**Institutional Review Board**

**Initial Application for Exempt Review**

**Office Use Only - IRB Protocol Number**: Click or tap here to enter text.

Project Title: Click or tap here to enter text.

Principal Investigator: Click or tap here to enter text.

Advisor, if PI is a student:Click or tap here to enter text.

1. **Exemption Checklist**

*Check all that apply. To qualify for exempt review,* ***all*** *statements must apply to your study. If your study does not meet* ***all*** *of these requirements, you will need to apply for expedited or full review.*

[ ]  The research does not involve prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively impaired adults.

[ ]  The research does not involve the collection or recording of behavior which, if known outside the research, could reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.

[ ]  The research does not involve the collection of information regarding sensitive aspects of participants’ behavior (such as, but not limited to: drug or alcohol use, illegal conduct, and sexual behavior).

[ ]  The research does not involve participants under the age of 18 **OR** only involves observation of participants under the age of 18 in which there is ***no interaction*** ***between the researcher and participants***or ***educational research***.

[ ]  The research does not involve deception

[ ]  The procedures of the research are generally ***free of foreseeable risk*** to participants.

[ ]  The research does not involve collecting images, voice recordings, or video recordings of participants.

**II. Access to Personal Identifiers and Protected Information**

*Will any researcher involved in this study collect or have access to any of the personal identifiers listed below? Select all that apply.*

[ ]  Name

[ ]  Date of Birth

[ ]  Mailing or Email Address

[ ]  Phone or Fax Numbers

[ ]  Social Security Number

[ ]  Medical Records (or other information protected by HIPAA)

[ ]  Educational Records (or other information protected by FERPA)

[ ]  License, Certificate, or Vehicle ID

[ ]  IP Address

[ ]  Biometric Identifiers

[ ]  Photos/Images/Audio Recordings

[ ]  Signatures or Handwriting Samples

[ ]  Any unique identifier not listed above: Click or tap here to enter text.

**If you have selected any of the above options, your study does not meet the requirements for an Exempt Review. Please complete an Expedited or Full Review application.**

[ ]  No member of the research team will have access to any personal identifiers or protected information. This option is only valid if none of the other options in Part II are selected.

1. **Exemption Categories**

*Check any categories that apply. You must be able to check* ***at least one*** *item to qualify for exempt review. If you cannot check* ***at least one*** *item, you will need to apply for expedited or full review. Categories are defined by the HHS Office for Human Research Protections.*

[ ]  [45 CFR 46.104(d)(1)] Research conducted in established or commonly accepted educational settings, that specifically involved 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.

[ ]  [45 CFR 46.104(d)(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 (check those that apply):

[ ]  (i) The information obtained is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained, directly or through identifiers linked to the participants.

[ ]  (ii) Any disclosure of the human participants’ responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants’ financial standing, employability, educational advancement, or reputation.

[ ]  (iii) The information obtained is recorded by the investigator in such a manner that the identiy of the human participants can readily be ascertained, directly or through identifiers linked to the participants, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7). [n.b. – the Delaware Valley University IRB does not grant exemptions for any video or audio recordings of participant interviews].

[ ]  [45 CFR 46.104(d)(3)(i)] **Note: read parts i, ii, & iii before checking any boxes.** 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 (check those that apply):

[ ]  (A) The information obtained is recorded by the investigator in such a manner that the identity of the human participants cannot be readily ascertained, directly or through identifiers linked to the participants.

[ ]  (B) Any disclosure of the human participants’ responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants’ financial standing, employability, educational advancement, or reputation.

[ ]  (C) The information obtained is recorded by the investigator in such a manner that the identity of the human participants can readily be ascertained, directly or through identifiers linked to the participants, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7). [n.b. – the Delaware Valley University IRB does not grant exemptions for any video or audio recordings of participant interviews].

(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 participants, and the investigator has no reason to think the participants will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the participants 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 participants regarding the nature or purposes of the research, this exemption is not applicable unless the participants authorizes the deception through a prospective agreement to participate in research in circumstances in which the participant is informed that they will be unaware of or misled regarding the nature or purposes of the research.

[ ]  [45 CFR 46.104(d)(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 participants cannot readily be ascertained directly or through identifiers linked to the participants, the investigator does not contact the participants, and the investigator will not re-identify participants.

[ ]  (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 154.512(b).

[ ]  (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch 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 section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

[ ]  [45CFR 46.104(d)(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 alternative 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.

[ ]  (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site 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 participants.

 [ ]  [45CFR 46.104(d)(6)] Taste and food quality evaluation and consumer acceptance studies:

 [ ]  (i) If wholesome foods without additives are consumed, or

[ ]  (ii) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site 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 participants.

[ ]  [45 CFR 46.104(d)(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).

[ ]  [45 CFR 46.104(d)(8)] Secondary research for which broad consent is required: Research involving the use if identifiable private information or identifiable biospecimens for secondary research use, if **ALL** 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 participants as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

*If you have checked* ***ALL*** *boxes in Part I,* ***no*** *boxes in Part II, and* ***at least one*** *box in Part III, proceed to Part IV on the next page. Otherwise, you will need to complete an expedited or full review application. If you are unsure which review level best suits your study, you may consult with the IRB chair (**irb@delval.edu**).*

1. **Study Description**

*Please answer all questions below in the provided text boxes. These boxes will expand to allow complete answers. Reviewers may come from outside of your discipline. Be clear and precise.*

1. What is the purpose of the proposed study? Provide a brief description of the background research, with citation, that informs your study. Provide references at the end of your text.

Click or tap here to enter text.

1. What is/are your research questions and hypotheses?

Click or tap here to enter text.

1. How will this research contribute to existing knowledge within the field?

Click or tap here to enter text.

1. How many participants are expected for this study? Click or tap here to enter text.
2. Describe the participants. What population will they be drawn from? How will you gain access to the participants? How will the be recruited? Include desired demographics and selection procedures to be used. Attach drafts of any communications, written or verbal, you intend to have with participants through the duration of your study. **If you are drawing participants from a particular institution, including DelVal, you must include a letter of support from an appropriate administrator at that institution showing that they understand what you wish to do and give permission for you to use their members are participants, pending IRB approval.**

Click or tap here to enter text.

1. Describe your research procedures. What will participants be asked to do? Approximately how much time will the be asked to invest? How many waves of data collection will there be?

Click or tap here to enter text.

1. Which type(s) of Informed Consent will you obtain? Choose all that apply.

[ ]  N/A – using existing data or specimens with broad consent

[ ]  N/A – using existing data or specimens without broad consent

[ ]  Signed Informed Consent – hard copy

[ ]  Unsigned Informed Consent – hard copy or electronic copy

[ ]  Assent (participants under 18, usually also requires parental permission)

[ ]  Parental Permission – signed

[ ]  Parental Permission – unsigned

[ ]  Other, specified here: Click or tap here to enter text.

**You must provide copies of all consent documents/scripts with your application.**

1. Describe the consent process. How, when, and where will consent be obtained?

Click or tap here to enter text.

1. If you plan to collect data directly from participants, list all instruments, surveys, interview questions, interventions, or other materials that are part of data collection. Provide references. **Include copies of all materials with your application**.

Click or tap here to enter text.

1. If you do NOT plan to collect data directly from participants, describe the data you will be accessing and your means of accessing it. Include permission from any relevant agencies or groups.

Click or tap here to enter text.

1. Describe how you will protect participants’ anonymity or confidentiality throughout collection, storage, analysis, and reporting of data.

Click or tap here to enter text.

1. Describe any incentives offered to participants (e.g. payments, extra credit, entries into raffles, etc.). Include the value of such incentives, how and when they will be distributed, and how you will handle incentives for participants who withdraw from the study.

Click or tap here to enter text.

1. Describe any possible conflicts of interest or multiple relationships between any researchers, funders, and participants (e.g. teacher-student, manager-employee, friendship, etc.). If any such relationships exist, describe how you will ensure that participants are free to decline participation without actual or perceived penalty and that no participants are directly, indirectly, or perceived to be coerced to participate.

Click or tap here to enter text.

**Once you have completed this application, save it as a .docx, .doc, or .pdf file and submit it, along with all of your other materials, to the IRB chair (****irb@delval.edu****).**