**Institutional Review Board**

**Initial Application for Expedited 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. **Expedited Review Checklist**

*Check all that apply. To qualify for expedited review,* ***all*** *statements must apply to your study. If your study does not meet* ***all*** *of these requirements, you will need to apply for a 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 procedures present **no more than minimal risk** to participants, meaning that the probability and magnitude of harm or discomfort are no greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological tests.

1. **Expedited Research Categories**

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

1. Clinical studies of drugs and medical devices when at least one condition (a or b) is met:

a. Research on drugs for which an investigational new drug application (21 CFR part 312) 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.)

b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) 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.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

a. from healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

b. from other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) musical and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant’s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography76, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects (45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.

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

7. 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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human participants (45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

*If you have checked* ***ALL*** *boxes in Part I and* ***at least one*** *box in Part II, proceed to Part III on the next page. Otherwise, you will need to complete a full review application. If you are unsure which review level best suits your study, you may consult with the IRB chair (*[*irb@delval.edu*](mailto:irb@delval.edu)*).*

1. **Study Description**

*Please answer all questions below in the provided text boxes. These boxes will expand to allow complete answers. If a certain question does not apply to your proposal, enter “N/A” into the text box rather than leaving it blank. 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 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. Describe 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. How will data be recorded (e.g. pen-and-paper, electronically, video/audio recording, etc.)? For any use of online data collection, transcription, or other services, provide security information from the online host that shows participant data will be confidential.

Click or tap here to enter text.

1. How will data be stored? Describe how you will preserve anonymity or confidentiality. How long will data be stored, where will it be stored, how will it be disposed of? This information must also be communicated to participants on your consent document.

Click or tap here to enter text.

1. If deception is part of your planned procedure, provide a scientific justification for it and describe your debriefing procedure (oral or written). Provide a copy of your debriefing materials. **If debriefing is not possible, a full review is required.**

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 1) that participants are free to decline participation without actual or perceived penalty; 2) and that no participants are directly, indirectly, or perceived to be coerced to participate; 3) that the research will be guided by science and ethics rather than the actual or suspected desires of the funder(s).

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**](mailto:irb@delval.edu)**).**