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

Determination of Exempt Status

1. Preliminary Information—Answer the following two questions about your proposed project to determine if you need to submit this Application for Determination of Exempt Status.

a. Is the proposed activity research? ☐ Yes ☐ No

Research is a systematic investigation that includes 1) research development, 2) testing, and 3) evaluation and is intended to develop or contribute to generalizable knowledge.

If YES, proceed to the next question. If NO, IRB review is not required and you do not need to complete this form.

b. Does the proposed research involve human subjects? ☒ Yes ☐ No

"Human subject" is a "living individual about whom an investigator (whether professional or student) conducting research obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information" (for example, information gathered through surveys or questionnaires).

If YES, proceed with the form. If NO, IRB review is not required and you do not need to complete this form.

If you answered yes to both questions above and you believe the project qualifies for exempt status [45 CFR 46.101(b)], you must complete this form and submit it (electronically and hard-copy) to the IRB for official determination of exempt status. No work with human subjects can be initiated on the proposed project until you receive a written response from the IRB confirming the exempt status of your project.

2. Contact and Study Information Date of report: _____

Study Title:

Principal Investigator:

Phone: E-mail:

Department and School:

All other study personnel (please indicate staff or student):

_____ ☐ Staff ☐ Student
_____ ☐ Staff ☐ Student
_____ ☐ Staff ☐ Student
_____ ☐ Staff ☐ Student
_____ ☐ Staff ☐ Student

Please list any additional study personnel on last page of application.

3. Eligibility for Exempt Status Review

a. Does the proposed activity involve children (anyone under 19 years of age) as research subjects? ☐ Yes ☐ No

If YES, the proposed activity must be submitted to the IRB for either Expedited Review or Full Board Review UNLESS the research involves only observation of public behavior when the investigators do not participate in the activities being observed. If NO, proceed to the next question.

b. Does the proposed activity involve either of the following groups as research subjects:

- Pregnant women, fetuses, or human in-vitro fertilization ☐ Yes ☐ No
- Prisoners ☐ Yes ☐ No

If YES to either of the above, the proposed activity must be submitted to the IRB for either Expedited Review or Full Board Review. If NO to both of the above, proceed to the next question.

c. If the proposed activity is funded by a federal department or agency, does the federal department or agency require IRB determination of exempt status? ☐ Yes ☐ No

4. Exempt Category—Identify the exempt category (or categories) of the proposed research:

☐ a. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior UNLESS: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **AND** (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

NOTE: This exemption DOES NOT apply to anyone under 18, unless it is research involving observation of public behavior when the investigators do not participate in the activities being observed.

☐ c. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph B above, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐ d. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

☐ e. Research and demonstration projects which are conducted by or subject to the approval of Federal Department or Agency heads, and which are designed to study, evaluate or otherwise examine: (i) Public benefit or service programs; (ii) Procedures for obtaining benefits or services under those programs; (iii) Possible changes in or alternatives to those programs or procedures; or (iv) Possible changes in methods or levels of payment for benefits or services under those programs.

☐ f. Taste and food quality evaluation and consumer acceptance studies if: (i) wholesome foods without additives are consumed; or (ii) 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.

5. **Submission Requirements**—Submit the original of the following documents, as applicable:

   ☐ Completed Application for Determination of Exempt Status
   ☐ Protocol or study design
   ☐ Questionnaires/surveys
   ☐ Interview questions
   ☐ Other (explain):

6. **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, 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.**

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

   d. **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.**

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

   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

7. **All Other Study Personnel (please indicate staff or student)**

_____ ☐ Staff ☐ Student
_____ ☐ Staff ☐ Student
_____ ☐ Staff ☐ Student
_____ ☐ Staff ☐ Student
_____ ☐ Staff ☐ Student
_____ ☐ Staff ☐ Student