IRB Number_____

Drake University Institutional Review Board

2507 University Avenue, Des Moines, IA 50311-4505 Phone: 515-271-3472
E-mail: irb@drake.edu

Application for

Expedited Review

1. Contact and Study Information Date of report: _____

All study personnel must complete the mandatory Drake University Human Subjects Research Education Program prior to approval of this study. For all personnel listed, please indicate whether or not this requirement has been met by checking yes or no under "IRB Trained?" below. Copies of certificates should be included with the application. If you have any questions regarding education requirements, please call the Institutional Review Board at 271-3472.

		IRB Trained?
Study Title:	_____	
Principal Investigator:	_____	☐ Yes ☐ No
Phone: _____	E-mail: _____	
Department and School:	_____	
Person Responsible for Regulatory Documents:	_____	☐ Yes ☐ No
Phone: _____	E-mail: _____	

All other study personnel* (all persons must have received their certificate of completion of Human Subject Training prior to involvement in this research project; persons who may do a procedure that is standard of care will not require training. When listing a person who does not require training include your rationale as why this is the case (include his/her role in parenthesis after his/her name). All persons involved in the consent process **must** be trained.)

_____	☐ Yes ☐ No
_____	☐ Yes ☐ No
_____	☐ Yes ☐ No
_____	☐ Yes ☐ No
_____	☐ Yes ☐ No
_____	☐ Yes ☐ No
_____	☐ Yes ☐ No
Additional study personnel (see last page of application)	☐ Yes ☐ No

All Personnel who are not Drake University personnel must provide a curriculum vitae and certificate of human participants training if certified outside of Drake University, with this application.

2. Conflict of Interest Statement

Can the results of the study provide a potential financial gain to you, a member of your family, or any of the co-investigators that may give the appearance of a potential conflict of interest? ☐ Yes ☐ No

If YES, provide a copy of your completed conflict of interest statement to the IRB, and include a provision in the informed consent document notifying potential subjects of your conflict of interest.

3. Expedited Review Category—Identify the expedited review category (or categories) of the proposed research. See the Federal Register, Vol. 63, p. 60355 (63 FR 60355) for additional details on each of the following categories.

☐ a. Research on a drug for which an investigational new drug application (IND) is not required, as long as the proposed research does not significantly increase the risks or decrease the acceptability of the risks associated with use of the drug.

☐ b. Research on a medical device for which 1) an investigational device exemption (IDE) is not required; or 2) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ c. Prospective collection of biological specimens for research purposes by noninvasive means. Examples include hair and nail clippings; deciduous teeth and permanent teeth extracted for routine care; excreta and external secretions, including sweat; uncannulated saliva; placenta removed at delivery; amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; supra- and subgingival dental plaque and calculus; mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; and sputum.

☐ d. Collection of data through noninvasive procedures, excluding procedures involving general anesthesia/sedation, x-rays, microwaves, or non-approved medical devices.

☐ e. 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 qualify for exempt status [45 CFR 46.101(b)(4)].

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

☐ g. Research on individual or group characteristics or 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 qualify for exempt status [45 CFR 46.101(b)(4)].

NOTE: Genetic studies require full board review, even if they otherwise would be in a category listed above.

4. Data Storage and Confidentiality—Please state where study data and records will be stored, both during study and when the study has been completed, to ensure subject confidentiality.

5. **Consent/Assent Process**—Please briefly describe your consent/assent process.

6. **Recruitment Process**—Please briefly describe your recruitment process, including compensation.

7. **Submission Requirements**

Submit a copy of the following electronically to the IRB (irb@drake.edu). Please note that if you do not have an electronic signature, hard copies of the signature page will need to be sent via campus mail to the IRB:

- ☐ Completed Application for Expedited Review
- ☐ Protocol or study design
- ☐ Informed consent document
- ☐ Assent document(s), if minors less than 18 years of age are involved
- ☐ Parental consent document, if minors less than 18 years of age are involved
- ☐ Questionnaires/surveys
- ☐ Interview questions
- ☐ Other (explain):

Submit *one copy* (electronically and/or hard copy) of each of the following, as applicable:

- ☐ Investigator's brochure, if any
- ☐ Advertising materials, if any
- ☐ If the research project being submitted has been previously reviewed by a local IRB other than the Drake IRB, a copy of the approval or disapproval letter from that IRB

8. **Principal Investigator's Assurance**

The following signature certifies that the principal investigator (PI) understands and accepts the following obligations to protect the rights of research subjects. It is the PI's responsibility to:

a. **Ensure that the submitted protocol provides a complete description of the proposed research (contains adequate information regarding subjects' rights and welfare and ensures that all applicable laws and regulations will be followed).**

b. **Ensure that the consent/assent documents meet all requirements set forth by applicable federal regulations (DHHS, FDA) and Drake University IRB policies.**

c. **Educate all involved project personnel as to the research responsibilities associated with the project and the process of informed consent/assent in accordance with all applicable federal and Drake University guidelines.**

d. **Ensure that, throughout the course of the study, all research personnel involved in the project conform to the applicable federal regulations and Drake University IRB policies when conducting the research.**

e. **Ensure that all valid informed consent/assent documents are obtained from the subjects prior to the subjects' involvement in the study.**

f. Ensure that only personnel identified as investigators in the IRB-approved protocol obtain informed consent from the potential subjects.

g. Secure all research-related records on file and acknowledge that the IRB may review these records at any time.

h. Promptly inform the IRB (and any other applicable agency) of any adverse events associated with the research project as soon as the adverse event is made known.

i. Promptly report any proposed changes to the research project (e.g., amendments, modifications, updates) to the IRB. Changes will not be initiated until such changes have been reviewed and approved by the IRB, except to eliminate immediate hazards to subjects.

j. Inform the IRB immediately of any information that may negatively influence the risk/benefit ratio of subjects enrolled in the study.

k. One month before the approval period expires, submit either a termination or continuation form to the IRB.

I understand that failure to comply with applicable federal regulations and Drake University IRB policies and procedures could result in suspension or termination of the research project.

_____ _____

Signature of Principal Investigator Date

9. All Other Study Personnel

	IRB Trained?	
_____	☐ Yes	☐ No
_____	☐ Yes	☐ No
_____	☐ Yes	☐ No
_____	☐ Yes	☐ No
_____	☐ Yes	☐ No
_____	☐ Yes	☐ No
_____	☐ Yes	☐ No
_____	☐ Yes	☐ No
_____	☐ Yes	☐ No
_____	☐ Yes	☐ No
_____	☐ Yes	☐ No
_____	☐ Yes	☐ No
_____	☐ Yes	☐ No
_____	☐ Yes	☐ No