

Drake University Institutional Review Board (IRB) Application for Research Project Review Please submit completed form to irb@drake.edu	Level of Consideration (please see 5.2 of the Drake IRB Manual): <input type="checkbox"/> Exempt <input type="checkbox"/> Expedited <input type="checkbox"/> Full Board
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To obtain IRB Review of a **research project with human participants**, submit this completed form to the IRB with all of the indicated attachments. Allow sufficient time for review before starting the project. Please consult the IRB website www.drake.edu/irb and contact irb@drake.edu or 515-271-3472 with any questions before submitting an application.

Research as used here means a systematic investigation designed to develop or contribute to generalizable knowledge. This includes research, development, testing, and evaluation. *This does not typically include classroom exercises, demonstrations, or other course requirements that receive grades.* Research does not include customer satisfaction surveys or similar data collections designed to improve the operations of a single institution.

Human participants. The Institutional Review Board (IRB) reviews all research projects at Drake University involving human participants. This means living individuals about whom an investigator obtains data through intervention or interaction with the individual or obtains identifiable private information from a separate source such as medical or school records or other individuals such as relatives.

Name of Study:	
PRINCIPAL INVESTIGATOR:	DRAKE E-MAIL ADDRESS:
DEPARTMENT:	TELEPHONE: () -
MAILING ADDRESS: Street: City: State: Zip Code:	ADDITIONAL INVESTIGATORS, if any:
PURPOSE OF RESEARCH: [Select] If Other, explain (80-character limit):	IRB approval requested from another institution? <input type="checkbox"/> NO <input type="checkbox"/> YES (<i>insert additional pages if needed</i>) Status: [Select] Date: Institution: Status: [Select] Date: Institution:
PROJECT PRECIS OR SUMMARY (<i>Do not exceed 200 characters, including spaces</i>):	
Is this project a sub-study of another project? <input type="checkbox"/> NO <input type="checkbox"/> YES* *If yes, ATTACH information that is pertinent to the approval of the primary object. However, in this application form, include only the particulars that pertain to the study under direct review.	Has this project received or requested external funding? <input type="checkbox"/> NO <input type="checkbox"/> YES—if yes, list: Status Date Source [Select] [Select] [Select]
STUDY SITES if other than Drake University (<i>insert additional pages if needed</i>):	
PARTICIPANTS (check all that apply): <input type="checkbox"/> Adults (18 years or older) <input type="checkbox"/> Minors (Less than 18 years) <input type="checkbox"/> Medical or other clinical Patients <input type="checkbox"/> Non-English Speaking <input type="checkbox"/> Mentally or Developmentally Disabled or Impaired <input type="checkbox"/> Prisoners, Parolees, or Incarcerated <input type="checkbox"/> Elected or Appointed Public Officials or Candidates	TYPE OF DATA (check all that apply): <input type="checkbox"/> Interviews (Face to Face) <input type="checkbox"/> Questionnaires or Surveys <input type="checkbox"/> Existing Data Banks, Archives, or Documents <input type="checkbox"/> Physiological Measurements or Blood Samples <input type="checkbox"/> Observations/Record of Public Record <input type="checkbox"/> Educational Tests

NATURE OF INFORMATION TO BE OBTAINED: <input type="checkbox"/> Participants and their responses <u>cannot</u> be identified <input type="checkbox"/> Filming, Video or Voice-Recording <input type="checkbox"/> Information only pertains to standard educational strategies and/or techniques <input type="checkbox"/> Collected with permission in collaboration with another agency/institution	OTHER: <input type="checkbox"/> Research conducted in an educational setting (this refers to research about specifically educational activities) <input type="checkbox"/> Project involves temporary deception of participant <input type="checkbox"/> Project is time sensitive due to an unforeseen research opportunity (not due to a late start on this application)— Explain:
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By signing below, the Principal Investigator and other Investigators (if any) assure the IRB that all procedures performed during this project will be conducted by individuals legally and responsibly entitled to do so, and that any significant systematic deviation from the submitted protocol (for example, a change in principal investigator, sponsorship, research purposes, participant recruitment procedures, research methodology, risks and benefits, or consent procedures) will be submitted to the IRB for approval prior to its implementation.

By signing below, the Principal Investigator and other Investigators, if any, certify the following: 1) The information in this application is accurate and complete; 2) I/we will comply with all federal, state, and institutional policies and procedures to protect human subjects in research; 3) I/we understand the ethical responsibilities of research investigators and have received the required **training** in human research participant protection as specified at www.drake.edu/irb; and 4) I/we will assure that the consent process and research procedures as described herein are followed with every participant in the research; 5) I/we will promptly report any deviations or adverse events to the IRB.

PRINCIPAL INVESTIGATOR NAME (please ATTACH training certificate if not through CITI):	TODAY'S DATE:
Additional INVESTIGATOR NAME (please ATTACH training certificate if not through CITI):	TODAY'S DATE:
Additional INVESTIGATOR NAME (please ATTACH training certificate if not through CITI):	TODAY'S DATE:
Additional INVESTIGATOR NAME (please ATTACH training certificate if not through CITI):	TODAY'S DATE:
Additional INVESTIGATOR NAME (please ATTACH training certificate if not through CITI):	TODAY'S DATE:

Student Principal Investigators are required to include an endorsement from their faculty advisor. The signature below certifies that the faculty advisor has reviewed and approved this complete Application and its attachments and accepts responsibility to supervise the work described herein in accordance with applicable institutional policies.

FACULTY ADVISOR SIGNATURE (if applicable):		DATE:
Faculty Advisor Name:		
Drake Email:	Telephone: () -	

Procedures for the Review of Research Projects with Human Participants

To protect the rights and welfare of individuals recruited to participate in research conducted by faculty or students at Drake University, DU policy requires that all research with human participants as defined on Page 1 be reviewed by the DU IRB. The DU IRB follows the Common Rule (45 CFR 46) and other applicable federal regulations as applicable, and generally adopts the policies and guidance published by the Office for Human Research Protections of the U.S. Department of Health and Human Services (<http://www.hhs.gov/ohrp/policy/index.html>).

Each of the following elements must be included in this Application. Note carefully the **REQUIRED ATTACHMENTS**. The information text for this form may be submitted on these pages or as a separate attachment labeled APPLICATION FORM PAGES using the identical outline numbers and headings as below.

I. **Research Summary:**

- a. Provide a brief description of the research, the role of human subjects, and the overall goals of this project in lay language (500 words or less). Include a brief summary of the research procedures, paying special attention to what will happen to participants and what they will be told about the research. If there are different phases or types of project with different participants, clearly enumerate these phases or types. *This research summary should be written or edited specifically for IRB review. Thesis proposals or grant applications are not appropriate substitutes and should not be included.*
- b. Provide a brief (no more than one page) literature review in narrative form which describes both (1) prior relevant research to give context for the work and (2) why the work is being proposed in terms of potential contributions or novelty, in a way a non-expert can understand. The narrative should be supported by appropriate referencing and reference list; however, standalone bibliographies or annotated bibliographies will not be accepted.

II. **Participants and Recruitment:**

- a. Describe the population to be studied, including the approximate **numbers** of participants to be recruited and expected to complete the study, differentiating these numbers for each phase or type of project element, if multiple. Clearly state all **inclusion/exclusion criteria** for participation.
- b. Describe recruitment procedures, including how potential participants will first be made aware of the project, for each phase or type of project element. Describe any **compensation or incentives** that will be offered. **ATTACH** flyers, letters of initiation, and recruiting scripts, if any.

- c. Describe the process of gaining informed consent to participate in each phase or type of research element. **ATTACH** a copy of each written consent or assent form or script is to be used. Include all versions of multiple forms or scripts, if applicable, highlighting relevant differences. If any temporary **deception** of participants is planned, describe the research features that would not be disclosed in the initial informed consent process and provide a specific research **justification** for this deception.
- d. **INCLUDE** a copy of each informed consent or assent document(s) to be used. If obtaining informed consent/assent electronically, provide the functional URL(s) that will be used in the actual study; IRB approval will be linked to the URL version(s) of the informed consent/assent document(s).

III. **Research Procedures and Methods:**

- a. Describe the **data collection procedures and materials**. **ATTACH** copies or images of the actual materials to be employed, in final form to the extent possible, otherwise in draft or outline form—such as questionnaires, interview protocols, media to be shown to participants, pictures of apparatus to be used, etc. Indicate whether attachments are draft or final.
- b. Describe procedures for maintaining participant **confidentiality** and/or anonymity, especially if tape recording, photographs, movies or videotapes will be used.
- c. **If** information about the research will be temporarily withheld during the consent process in order to mislead or deceive the participant, the deception must be fully disclosed in a debriefing after participation is completed, and an opportunity offered to withdraw from the study. If applicable, describe the participant **debriefing** procedures and **ATTACH** debriefing documents or scripts.
- d. Research data remain the property of the PI and should be retained for **at least 3 years** after the completion of the project. Indicate where data will be stored, how the individually identifiable data will be safeguarded, and method of destruction.

IV. **Potential Risks and Benefits:**

- a. Describe real and potential **risks to the participant** including possible inconvenience and discomforts; and any risks to nonparticipants. The lowest level of risk may be described as “minimal.” *The extent of risks described here should not exceed the extent of risks communicated*

during the informed consent procedure, otherwise the research employs deception--see section II.c.
Separately describe procedures for minimizing potential risks and for managing any anticipated adverse effects that may arise.

- b.** –Describe definite or potential **benefits to the participant** due to completing the study, if any.
- Describe definite or potential benefits **beyond** the participant, including benefits to the researcher; and to a specific social group or institution, if any.
- Only if the risks to participants are **more than minimal**, then describe the expected **scientific benefits** that justify exposing participants to above-minimal risks.
- The benefits described during the informed consent procedure should not exceed those described here. Otherwise the research employs deception—see section II.c above.
- Compensation is separate from benefits—compensation should be described above in section II.b.*

Signature (Principal Investigator or Instructor)

Date

Signature (Department Chair)

Date