**OLD DOMINION UNIVERSITY**

**HUMAN SUBJECTS RESEARCH EXEMPT APPLICATION FORM**

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| Study Title |
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| Responsible Project Investigator (RPI) |
| **The PI must be an ODU faculty or staff member who will serve as the project supervisor and be held accountable for all aspects of the project. Students cannot be listed as the PI.** |
| **First Name:**  | **Last Name:**  |
| **Telephone:**  | **E-mail:**  |
| **Office Address:**  |
| **City:**  | **State:**  | **Zip:**  |
| **Department:**  | **College:**  |
| **CITI Completion Date:**  |

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| Investigators |
| **Investigator(s): Individuals who are directly responsible for any of the following: the project’s design, implementation, consent process, data collection, and/or data analysis.** **Investigators must complete the CITI Basic Human Subjects Protection Training.** |
| **First Name:**  | **Last Name:** |
| **Telephone:**  | **Email:**  |
| **Office Address:**  |
| **City:**  | **State:**  | **Zip:**  |
| **Department:**  | **College:** |
| **Affiliation:** [ ]  Faculty [ ]  Graduate Student [ ]  Undergraduate Student[ ] Staff [ ]  Other:       |
| **CITI Completion Date:**  |
|  |
| **First Name:**  | **Last Name:**  |
| **Telephone:**  | **Email:**  |
| **Office Address:**  |
| **City:**  | **State:**  | **Zip:**  |
| **Department:**  | **College:**  |
| **Affiliation:** [ ]  Faculty [ ]  Graduate Student [ ]  Undergraduate Student[ ] Staff [ ]  Other:       |
| **CITI Completion Date:**  |
| Upload a copy of the Additional Investigators form if more rows are needed. |

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| Type of Research |
| 1. **This study is being conducted as part of (check all that apply):**

[ ] Faculty Research [ ] Non-Thesis Graduate Student Research[ ] Doctoral Dissertation [ ] Honors or Individual Problems Project[ ] Masters Thesis [ ] Other:       |

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| Funding |
| **2. Funding Status:** [ ]  Research is **not funded** **(go to 3)**[ ]  Research is **funded** **(go to 2a)**[ ]  **Funding decision is pending** (funding decision has not been made) **(go to 2a)****2a. Type of funding source: (Check all that apply)**[ ] Federal Grant or Contract **(Must submit to IRB for review)** [ ]  State or Municipal Grant or Contract [ ]  Private Foundation[ ]  Corporate contract [ ]  Other (specify):      |
| **Funding Agency Name:** |  |
| **Agency Proposal Number:** |  |
| **Grant Start Date (MM/DD/YY):** |  |
| **Grant End Date (MM/DD/YY):** |  |
| **2b. List the point of contact at the funding source:** |
| **Name:** |  |
| **Mailing Address:** |  |
| **Telephone:** |  |
| **Email:** |  |

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| Research Dates |
| **3a. Date you wish to start research (MM/DD/YY):**  |

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| Research Location |
| 1. **Where will the experiment be conducted? (Check all that apply)**
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| [ ]  On Campus | Building and Room Number:       |
| [ ]  Off-Campus | Site Name and Street Address:       |

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| Human Subjects Review |
| 5.Has this project been reviewed by any other committee (university, governmental, private sector) for the protection of human research subjects? [ ]  Yes [ ]  No **(If no, go to 6)****5a. List the other committee(s) that have reviewed this project and indicate which IRB is serving as the primary IRB.**      |

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| Exempt Categories |
| NOTE: IRB Review is required for Categories 2, 3, and 4 if your research involves sensitive and identifiable information. IRB Review is also required for Categories 7 and 8.  |
| [ ]  **Category 1** Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.  |
| [ ]  **Category 2** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: 1. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
2. Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or
3. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §\_\_.111(a)(7).
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| [ ]  **Category 3**1. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
	* + The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
		+ Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or
		+ The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §\_\_.111(a)(7).

ii. For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. iii. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research. |
| [ ]  **Category 4** Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: 1. The identifiable private information or identifiable biospecimens are publicly available;
2. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
3. The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or
4. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.
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| [ ]  **Category 5** Research and demonstration projects that are conducted or supported by a Federal department or agency… (Not common at ODU) |
| [ ]  **Category 6**Taste and food quality evaluation and consumer acceptance studies (Not common at ODU) |
| [ ]  **Category 7**Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §\_\_.111(a)(8).  |
| [ ]  **Category 8**Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: 1. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §\_\_.116(a)(1) through (4), (a)(6), and (d);
2. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §\_\_.117;
3. An IRB conducts a limited IRB review and makes the determination required by §\_\_.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and
4. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.
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| Study Purpose |
| **6. Describe the rationale for the research project:**            |

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| Subjects |
| **7. What will be the maximum number of subjects in the study?**  |  |
| **7a. Indicate the approximate number of** | **Males:** | **Females:** |
|  | **Non-Binary:** | **Transgender:** |
|  | **Other (please specify):** |  |
| **7b. What is the age of subjects? (Check all that apply)**  |
| [ ]  Children (Birth-17 years old) | [ ]  Adults (18-89 years old) | [ ]  Elderly (90+ years and older)  |
| **7c. Will students be enrolled in the study? (Check all that apply)** \*If students are under 18 years old, parental consent must be obtained |
| [ ]  Undergraduate students | Department:      | [ ]  Advanced students | Department:      |
| **7d. Provide rationale for the choice of subjects. Enumerate any additional defining characteristics, including age, of the subject population. (e.g., symptomatology, history, socio-economic status).**                               |

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|      Vulnerable Subjects |
| **8. Are research subjects being used whose ability to give informed voluntary consent may be in question? (e.g., children, persons with AIDS, mentally disabled, psychiatric patients, prisoners.)** [ ]  Yes [ ]  No  |
| **8a. What type of vulnerable subjects are being enrolled? (Check all that apply)** |
| [ ]  Critically Ill Patients  | [ ]  Mentally Disabled or Cognitively Impaired Individuals |
| [ ]  Prisoners | [ ]  Physically Handicapped |
| [ ]  Pregnant Women | [ ]  Children |
| [ ]  Other (describe):      |
| **If yes, explain the procedures to be employed to enroll them and to ensure their protection:**           |

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| Recruitment**Copies of all recruitment materials must be attached to this application.** |
| **9. Check all types of recruitment that will be utilized in the study.** |
| **[ ]  E-mail/Social Media** | **[ ]  Letters** |
| **[ ]  Newspaper/Radio/Television/Website advertising** | **[ ]  Posters/Brochures** |
| **[ ]  Other:**  |
| **9a. What methods will be used to identify and recruit prospective subjects? Specify the source of potential subjects. If an outside agency or organization will recruit subjects on the investigators behalf, a support letter must be included.**  |

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| **Inclusion and Exclusion Criteria** |
| **Outline the inclusion and exclusion criteria for the study below.****Inclusion:** **Exclusion:**  |

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| **Procedures** |
| **11. Describe the procedures that will be followed. (Include a succinct, but comprehensive statement of the methodology relating to the human subjects. You are encouraged to include a discussion of statistical procedures used to determine the sample size.)**  |
| **11a. Will the deliberate deception of research participants be involved as part of the experimental procedure?****Subjects must be prospectively informed that he or she will be unaware of or misled regarding the nature or purposes of the research.** [ ]  Yes **(If yes, explain the nature of the deception, why it is necessary, any possible risks that may result from the deception, and the process of prospective agreement and debriefing of the subject).**[ ]  NoComments:       |

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| Compensation |
| **12. How much time will be required of each subject?**  |
| **12a. Will research subjects receive course credit for participating in the study?** [ ]  Yes **(If yes, please explain in comments section.)**[ ]  No Comments:       |
| **12b. Are there any other forms of compensation that may be used? (e.g. Money, Gift Cards)**[ ]  Yes **(If yes, please explain in comments section.)**[ ]  No Comments:      |

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| Protection of Anonymity |
| **13. Describe in detail the procedures for protecting the anonymity (meaning that no one will ever be able to know the names) of the research subjects. If anonymity is impossible, then describe in detail the procedures for safeguarding data and confidential records. These procedures relate to how well you reduce the risk that a subject may be exposed or associated with the data.**       |

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| Training |
| 14. Briefly explain the nature of the training and supervision of anyone who is involved in the actual data collection, research design, or in conducting the research. This information should be sufficient for the IRB to determine that the RPI and investigators possess the necessary skills or qualifications to conduct the study.      |

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| **PLEASE NOTE:** |
| 1. You may begin research when you receive final WRITTEN notice of your projects approval through IRBnet.
2. You MUST inform the committee of ANY adverse event, changes in the method, personnel, funding, or procedure.
3. At any time, the committee reserves the right to re-review a research project, to request additional information, to monitor the research for compliance, to inspect the data and consent forms, to interview subjects that have participated in the research, and if necessary to terminate a research investigation.
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