

Drake University Institutional Review Board

2507 University Avenue, Des Moines, IA 50311 Phone: 515-271-3472

Email: irb@drake.edu

Application for

Full Board 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.

Study Title: _____	IRB Trained?
Principal Investigator: _____	<input type="checkbox"/> Yes <input type="checkbox"/> No
Phone: _____ E-mail: _____	
Department and School: _____	
Person Responsible for Regulatory Documents: _____	<input type="checkbox"/> Yes <input type="checkbox"/> 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.)

_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
Additional study personnel (see last page of application)	<input type="checkbox"/> Yes <input type="checkbox"/> 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. Project Sites—This project is being conducted at the following Drake sites or Drake-affiliated sites:

Drake University

Other (please specify):

If the study is being done at a non-Drake affiliated site which does not have IRB oversight, an agreement between that site and the Drake IRB must be completed prior to starting the project.

4. Special Considerations

Please identify any of the following that will be involved in the project as research subjects:

Minors (<18 years if age)

Females of child bearing potential

Pregnant women, fetuses, or neonates

Members of Native American tribes

Mentally disabled persons

Economically or educationally disadvantaged persons

Other vulnerable population (identify): _____

Will the research involve genetic testing? Yes No

5. How many subjects will be enrolled:

Multi-center projects: How many subjects will be enrolled at this site? _____

Single center projects: How many subjects will be enrolled at this site? _____

Please give a brief explanation of how you chose this number of subjects to meet your objectives address if this number will allow for statistical determination of the significance of your results.

Are you enrolling both males and females? Yes No

If not, please explain:

6. Risk Category (to be provided by the PI)—Identify the perceived risk to human subjects expected to participate in the research project, including your rationale for the level of risk identified.

a. Research involving adults (check perceived risk)

Low Moderate High

Rationale:

b. Research involving minors < 18 years of age (check perceived risk)

Minimal Risk

Greater than minimal risk, but presents the prospect of direct benefit to individual subjects

Greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder/condition

Rationale:

7. 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.

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

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

10. Safety Monitoring

Is there a Data Safety Monitoring Board (DSMB) Yes No

If YES, provide a brief description, to include the following: a) how often the DSMB meets, b) the material reviewed by the DSMB, c) how often summary reports are issued, and d) the procedures for transmitting DSMB summary reports to the IRB.

If NO, provide a brief description of how the safety of subjects enrolled in of this project will be monitored and who will be responsible for defining when a protocol/consent modification is needed for the safety of subjects enrolled.



11. 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 Full Board Review
- Protocol or study design
- Informed consent document (See consent checklist to assure all elements of consent are included)
- Assent document(s), if minors less than 18 years of age are involved
- Parental consent document, if minors less than 19 years of age are involved
- Genetic consent document (Primary Genetic, Secondary Genetic and/or Storage)
- HIPAA Authorization if the project involves protected health information (PHI)
- Questionnaires/surveys
- Interview questions
- Diary cards
- Other (explain): _____

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

- Investigator's brochure or device manual (for pharmaceutical agents or devices)
- Signed 1572 form or Investigator Agreement (for pharmaceutical agents or devices)
- 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
- Any other documents that will be given to research subjects

12. 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.**

