

**Appendix A: Level of Review Request**

**Project Title:**

**Principal Investigator:**

**Please check the appropriate box(es) to indicate the category of research eligible into which this project falls:**

**1. EXEMPT REVIEW:** Research that involves no risk or no more than minimal risk to participants.The following are the exemption categories most used by SUNY Potsdam researchers.

[ ]  (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. **(Examples of research acceptable in this category include research in colleges with students +18, research with peer educators/administrators in schools. Research with children is NOT eligible for this category of exemption)**

[ ] (2) Educational Tests, Surveys, Interviews, or Uninfluenced/Unmanipulated Observation of Public Behavior: 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

**(Research with children involving ONLY educational tests or the observation of public behavior when the investigator(s) do NOT participate in the activities being observed for paragraphs (i) and (ii) is eligible for this category of exemption)**

[ ]  (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 audiovisual recording if the subject prospectively agrees to the intervention and information collection and 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

(\*Benign behavioral interventions are defined as “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.” **Research with children is NOT eligible for this category of exemption. Research involving deception is NOT eligible for this category of exemption, unless subjects prospectively agree that they will be unaware of or misled regarding the nature and purpose of the research**)

[ ]  (4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens that were initially collected for non-research purposes, 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.

**(Research with secondary data from children is NOT eligible for this category of exemption)**

[ ]  (5) Research or demonstration projects which are conducted by or subject to the approval of federal department or agency heads and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs, (ii) procedures for obtaining services or benefits under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

[ ]  (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.

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**2. LIMITED IRB REVIEW:** Research that involves no risk or no more than minimal risk to participants and is exemptible but requires that a limited IRB review is conducted to ensure that there are adequate privacy safeguards for identifiable private information and identifiable biospecimens.

[ ] (1)Educational Tests, Surveys, Interviews, or Uninfluenced/Unmanipulated Observation of Public Behavior: 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 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. **(Research with children does NOT qualify for this category of Limited Review)**

[ ]  (2) 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 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.

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**3. EXPEDITED REVIEW:** Research that involves no more than minimal risk to the participant AND falls into one of the categories below MAY qualify for expedited review UNLESS, the research takes place in another country, or participants are members of vulnerable populations (SOME research with children and pregnant women may be eligible for Exempt and Limited review. For a FULL description of Expedited research categories as presented in the federal guidelines, please read the SUNY Potsdam Policy on the Use of Human Subjects in Research- Par III. B. 11. c., available in the IRB website).

[ ]  Research on drugs for which an investigational new drug application 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.)

[ ]  Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

[ ]  Collection of blood samples by finger stick, heel stick, ear stick or venipuncture

[ ]  Prospective collection of biological specimens for research purposes by noninvasive means

[ ]  Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

[ ]  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).

[ ]  Collection of data from voice, video, digital, or image recordings made for research purposes.

[ ]  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.

[ ]  Continuing review of studies approved under the Full Board procedure.

[ ]  Continuing review of a study previously approved by the Expedited procedure, if at the time of the review a reviewer determined that continuing review would enhance the protection of research subjects.

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**4. FULL BOARD REVIEW:** Research involving more than minimal risk to the participant that requires review by the full IRB in a convened meeting. Full-board review covers all research that does not qualify for expedited review or review for certification of exemption. For example, a proposal must go through full-board review if any one of the following is true:

[ ]  Research that is non-eligible for Exempt Review, Limited Review or Expedited Review

[ ]  Research that entails more than minimal risk (physical, psychological, social) to subjects

[ ]  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 implemented so that risks related to invasion of privacy and breach of confidentiality are greater than minimal.

[ ]  Subjects are deceived in the research

[ ]  The research is taking place in another country

[ ]  Subjects are members of vulnerable populations such as decisionally-impaired persons, economically or educationally disadvantaged persons, prisoners, fetuses and human in vitro fertilization, other potentially vulnerable groups (SOME research with children and pregnant women MAY be eligible for other categories of review).