

**Institutional Review Board**

**Application for Research Designated as Exempt**

Principal Investigator Eligibility: Faculty at the assistant, associate, or full professor level, academic, research, or professor-of-practice faculty, department chair/dean, or administrative staff with the position of director or higher may serve as the Principal Investigator (PI) or Co-Investigator (Co-PI). If you have any questions regarding this Syracuse University institutional policy, call the IRB office at 315.443.3013 for guidance.

**This application must be typewritten and all questions must be answered. To complete form, tab to each field. Incomplete forms will be returned to the investigator for additional information. Outdated applications will not be accepted for review.**

## Principal Investigator/Faculty Member Information

|  |  |  |
| --- | --- | --- |
| First Name:       | Middle Initial:       | Last Name:       |
| Title:       |  |  |
| Department:       | College:       |
| Campus Address:       |
| Campus Phone :       | Fax :       |
| Email:       | Cell Phone (optional):       |

**Co-Researcher/Student Researcher/Research Staff Information [ ]  [ ] NA**

|  |  |
| --- | --- |
| First Name:       | Last Name:       |
| [ ]  Faculty [ ]  Graduate Student [ ]  Undergraduate Student [ ]  Staff [ ]  Other:       |
| Department:       | College:       |
| Local/Campus Address:       |
| Local/Campus Phone:  | Fax:       |
| Email:       | Cell Phone (optional):       |

**Research Protocol Title:**

\*NOTE: Collaborative Institutional Training Initiative (CITI) is ***not*** required for research determined to be exempt. CITI is required for researchers involved in expedited or full board studies.

**Please answer each question in the application. A response is required for each bolded and underlined question; incomplete applications will cause a delay in the review process.**

**Section 1 - IS IT RESEARCH?**

The definition of research as defined by the Department of Health and Human Services (DHHS) regulations: “Research means a ***systematic investigation***, including research development, testing and evaluation, designed to develop or contribute to ***generalizable knowledge.***”

To be considered a “systematic investigation”, the concept of a research project must:

* Attempt to answer research questions (in some research, this would be a hypothesis).
* Be methodologically driven, that is, it collects data or information in an organized and consistent way.
* Analyze data or information in some way, be it quantitative or qualitative data.
* Draw conclusions from the results.

**1-A Is this research project a systematic investigation?** [ ]  Yes (Please explain below) [ ]  No

**When “Yes” is indicated a response is required**:

“Generalizable knowledge” would include one or more of the following concepts:

* The knowledge contributes to a theoretical framework of an established body of knowledge.
* The primary beneficiaries of the research are other researchers, scholars and practitioners in the field of study.
* Publication, presentation or other distribution of the results is intended to inform the field of study.
* The results are expected to be generalized to a larger population beyond the site of data collection.
* The results are intended to be replicated in other settings.
* Web based publication for professional purposes.
* Web based publication intended to display student work.

**1-B Will this research project contribute to generalizable knowledge?** [ ]  Yes (Please explain below) [ ]  No

**When “Yes” is indicated a response is required**:

**Section 2 – IS IT HUMAN SUBJECTS RESEARCH?**

The definition of Human Subject as defined by the Department of Health and Human Services (DHHS) regulations (45 CFR 46.102(e):

“Human Subject means a living individual about whom an investigator (whether professional or student) conducting research:

1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies or analyzes the information or biospecimens; *or*
2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.”

*Intervention* includes both physical procedures by which information or biospecimens are gathered (e.g.-venipuncture) and manipulations of the participant or the participant’s environment that are performed for research purposes.

*Interaction* includes communication or interpersonal contact between the investigator and the participant.

*Private information* includes information about behavoir that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual that the individual can reasonably expect will not be made public.

*Identifiable private information* is information or biospecimens for which the identity of the participant is or may be readily ascertained by the investigator or associated with the information or biospecimens.

**2-A Will the information or biospecimens obtained be about living individuals?**

[ ]  Yes [ ]  No

**2-B Will the information or biospecimens obtained through intervention or interaction with individuals be used, studied, and/or analyzed?**

[ ]  Yes [ ]  No

**2-C Will the researcher obtain, use, study, analyze or generate identifiable private information or identifiable**

**biospecimens ?**

[ ]  Yes [ ]  No

**Section 3 – Categories for Exemption**

**Select the category or categories appropriate to your research design**.

[ ]  **Category 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 (e.g.- cannot take time or attention away from normal instruction that might negatively impact student achievement) or the assessment of educators who provide instruction (e.g.-have a negative impact on the employment/evaluation of instructors). This includes most research on regular and special educational strategies, and research on the effectiveness of, or the comparison among instructional techniques, curricula, or classroom management methods. Not allowable: Randomization to unproven teaching/educational techniques or research involving employment decisions.

May include pregnant women, children, and prisoners if the research is aimed at a broader population and only incidentally includes prisoners.

[ ]  **Category 2**

Research involving **one** or more of the following:

1. Educational tests (cognitive, diagnostic, aptitude, achievement):

Only applies to minors/children if the research activities are exclusively limited to educational tests.

* 1. If the information is recorded in a manner that individuals cannot be identified (either directly or through identifiers linked to the individual), *or*
	2. Any disclosure of the participant’s responses outside of the research would not reasonably place the participant at risk of criminal or civil liability or be damaging to the participants’ financial standing, employability, educational advancement, or reputation. *or*
	3. If the information is recorded in a manner that individuals can be identified (either directly or through identifiers linked to the individual) and the IRB determines there are adequate provisions in place to protect both the privacy of the participant and the confidentiality of the information obtained.
1. Survey, interview procedures, or focus groups that do not include research activities with minors/children:
	1. If the information is recorded in a manner that individuals cannot be identified (either directly or through identifiers linked to the individual), *or*
	2. Any disclosure of the participant’s responses outside of the research would not reasonably place the participant at risk of criminal or civil liability or be damaging to the participants’ financial standing, employability, educational advancement, or reputation. *or*
	3. If the information is recorded in a manner that individuals can be identified (either directly or through identifiers linked to the individual) and the IRB determines there are adequate provisions in place to protect both the privacy of the participant and the confidentiality of the information obtained.
2. Observation of public behavior (including visual or auditory recording) of adults. This includes observation of public behavior that occurs in a public place where there is no expectation of privacy and where no special permission is required to observe others, such as public locale, street, park, etc.:
	1. If the information is recorded in a manner that individuals cannot be identified (either directly or through identifiers linked to the individual), *or*
	2. Any disclosure of the participant’s responses outside of the research would not reasonably place the participant at risk of criminal or civil liability or be damaging to the participants’ financial standing, employability, educational advancement, or reputation. *or*
	3. If the information is recorded in a manner that individuals can be identified (either directly or through identifiers linked to the individual) and the IRB determines there are adequate provisions in place to protect both the privacy of the participant and the confidentiality of the information obtained.

May include pregnant women and prisoners if the research is aimed at a broader population and only incidentally includes prisoners. May include minors/children ONLY if the researcher *does not* participate in or manipulate the activities being observed.

[ ]  **Category 3**

1. Research involving benign behavioral interventions in conjunction with the collection of information from an **adult** participant through verbal or written responses (including data entry) or audiovisual recording if the participant prospectively agrees to the intervention and information collection and at least **one** of the following criteria is met:
2. If the information is recorded in a manner that individuals cannot be identified (either directly or through identifiers linked to the individual), *or*
3. Any disclosure of the participant’s responses outside of the research would not reasonably place the participant at risk of criminal or civil liability or be damaging to the participants’ financial standing, employability, educational advancement, or reputation. *or*
4. If the information is recorded in a manner that individuals can be identified (either directly or through identifiers linked to the individual) and the IRB determines there are adequate provisions in place to protect both the privacy of the participant and the confidentiality of the information obtained.
5. For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the participant and the investigator has no reason to believe the participant will find the interventions offensive or embarrassing. (Examples of such benign behavioral interventions might include playing an online game, solving puzzles under various conditions, deciding how to allocate a nominal amount of money between self and others, etc.).
6. If the research involves deceiving the participants regarding the nature or purpose for the research, the exemption is ONLY applicable if the participant authorizes the deception through a prospective agreement to engage in the research under circumstances in which the participant has been informed that they will be unaware of and/or misled regarding the nature or purposes of the research.

May include pregnant women and prisoners if the research is aimed at a broader population and only incidentally includes prisoners. Category 3 research is limited to **adult** participants. Minors/children and decisionally-impaired persons are **NOT** eligible for this exemption.

*Behavioral Intervention* involves the performance of a cognitive, intellectual, educational, or behavioral task; or the manipulation of the participant’s physical, sensory, social, or emotional environment.

*Methods of data collection* are limited to verbal or written responses, observation, and audio/visual recording. Data cannot be collected via physical procedures such as blood pressure monitoring, the use of EEG, activity trackers (e.g.-Fitbit), eye tracking, and blood draws.

[ ]  **Category 4**

Secondary research (involving the use of identifiable private information or identifiable biospecimens) for which consent is not required; if at least **one** of the following criteria is met:

1. The identifiable private information or identifiable biospecimens are publicly available; *or*
2. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained directly or thorugh identifiers linked to the participants, the investigator does not contact the participants, and the investigator will not re-identify participants (e.g.-use codes such as pseudonyms, assign ID#’s, etc.); *or*
3. The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164512(b); *or* for “public health activities and purposes” as described under 45 CFR 164.512(b); *or*
4. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with applicable federal policy standards found in the E-Government Act, Privacy Act and the Paperwork Reduction Act.

Data/specimens would be allowed from pregnant women, children, decisionally-impaired persons, and prisoners if the research is aimed at a broader population and only incidentally includes prisoners.

[ ]  **Category 5**

Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve or otherwise examine public benefit or service programs, including 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. 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 section 1115 and 115A of the Social Security Act, as amended. Each Federal department or agency conducting or supporting the research an demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

Projects eligible for this exemption will be posted on a Federal website.

[ ]  **Category 6**

Taste and food quality evaluation and consumer acceptance studies: if wholesome food 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 U.S. Department of Agriculture.

May include pregnant women, children, prisoners if the research is aimed at a broader population and only incidentally includes prisoners, and decisionally-impaired persons if their inclusion can be justified.

[ ]  **Category 7**

Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review an makes the determinations required by §\_.111(a)(8).

May include pregnant women, children, and prisoners if the research is aimed at a broader population and only incidentally includes prisoners.

[ ]  **Category 8**

Secondary research for which broad consent is not required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

1. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §\_.116(a)(1) through (4), (a)(6), and (d);
2. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §\_.117;
3. An IRB conducts a limited IRB review and makes the determination required by §\_.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and 479;
4. The investigator does not include returning individual research results to participants as part of the study plan. This provision does not prevent an investigator from any legal requirements to return individual research results.

May include pregnant women, children, and prisoners if the research is aimed at a broader population and only incidentally includes prisoners.

**Section 4– Study Design, Methods and Procedures**

**4-A Provide a lay description of the proposed research including the purpose and the hypothesis to be**

 **evaluated.**

**4-B Select all methods of data collection that will be employed in the study (more than one may apply):**

**[ ]  In person, telephone and/or Skype interviews**

 **[ ]  Paper, telephone, and/or Internet surveys (including online and email based data collection)**

 **[ ]  Use of Social Networking Sites**

 **[ ]  Data collection using other communication/electronic devices (e.g.-cell phones, texting devices, etc.)**

 **[ ]  Observation**

 **[ ]  Focus Groups**

 **[ ]  Audio/Visual Recording of any kind (including photographs)**

 **[ ]  Other (please describe):**

**4-C Provide a detailed description of what participants will be required to do. Note: Copies of all research instruments including sample interview questions, questionnaires, surveys, etc. must be provided as an attachment to the application. (Without this information a determination of exemption cannot be made and review of your research will be delayed.)**

**4-D Describe how participants will be recruited and/or learn about involvement in the research. Note: If the researcher will be provided with private identifiable participant contact information (e.g.-names, email/home addresses, phone numbers, etc.) from any source (e.g.-SU department/school/college, other school/college, private organization/agency/company, church etc.) a letter of support signed by the individual authorized to provide you with this information must be provided. More than one letter may be required. Submission of your recruitment instruments/tools is not required.**

**4-E Will this research be conducted in a primary or secondary school or is it funded by the US Department of Education?**

 **[ ]  No**

 **[ ] [ ]  Yes If yes, complete the form found at:** [**Department-of-Education-Schools-Form**](http://researchintegrity.syr.edu/wp-content/uploads/2016/10/Department-of-Education-Schools-Form.doc)

**4-F Will the SU investigators travel to a foreign country to conduct this research? [This does not include research that will be conducted remotely from the U.S. and targets foreign participants (e.g.- online surveys, Skype/telephone interviews, etc.)].**

**[ ]  No**

 **[ ]  Yes If yes, an additional form related to international research must be completed and submitted with**

 **this application:** [**International-Research-Form**](http://researchintegrity.syr.edu/wp-content/uploads/2016/10/International-Research-Form-2013.doc)

**5. Informed ConseNT**

**Please provide a copy of the written or electronic informed consent document or oral consent script you will use in your study. This document must include the following minimum required elements:**

1. A statement that clearly explains that the study is research. The purpose of the research should be described in lay language, avoiding the use of technical terms and using language appropriate to the targeted subject group.
2. A statement that describes what procedures will be followed, clearly explaining what participation in the study will involve.
3. It must be clear that participation is voluntary and participants can withdraw from the study at any time without penalty.
4. Contact information for the investigator.
5. For adult participants, a statement that the subject is 18 years or older must appear as part of the consent.
6. When applicable: Notification of the potential secondary use of information or biospecimen must be provided.
7. For internet research add the following statement:

Whenever one works with email or the internet there is always the risk of compromising privacy, confidentiality, and/or anonymity. Your confidentiality will be maintained to the degree permitted by the technology being used. It is important for you to understand that no guarantees can be made regarding the interception of data sent via the internet by third parties.

**6. Signature Page**

**Investigators of studies exempt from IRB review are responsible for the ethical conduct of research and obtaining informed consent when appropriate.** If this study is being conducted by a student, a faculty member must confirm review and oversight using one of the following methods: provide a signature in the space provided; the use of an E-signature (not computer font); submission of the application directly from their email; and/or provide a confirmation email stating the application has been reviewed.

This is to acknowledge that I take full responsibility for the conduct of the research.

Faculty member/Principal Investigator:

Name (printed):

Date:

If Applicable:

Co-Researcher/Student:

Name (printed):

Date:

Applications can be submitted via campus/US mail, hand delivery to 214 Lyman Hall, or as an attachment to an email sent to orip@syr.edu.

**SYRACUSE UNIVERSITY**

**INSTITUTIONAL REVIEW BOARD**

**Office of Research Integrity and Protections**

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