Canisius University IRB Application

Directions: When complete, please save the file and email it to Michael Dolan, mdolan@canisius.edu Chair of the Canisius IRB. Please print and sign the signature page at the end of this document and return it via campus mail to:

Michael Dolan, KC 211

**1. Project Title**

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| Title of Project:  |  |

**2. Type of Review:**

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| This project may fall under an exempt or expedited review category.  |  |  |

**3. Project Dates**

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| **a.** Anticipated starting and completion dates:  |  | to |  |
| **NOTE: The project may not start before approval from the IRB.** |

**4. Principal Investigator Information**

**a. Contact Information**

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| Principal Investigator:  |  |
| Department or Affiliation: |  |
| Telephone: |  | Email: |  |
| Name of chair/supervisor: |  |
| Email of chair/supervisor: |  |

**b. Status**

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| PI status: | Undergraduate: |  | Graduate: |  | Faculty: |  | Staff: |  | Other: |  |  |
| Students and outside researchers must provide their current address: |
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**c. Student / Outside Researcher Information**

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| If you are a student or outside researcher, please provide the following as applicable: |
| Type of project: | Thesis/Essay: |  | Independent Study: |  | Class Project:  |  | Other: |  |  |
| Course # & Name: |  |
| Faculty Sponsor: |  | Dept: |  |
| Faculty Email: |  | Phone: |  |
| NOTE: An application by a student or outside researcher must have the following statement signed by a university sponsor: |
|  | I have examined this completed form and I am satisfied with the adequacy of the proposed research design and the measures proposed for the protection of human participants. For student projects, I will take responsibility for informing the student of the need for the safekeeping of all raw data (e.g., test protocols, tapes, questionnaires, interview notes, etc.) in a College or computer file. |
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**5. funding**

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| --- | --- | --- | --- | --- |
|  Is this project being funded? |  | Yes |  | No |
| If yes, list the funding source: |  |

**6. Research Statement:** Indicate the reason for the research and a short justification:

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**7. Participants**

**a.** Indicate which, if any, of the following groups will be research participants (check all that apply):

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|  | Minors (under 18) |  | Senior Citizens (over 65) |  | Terminally Ill |
|  | Students |  | Prisoners |  | Cognitively Impaired |
|  | Non-English Speakers |  | Mentally/Physically Disabled |  | Pregnant Women |
|  | Institutional Residents |  | Employees |  | No Special Groups |
|  | Single Subject Populations (by Race, Ethnicity, Sex, or Religion) |
|  | Other (specify):  |  |

**b.** If any of the above groups are selected, state the rationale for using special groups.

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| **c.** What is the approximate number of participants to be recruited? |  |  |

**d.** How will the participants be solicited (check all that apply)?

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|  |  | Advertisements |  | Letters |  | Random Calls |
|  |  | Telephone Lists |  | Notices |  | Direct Solicitation |
|  |  | Student Newspaper |  | Other (specify): |  |

8. Informed Consent.

a. Type of Consent/Minor Assent Requested (check all that apply):

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| --- | --- | --- |
| **(i)** |  | Adult Consent |

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| --- | --- |
| **(ii)** | Use of Minors (under 18 years of age) |
|  |  | Parent/Guardian Consent |
|  |  | Child/Minor Assent (Non-readers: Not able to read or not proficient at reading) |
|  |  | Child/Minor Assent (Proficient readers: Can read & understand a simple assent form) |

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| **(iii)** | In certain circumstances, a waiver of informed consent/minor assent may be requested. In this case, participants are not informed or only partially informed about a study. To request that informed consent or assent be waived, indicate the category below (check all that apply). |
|  |  | Informed consent will not be obtained |
|  |  | Parental consent will not be obtained |
|  |  | Child/minor assent will not be obtained |
|  |  | Partial Consent/Assent: This study involves deception |

Justify why informed consent will not be obtained or why deception is necessary for this study. For studies that involve deception please include plans for how and when participants will be debriefed. If a debriefing statement will not be used, explain why.

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| **b.** **Method** to obtain consent/minor assent. |
| **(i)** |  | Written Consent/Assent (written signature will be obtained from participants) |
| **(ii)** |  | No Written Consent/Assent Obtained (a written signature will not be obtained from participants. Documentation of a signature is waived.)  |
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| If a waiver of a signature is requested, indicate below how participants will be informed: |
|  |  | An Information Sheet will be used. Explain the rationale below. |
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|  | Oral Consent will be obtained. Explain the rationale below. |
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|  | Electronic Consent |

9. Data & CoNSENT Collection

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| **a.** Data collection methods (check all that apply): |
|  |  | Questionnaire or Survey |  | Archival Data |
|  |  | Web or Internet  |  | Intervention |
|  |  | Interview |  | Focus Groups |
|  |  | Observation |  | Testing/Evaluation |
|  |  | Video or Audio Taping |  | Instruction/Curriculum |
|  |  | Computer Collected Task Data |  | Physical Tasks |
|  |  | Other: |  |

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| **b.** Will the data be collected with identifiers? |  | Yes |  | No |
|  |  If yes, will the data be rendered anonymous for analysis? |  | Yes |  | No |
|  |  Will the data be rendered anonymous for reporting? |  | Yes |  | No |
|  |  |

**c.** Describe how the consent forms and other study material (e.g., data instruments, computer task data, interview questions) will be distributed and collected to protect the privacy of the participants and how confidentiality/anonymity will be maintained throughout the consent and data collection process.

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**d.** Describe the security of the data, including where the consent forms and other study material will be stored, who will have access, and how and when the material will be destroyed. Note that signed consent forms must be retained for **three years** after the end of the study. State who will maintain the consent forms for the specified three years. (Note: faculty/staff sponsors should retain the original or a copy of signed consent forms collected from student projects.)

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10. Methodology: Describe in detail how the research will be conducted making sure to address (1) how participants will be identified and the process of contacting, selecting and excluding participants; (2) how consent will be obtained, and if children will be used, describe how parental consent and child assent will be obtained; and (3) how data will be collected, including how data instruments, if used, will be distributed and collected, and the location where the study will take place. Essentially, describe how the study will be practically implemented step by step.

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**11.** **Risk Factors:** A research participant is considered to be at risk if he or she may be exposed through the procedures of the planned experiment to the possibility of physical or mental harm, coercion, deceit, or loss of privacy. The most obvious examples of placing participants at risk of harm include the administration of unusual physical exertion, deceit, and public embarrassment or humiliation. Coercion may be present when the potential participants are not able to exercise their right to decline participation, particularly when the researcher is in a relationship of greater power over the participants.

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| **a.** | Risk Criteria | **CHECK ONE** |
|  | Deceit, coercion, or possible embarrassment/humiliation |  | Yes  |  | No |
|  | Experimental drugs will be used. |  | Yes  |  | No |
|  | Potential medical problems exist. |  | Yes  |  | No |
|  | Participants may experience physical discomfort. |  | Yes  |  | No |
|  | Participants may experience mental discomfort. |  | Yes  |  | No |
|  | Electrical equipment will be used. |  | Yes  |  | No |
|  | Participants will be tape-recorded, photographed, or videotaped. |  | Yes  |  | No |

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| **b.** Does any part of this activity have the potential for coercion of the participant? If yes, explain and describe the proposed safeguards. |  |  |  |  |
|  | Yes |  | No |

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**c.** Assess the likelihood and seriousness of risks (physical, mental, or other) to the participants. Describe alternative methods that would not entail comparable risks and why these were not used.

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**d.** Description of the anticipated benefits to participants and contributions to general knowledge in the field of inquiry:

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**e.** If the research participants will be compensated or rewarded, indicate the type and amount of compensation and the milestone for each payment. If participants are being recruited from Canisius University, indicate whether students are receiving course credit (regular or extra credit) and, if so, what alternatives are offered to those students who do not wish to participate in the research.

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| **12.** **Submission Material**The IRB must review copies of all final material presented to participants. The IRB cannot approve a project without a complete and accurate application and final copies of all supporting materials. Please indicate below what materials have been attached to this application (check all that apply): |

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|  |  | Recruitment material (flyer, announcement, oral script, email, letter, etc.) |
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|  |  | Data instruments (surveys, interview questions, tests, web surveys, etc.) |
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|  |  | Informed consent (consent and assent forms, information sheet, oral consent script, (etc.) |
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|  |  | Debriefing statement |
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|  |  | Video clips, music CDs, photos, etc. |
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|  |  | Other: (specify) |  |

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| **13. Certification Statement** *I acknowledge my obligation to: (1) obtain written approval of significant deviations from the originally approved protocol BEFORE making those deviations; and (2) report immediately all adverse effects of the study on the participants to the Chairperson of the Institutional Review Board and the Chairperson or Supervisor of my Department.*

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| Principal Investigator signature |  | Date |
|  **Co-Investigators:** |
| **a.** Name: |  | Title:  |  |
| Signature: |  | Affiliation: |  |
| **b.** Name: |  | Title: |  |
| Signature: |  | Affiliation: |  |
| **c.** Name: |  | Title:  |  |
| Signature: |  | Affiliation: |  |
| **d.** Name: |  | Title: |  |
| Signature: |  | Affiliation: |  |
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**14. Submission Information**

When complete, please save the file and email it to Michael Dolan at mdolan@canisius.edu Chair of the Canisius IRB. Please print the signature page, sign and place it in campus mail to:

Michael Dolan, KC 211