**SUNY Polytechnic Institute**

**Institutional Review Board (IRB)**

**Application for Determination of Research Exemption Status Form**



Research may be exempt from IRB review if the activities involve no more than minimal risk, and the only involvement of human subjects falls within one or more of the exemption categories listed below. Research that does not fulfill the following ethical principles of the *Belmont Report* will not be considered exempt.

1. **Respect for persons** –Individuals should be treated as autonomous agents, and persons with diminished autonomy are entitled to protection.
2. **Beneficence** – Minimize risks and maximize benefits.
3. **Justice** – Risks and benefits of research must be distributed fairly.

***Use this form to identify the category of research that may qualify for exempt status. Submit the completed form to irb@sunypoly.edu, or submit a paper copy of the required signatures to the Chair of the IRB.***

(SUNY POLY IRB phone number: (315)351-3472

**NOTE**: Exemptions may be applied to research involving the following human subject populations with additional protections:

* + Pregnant women, human fetuses, and neonates: If the conditions of exemption are met.
	+ Prisoners: If the research is aimed at involving a broader subject population that only incidentally includes prisoners.
	+ Children:
		- For Categories 1, 4, 5, 6, 7, or 8: If the conditions of exemption are met
		- For Category 2(i) or 2(ii): Only if the research involves educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed.

***Instructions: Please complete the information in sections A, B and C below.***

Section A asks for names and signatures of the principal investigator and student researcher (if applicable), the title of the research project, and date(s) of completion of CITI training.

Section B lists the eight categories of which at least one must fit the research project.

Section C is to be submitted in a separate document and requires information on the nature of the project, the subject population, risks to subjects, the consent form and protection of data on human subjects. Other information as applicable to the research project also needs to be provided in the document.

# Section A

Include the name(s) and title(s) / role(s) (e.g., Professor, Associate Professor, Assistant Professor, Lecturer, Student, Faculty Advisor) of all key personnel involved in conducting the research.

Note: All student research must be supervised by a faculty member, who is ultimately responsible for the protection of human subjects, even if the student is the principal investigator (Policy on Student Research and Classroom Projects).

**Principal Investigator Name and title / role:**

**Principal Investigator Signature**

 **List the name(s) and title(s) / role(s) of all other key personnel (e.g., co-principal investigator, faculty advisor, research assistant, medical professional, etc.) involved:**

**Title of Research Project -**

**For all key personnel involved in the research, provide the following information and attach a copy of valid certification document:**

**Title of CITI training completed; Date of the completion of CITI Training:**

For IRB use only:

If accepted, Exempt Category:

If denied, reason for denial:

Signature of reviewer

Date:

# Section B

To be eligible for exemption, **ALL** of the research activities for the project must fit into one or more of the eight categories listed below.

***Indicate by check mark which of the following categories describes the research project:***

☐ 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. §46.104(d)(1)

☐ 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: §46.104(d)(2)

(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 there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

(**Explanatory Note for iii**: In this case, the IRB conducts a limited IRB review to make the determination required by adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data)

Note: Children can be subjects so long as the following conditions are satisfied

* Only includes educational tests or public observation.
* Investigator does not take part in activities being observed.

☐ 3. 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 audio visual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: §46.104(d)(3)

(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.

**Notes**:

* 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.
* 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.

☐ 4. Secondary research uses of identifiable private information or identifiable biospecimens for which informed consent is not required if at least one of the following conditions is met: §46.104(d)(4)

* The identifiable private information or identifiable biospecimens are publicly available;
* Information is recorded by the investigator in such a way that the identity of subjects cannot be readily ascertained, and the investigator will neither contact the subjects nor re-identify the subjects.
* Research use of identifiable health information when that use is regulated by HIPAA as healthcare operations, research or public health activities and purposes as those terms are defined as HIPAA.
* Analysis of data on behalf of a federal agency or department- as opposed to an investigator- initiated analysis of federally supplied data – if the requirements of certain federal laws are met.

**Note**: Data does not need to be existing at the time of the research study. They may be collected prospectively.

☐ 5. Research and demonstration projects that are conducted or supported by a Federal department or agency and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs including: §46.104(d)(5)

* 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.

**Notes:**

* 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.
* The research or demonstration project must be published on a publicly available Federal Web site or equivalent manner prior to commencing the research involving human subjects.

☐ 6. Taste and food quality evaluation and consumer acceptance studies, §46.104(d)(6)

* If wholesome foods without additives are consumed or
* 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 Services of the US Department of Agriculture.

☐ 7. Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review to ensure that adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of data and if broad consent is obtained. §46.104(d)(7)

**Broad consent** is the seeking of prospective consent from subjects to unspecified future research for the storage, maintenance, and secondary research use of private information or identifiable biospecimens. Broad consent for secondary research use is permitted as an alternative to the standard informed consent requirements for a specific research study. This is not a waiver of consent, but an alternative.

**Secondary research** is “re-using identifiable information and identifiable biospecimens that are collected for some other primary or initial activity”.

☐ 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: §46.104(d)(8)

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained;

(ii) Documentation of informed consent or waiver of documentation of consent was obtained;

(iii) An IRB conducts a limited IRB review and makes the determination that the research to be conducted is within the scope of the broad consent referenced in (i) above. 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.

**Note**: For the definition of Broad Consent, please see Category 7 above.

# Section C

Provide additional information as applicable below in a separate document.

1. Please describe the nature of the research project. Include a sufficient level of detail so that the IRB may make a determination about the nature of the interaction with human subjects. Please be specific about which of the above criteria you are applying to your research activities in order that the SUNY POLY IRB may make a determination that the research is exempt.
	1. A description of the research in layman’s terms
	2. The location of the primary site
	3. If applicable, list source(s) from where participants outside SUNY Polytechnic Institute will be recruited.
	4. Description of the expertise of the researcher(s)~~.~~
2. Provide the copy of consent form
	1. The consent form must conform to the template provided on the IRB website, or
	2. If requesting a waiver of consent, provide a justification.
3. Describe the subject population, such as number to be enrolled, age range, gender, ethnic background and health status. Include how the population will be recruited. Identify inclusion and exclusion criteria.
4. Describe the minimal risks: physical, psychological, social, legal or others.
	1. You must list the risks under each category
5. Provide a description of how information acquired during your project will be managed and how confidentiality will be safeguarded and provide Data Collection forms.
	1. Include information about who will have access to the data and how access will be restricted
	2. Include information about how and when the data will be destroyed.
6. Provide Research procedures.
7. If a survey is to be used, please provide a copy of the survey instrument (the questions and details about how it will be administered).
8. If any de-identification forms are used, please provide the information (i.e., chart/specimen review).
9. If Advertisement/recruitment/Investigator’s Brochure is used please provide the information material.
10. If any other supporting documents are applicable and if any other written information is being provided to the subject, please describe and provide them.
11. Provide a Copy of FDA Form 1572, if appropriate.