FORM A-1
SUNY Polytechnic Institute
Request for Expedited Review of Research Certification Form

Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in the allowable categories of research may be approved by the IRB through the expedited review procedure. Activities listed should not be deemed to be of minimal risk simply because they are included on the list. Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

Use this form to indicate the category of research which you think may qualify for expedited review. Follow the instructions and submit the completed form and any other required documents electronically to: IRB@sunyit.edu.

Researcher or Faculty Member Name –

Student Researcher Name –

Title of Proposal -

INSTRUCTIONS:

1. *Please answer the three **Expedited Review Criteria** questions by placing a checkmark in the appropriate boxes.*
2. *Identify, by checkmark, the **Expedited Review Category** that applies to this research activity.*
3. *Complete and attach **Form A-2 Proposal for Research Involving Human Subjects** (see Form A-2-1 for proposal instructions).*
4. *Complete and attach **Form A-3 Consent Form**.*

EXPEDITED REVIEW CRITERIA

1. The research is no more than minimal risk.
   ☐YES ☐NO
2. The research is not classified.
   ☐YES ☐NO
3. Identification of the subjects, and/or their responses might reasonably place them at risk of criminal or civil liability or may be damaging to the subject (s) financial standing, employability, insurability, reputation or be stigmatizing.
   ☐ NO
   ☐ YES (If YES, have reasonable and appropriate protections been implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal? Describe these protections.)

ELIGIBLE CATEGORIES

☐ 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.
   (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 vein-puncture as follows:

(a). From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550ml 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.

☐ 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.)

☐ 5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). **(NOTE – some research in this category may be exempt from the HHS regulations for the protection of human 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.

☐ 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 HHS regulations for the protection of human subjects (45 CFR 46.101 (b) (4)). This listing refers only to research that is not exempt.)**

☐ 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) above do not apply but the IRB had determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

FOR IRB USE ONLY	YES	NO	N/A
Risks to participants are minimized by using procedures which are consistent with sound research design and do not unnecessarily expose participants to risk.	☐	☐	☐
Risks to participants are minimized whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.	☐	☐	☐
Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.	☐	☐	☐
Selection of participants is equitable, taking into account the purposes of the research, the setting in which the research will be conducted, the special problems of research involving vulnerable populations, the selection criteria, and the recruitment procedures.	☐	☐	☐
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 regulations.	☐	☐	☐
When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.	☐	☐	☐
When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.	☐	☐	☐
When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants.	☐	☐	☐
If the reviewer answered NO to any of the above, the research activity cannot be approved through the Expedited review procedure.			
1. Risk Evaluation: ☐No Risk ☐Minimal Risk			
2. Consent Form: ☐Required ☐Waived			
3. Child Assent: ☐Less than 18 years of age ☐N/A			
4. Regulatory requirements of subparts B and/or D satisfied ☐YES ☐No ☐N/A			
5. Request for Expedited Review: ☐Approved ☐Not Approved (*refer to Full IRB*)			
6. Expedited review categories:			
7. ☐I certify that I do not have any conflict of interest related to this research or my review of the research.			
8. Comments:			
Reviewer 1 Name/Date: Reviewer 2 Name/Date: Reviewer 3 Name/Date:			