously approved research that occur during the year for which approval is granted.

The IRB will not use the expedited review procedure to review research involving prisoners as subjects.

The expedited review procedure permits the review and approval of research without convening a full board. All of the criteria (*45 CFR 46.111*) for approval of research and the requirements for informed consent *(45 CFR 46.116),* including waiver, alteration or exception, apply.

Expedited review shall be conducted by the IRB Chairman, designated representative or a subcommittee of members authorized by the Chairman to conduct the review. The reviewer may exercise all of the authority of the full board, except may NOT disapprove the research. Only the convened board may disapprove a research activity.

All members of the IRB shall be informed through the IRB Agenda and IRB minutes of research approved through expedited review procedure.

Guidance and Procedures

The Institutional Review Board uses the expedited review procedure for the research categories specified by federal regulations that involve no more than minimal risk, and for minor revisions in previously approved research that occur during the approval period. To effect this review, applications that qualify for expedited procedure will be reviewed as received. If it is determined that the proposal does not qualify for expedited review procedure, it will be submitted on the Agenda to the next appropriate convened meeting.

A. Approval Criteria

Criteria for approval of research using expedited review must satisfy the basic approval requirements defined by DHHS at *45 CFR 46.111* (and, where appropriate, FDA 21 CFR 56.111) including a determination of:

1. Sound research design.
2. Risks that are reasonable in relation to benefits.
3. Equitable selection of subjects.
4. Informed consent sought and documented unless waived according to criteria in 45 CFR 46 (and where appropriate, FDA 21 CFR50.20: 25; 27).
5. Appropriate plan to collect and monitor data, as required.
6. Privacy and confidentiality protected and maintained.
7. Additional safeguards to protect vulnerable subjects, where necessary.

B. Approval Actions

The IRB utilizes three approval actions when conducting expedited review:

1. **APPROVED** – The proposal is approved as submitted with no additional materials or amendments required. A certification letter will be issued specifying the approval period.
2. **APPROVED PENDING MODIFICATIONS** – The proposal is approved pending receipt of additional materials or minor modifications as requested by the IRB. Upon receipt *and approval* of the requested information or modifications, the IRB Coordinator will issue a certification letter to the PI and include the expiration date as well as any other applicable instructions or information as determined by the reviewer (Chair or designated member).
3. **REFER TO FULL BOARD** – The study does not qualify for expedited review, or, significant modifications are required in the protocol or the consent form. The IRB Coordinator will notify the PI in official letter format.

C. Responsibilities

1. **Principal Investigator (PI)**

(a) Initial Review

(1) The PI may initiate a request for expedited review, but the final determination is made by the IRB. If initiating a request for expedited review, the PI submits the following documents to the Office of the IRB for review and distribution to the IRB or appropriate reviewer/s:

(a) SUNY POLYTECHNIC INSTITUTE FORM A-1 *Request for Expedited Review of Research Certification Form*

(b) SUNY POLYTECHNIC INSTITUTE FORM A-2 *Proposal for Research Involving Human Subjects*

(c) SUNY Poly FORM A-3 *Consent Form*, if applicable

(d) Research protocol (if available);

(e) Data collection forms, if applicable;

(f) HIPAA form, if applicable;

(g) Distribution forms or other research instruments;

(h) Any other written documents or information to be provided to subjects;

(i) Investigator's Brochure, if available;

(j) Recruitment materials or any advertising materials that will be seen or heard by potential subjects

(k) A copy of FDA Form 1572, if appropriate (*An agreement signed by the investigator to provide certain information to the sponsor and to assure compliance with FDA regulations regarding the conduct of an investigational drug or biologic*);

(l) Any relevant grant applications, if appropriate.

NOTE: *Forms A-1, A-2,* and *A-3* must be submitted electronically. Any other documents capable of being submitted electronically should be.

(b) Continuing Review (CR)

(1) The PI will submit the following:

(a) *Application for Continuing Review of Research* along with any attachments required on the CR Form;

(b) One copy each, of the current and proposed consent form;

(c) Any amendments or proposed changes to the protocol or consent document that have not been previously submitted;

(d) A description of any unreported adverse events and the reason why not previously reported as occurred;

(e) For studies in which another IRB is the IRB of record, provide a copy of the *Study Progress Report*, current IRB approved consent document and information pertaining to local serious adverse events that occurred since last IRB review;

(f) Any other information as requested by the IRB.

2. <u>IRB Coordinator</u>

(a) Screens the application and supporting documents for completeness. Coordinates with the Investigator for additional or information.

(b) Makes a preliminary decision whether the research meets the requirements for expedited review including the determination of minimal risk and the expedited review category.

(c) Forward the application and all supporting documents to the Chairman/designated representative and consults for final determination.

(d) Notify the Investigator in official letter form of the review decision. If appropriate, specify the expedited review category, terms of approval, and any other instructions.

(e) Notify the IRB membership of all studies approved by expedited review, by including on the Agenda for the next scheduled meeting, including a synopsis of the study and the expedited review category for which the study qualified and document the approval in the minutes.

(f) Refer the study to the full board for review if approval is not rendered through the expedited review process.

3. <u>IRB Reviewer (Chairman/Representative)</u>

(a) Confirm all research activities fit into one or more of the expedited review categories by conducting review of application and all documents submitted by the PI. If any of the research activities do not fit into one or more of the categories authorized by DHHS, the study is not eligible for expedited review procedure.

(b) Confirm all of the research activities present no more than minimal risk to the subjects. If any research activity presents greater than minimal risk as defined below, then the study cannot be approved through the expedited review procedure.

(c) Ensure the research satisfies the basic criteria for IRB approval as specified at 45 CFR 46.111 using the *Criteria for Approval Checklist.*
(d) Ensure the legally effective informed consent is sought from the subject or legally authorized representative in accordance with the requirements of *45 CFR 46.116*, unless a waiver is approved *(Informed Consent Checklist and Policy).*
(e) Determine the approval action as specified in **Section B - Approval Actions** above.
(f) Determine the frequency of review based upon risk assessment, as specified by HHS regulations at *45 CFR 46.103(b)(4)(ii).*
(g) Notify the IRB Office of the review decision, including the expedited review category. If the study does not qualify for expedited review, refer to full board for determination through the Office of the IRB.
(h) For expedited review of studies undergoing **continuing review**: Determine that the study involves no greater than minimal risk and that the frequency of review is appropriate for the degree of risk. If the study involves greater than minimal risk, the study is no longer eligible for expedited review and must be submitted to the full board.

D. Minimal Risk

Federal regulations authorize the IRB to provide expedited review of research if certain conditions are met:

1. The involvement of human subjects must fall into one or more of the categories authorized by DHHS; and
2. **All of the research activities** must present no more than minimal risk to human subjects (45 CFR 46.110(b)(1)).

Minimal Risk – Is defined by the Department of Health and Human Services to mean 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 *(45 CFR 46.102(i)).*

1. If the research does not fall into one of the specified categories, it cannot qualify for expedited review even if it involves only minimal risk.
2. If the research falls into one of the specified categories, but the **probability OR magnitude** of harm is greater than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests, it cannot qualify for expedited review.

E. Minor Changes to Previously Approved Research – Minor revisions involve procedures that are no more than *minimal risk,* or risks to subjects are not increased, and /or the revision is not a significant alteration of the study design. Examples may include changes in telephone numbers, the addition or deletion of associates or staff, the reduction in the number of research participants, or the deletion of questions in a survey (*Bankert & Amdur, 2006, Chap 7*).

F. Continuing Review

The IRB may use expedited review procedures for continuing review of research under the following circumstances:

1. The study was initially eligible and continues to be eligible for expedited review procedures; OR
2. 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
3. No subjects have been enrolled and no additional risks have been identified; OR
4. The remaining research activities are limited to data analysis. The IRB must have determined and documented that the research is no greater than minimal risk and no additional risks have been identified.

Federal regulations at *46.109(e)* require that continuing review occur at intervals appropriate to the degree of risk but not less than once per year. If the IRB approval expires, the PI must cease enrollment of new participants and all research activity for that particular study. Regulations provide for continuation of research activity for subjects who are already enrolled for the period of time necessary to effect continuing review, if the IRB determines it is in the best interest of those subjects.

Generally, continuing review of research may be accomplished through the expedited review process only if the initial review was conducted by expedited review. **Categories 8 and 9** describe situations in which the expedited review of a continuing review requirement may be authorized.

References

Bankert, E., & Amdur, R. (2006) *Institutional Review Board Management and Function, 2nd Ed.*
Code of Federal Regulations: Title 45 Part 46 (45 CFR 46)
Code of Federal Regulations: Title 21 Part 56 (21 CFR 56)
Code of Federal Regulations: Title 21 Part 812 (21 CFR 812)
63 FR 60364-60367, November 9, 1998 *(Categories of Research That May be Reviewed by Expedited Procedure)*
Northshore Long Island Jewish IRB - http://www.northshorelij.com/NSLIJ/irb
OHRP Guidance Documents
Public Responsibility in Medicine and Research (PRIM&R) training resources – www.primr.org
SUNY Binghamton IRB - http://research.binghamton.edu/compliance/humansubjects
SUNY Upstate University IRB
University of Kentucky IRB - (http://www.research.uky.edu/ori/

Attachment - Office for Human Research Protections (OHRP) Department of Health and Human Services (HHS)

Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure

Federal Expedited Review: Application and Categories

Applicability

A. Research activities that

1. Present no more than minimal risk to human subjects, and

2. Involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included in 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.

B. The categories in this list apply regardless of the age of subjects, except as noted.

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

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

E. Standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review – expedited or convened- utilized by the IRB.

F. Categories one (1) through seven (7) pertain to both *initial and continuing* IRB review.

Research Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (be) 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

(1) An investigational device exemption application (21 CFR Part 812) is not required; or

(2) 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-, heel -, or ear stick, or veni-puncture as follows:

(a) From health, 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 ta 2 times per week. ***(COMMENT – Consideration should be given to needle phobia (real or perceived fear) of venipuncture in the pediatric population – (IRB Management and function))***

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

(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) Un-cannulated saliva collected either in an un-stimulated fashion or stimulated by chewing gum-base 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 membrane rupture prior to or during labor;

(h) Supra- and sub-gingival 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 devise are employed, they must be cleared / approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications. Examples:

(a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;

(b) Weighing or testing sensory acuity;

(c) Magnetic resonance imaging;

(d) Electrocardiography, electro-encephalography, thermography, detection of naturally occurring radioactivity, electro-retinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography;

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

(COMMENT – exceptions might include exercise, strength, or flexibility testing; especially on enrollment of a more debilitated subject population due to risk – IRB Management and Function)

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).
(COMMENT - some research in this category may be exempt from the HHS regulations for the protection of human subjects (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.
(COMMENT – The IRB should carefully review for types of information being recorded; determine whether potentially damaging financially, employability, insurability, reputation, etc. If voices can be recognized, employ mechanisms to disguise the voice – this would not qualify for expedited procedures. – IRB Function and Management)

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.
(COMMENT – (1) Some research in this category may be exempt from the HHS 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. (2) The IRB should be cognizant of studies that might result in stigmatization such as studies on the intelligence of a specific segment of society.)

8. *Continuing review* of research previously approved by the convened IRB
   (a) Where:
      (1) The research is permanently closed to the enrollment of new subjects;
      (2) All subjects have completed all research-related interventions; and
      (3) 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.

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[1] An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

[2] Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).

Source: 63 FR 60364-60367, November 9, 1998.