Office of Sponsored Programs
Institutional Review Board
1200 North DuPont Highway
OSCAR Building, 3rd Floor
Phone: 302.857.6810
Fax: 302.857.6804

APPLICATION REQUESTING EXEMPT REVIEW OF A RESEARCH PROTOCOL INVOLVING HUMAN SUBJECTS

Research studies involving children or vulnerable individuals must be submitted for full review.

General Information

Date: _____

Principal Investigator Name: _____

Department: _____

Preferred Phone #: _____

Preferred Email Address: _____

Co-Investigator Name: _____

Department: _____

Faculty Sponsor Name: _____

Faculty Sponsor Department: _____

Faculty Sponsor Phone #: _____

Research Project Title: _____

Anticipated Start Date: _____**Anticipated End Date:** _____

- All applicants must submit a complete signed copy of the application (faculty sponsor must also sign if applicant is student or an adjunct)
- Submit a CITI Responsible Conduct of Research Training Certificate
- Submit copies of all survey instruments, interview questions, emails, advertisements
- Site permission (if applicant is conducting research anywhere other than Delaware State University

IRB Exempt Categories

Please select the appropriate category that applies to your research

☐ **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 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.

☐ **Category 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: (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 an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

☐ **Category 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: (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 by §46.111(a)(7). (ii) 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 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. (iii) 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 in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

☐ **Category 4-**Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, 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; (iii) 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 164.512(b); or (iv) 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

☐ **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 sections 1115 and 1115A of the Social Security Act, as amended.

☐ **Category 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.

☐ **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 and makes the determinations required by §46.111(a)(8).

☐ **Category 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: (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d); (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117; (iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(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 (iv) 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.

Are there any additional Key Personnel to be listed on this study? ☐ Yes ☐ No
If so, please name the Key Personnel:
_____
_____
_____

Other Collaborating Institutions/Facilities

If you are collaborating with other sites, provide the name of each institution/facility (e.g. other than university, k-12 school, nursing home, tribal affiliation, etc.) and describe the type of involvement of each institution (e.g. recruitment, enrollment/consenting, study procedures, follow up, data analysis.) Indicate if IRB approval/site permission is attached (indicate yes, no or pending.) You will need to obtain IRB approval from every collaborating institution that has an IRB before you can initiate research there.

Will the research be conducted with involvement of a collaborating institution?
☐ Yes
☐ No
☐ Pending

IRB Approval/Site Permission Attached?
☐ Yes
☐ No

International Research

Note: You may need to obtain IRB Approval in the country where the research is taking place and/or a Federal Wide Assurance Number with the Office of Human Research Protocol (OHRP). Please see the OHRP Website for additional information.

List Location(s):

_____
_____
_____
_____

Name Collaborating Institution/Facility:

_____
_____

Describe involvement:

_____
_____
_____
_____

If the Principal Investigator, Student Researcher or other key personnel has an affiliation and or appointment with an institution listed above please explain:

_____
_____
_____

Funding

It is the responsibility of the Principal Investigator to notify the IRB via an Amendment (IRB-3) form if the funding source changes

☐ **Department Funds**
☐ **External (including subawards)**
☐ **Research Incentive Account**
☐ **Faculty Start-Up Funds**
☐ **Investigator Out-of-Pocket**
☐ **Unfunded**
☐ **Other**

_____
_____

IRB USE ONLY
DATE RECEIVED: _____ DATE REVIEWED: _____
Revised 10.2019

Human Participants

Total Numbers of participants to be enrolled?

_____

If you are enrolling more than one, population describe the total enrollment including an explanation of gender, ethnicity, income, level of education and age range:

_____
_____
_____
_____

Describe how participants will be recruited. Submit copies of all advertisement/recruitment materials for IRB review.

_____
_____
_____
_____

Special populations. Identify any special participant populations(s) that you will be specifically targeting for the study. Check all that apply

☐ **Minors** ☐ **Pregnant Women/Neonates**
☐ **Members of the Armed Forces** ☐ **Students**
☐ **Employees** ☐ **Economically/Educationally Disadvantaged**
☐ **Other** _____

By signing this form, I certify that I am familiar with federal and state regulations regarding the protection of human subjects in research. I will not begin this study until I received a written notice of approval, without provisions, from the IRB. I will report any adverse events or emergent problems to the IRB. Additionally, I will obtain approval before implementing any modifications of the protocol.

PI Signature: _____ **Date:** _____

Co-Investigator Signature: _____ **Date:** _____

Faculty Sponsor signature is only required for Student research proposals

By signing this form, I attest that I have read/review this application for quality, completeness, and accuracy. I certify that I am familiar with federal and state regulations regarding the protection of human subjects in research. This study meets the guidelines and requirements of the IRB and has my endorsement.

Signature of Faculty Sponsor: _____ **Date:** _____

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DATE RECEIVED: _____ DATE REVIEWED: _____
Revised 10.2019