**TOWSON UNIVERSITY**

**INSTITUTIONAL REVIEW BOARD**

**APPLICATION FOR ACCELERATED REVIEW – STUDIES INVOLVING ADULTS ONLY**

|  |
| --- |
| *This form should be used only for research involving individuals who have reached the age of majority (i.e., 18 years in the state of Maryland). The research must also meet the criteria for one of the accelerated review categories listed below.* |
| **I. PROJECT INFORMATION** |
| **A. Project Title** |  |
| **B. Principal Investigator**(*Name, Address, Phone Number, E-mail, Fax*) |  |
| **C. Is the PI a Student? (circle One)** | **YES** If **YES** (circle one): Graduate Undergraduate **NO** If **YES**, indicate the purpose of the study in the space below (e.g., MA Thesis,  Undergraduate Thesis, Dissertation, etc) |
| **D. Faculty Advisor for Student PI**(*Name, Address, Phone Number, E-mail, Fax*) |  |
| **E. Co-Investigator** (list all)(*Name, Phone Number, E-mail*)\*\*Include affiliation if Co-I is not a TU Faculty, Staff Member or Student |  |
| **F. Primary Contact Person (If different from PI or Faculty Advisor)**(*Name, Address, Phone Number, E-mail, Fax*) |  |
| **G. Is the Research Currently Funded? (circle one); If NO, then…****Are you Attempting to Secure Funding for the Research?** | **YES** If YES, Indicate the source in the space below **NO****YES** If YES, Indicate the source in the space below **NO** |
| ***H. Do you intend to…?**** Collect information that could place the person at risk for criminal or civil liability such as illicit drug use, underage drinking, or criminal behavior, etc.
* Collect information that could cause the participant significant distress such as past sexual abuse/assault, prior traumatic experiences, etc.
* Collect sensitive medical or mental health information such as history of STDs, HIV, abortions, schizophrenia, etc.
* Collect reportable information (i.e., child abuse or neglect, elder abuse or neglect, incest, suicidal or homicidal thoughts or behaviors, sexual experiences with a USM faculty member)
* Collect information that could damage the participants’ financial standing, employability, educational advancement, or reputation
* Use deception and you do not have prospective consent from potential subjects to participate in research involving deception
* Include a behavioral intervention that does not meet the criteria for benign as defined in Category II.3, below.
* Collect data from voice, video, digital, or image recordings (this excludes recordings of public observation)?
* Collect data with individual identifiers (this excludes secondary research of existing data)?

***\*\*Note: YES to any of these items, Complete the Application for Standard or Full Board Review******If NO, Proceed to Section II. ACCELERATED REVIEW CATEGORIES*** | [ ] YES [ ] NO[ ] YES [ ] NO[ ] YES [ ] NO[ ] YES [ ] NO[ ] YES [ ] NO[ ] YES [ ] NO[ ] YES [ ] NO[ ] YES [ ] NO[ ] YES [ ] NO |

 **Continued on the Next Page**

|  |
| --- |
| **II. ACCELERATED REVIEW CATEGORIES** |
| *Place a check mark next to the appropriate category that applies to your research.* |
|[ ]  1. Research conducted in established or commonly accepted educational settings involving normal educational practices, such as (a) research on regular and special educational instructional strategies, OR (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
 |
|[ ]  1. Research that only includes educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording)

**AND** at least one of the following criteria(*check the appropriate criterion that applies to your research)*:[ ]  (i) 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? OR [ ]  (ii) Any disclosure of responses outside of 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 |
|[ ]  1. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subjectthrough 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(*check the appropriate criterion that applies to your research)*:

[ ]  (i) 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? OR [ ]  (ii) Any disclosure of responses outside of 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***\*\*Note:******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; e.g., playing an online game; solving puzzles under various noise conditions.**** *Does your study meet the criteria for a benign behavioral intervention?* [ ] YES [ ] NO

***\*\*Note: Studies involving deception are only exempt under this category IF the subject provides their prospective consent to participate in research studies that may involve deception.**** *Does your study involve deception about the nature or purpose of the study?* [ ] YES [ ] NO
* *IF YES, Have you obtained prospective consent from potential subjects to participate*

*in research in which they may be unaware of or misled about the nature or* [ ] YES [ ] NO*purpose of the study? OR** *Will you obtain prospective consent from potential subjects to participate*

*in research in which they may be unaware of or misled about the nature or* [ ] YES [ ] NO*purpose of the study?**\*\*****Note: Forms used to obtain prospective consent to participate in studies involving deception must be approved by the IRB. DO YOU HAVE AN IRB APPROVED FORM FOR THIS PURPOSE?*** [ ] YES [ ] NO ***If NOT, please submit one with this application for approval*** |
|[ ]  1. Secondary research involving the collection or study of existing data, documents, or records containing identifiable private information, or identifiable biospecimens research for which consent is not required **AND** one of the following criteria (*check the appropriate criterion that applies to your research):*

[ ] (i) The data are publicly available[ ]  (ii) 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?[ ]  (iii) The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45CFR Parts 160 AND 164, subparts A and E, for the purposes of “health care operations” (<https://www.law.cornell.edu/cfr/text/45/164.501>) or “research” or for “Public health activities and purposes” (<https://www.law.cornell.edu/cfr/text/45/164.501>).[ ]  (iv) 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 according to specifically federal guidelines. |
| [ ]  | 1. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated the authority to conduct the research and demonstration projects) **AND** it must also fall within one of the following categories (please check any that apply):

[ ] (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 these programs. |
| **III. STUDY INFORMATION** |
| *In this section, you are being asked to provide information about your study that will help support your selection of an accelerated review category, above. Although you are asked to provide a brief description, you should be certain to include enough information so as to support your study’s eligibility for accelerated review.* |
| ***A. Briefly describe the purpose of the study. Be sure to specify any anticipated benefits of the research (this should not include compensation for participation)*** |
| ***B. Please describe your study population. Be sure to include an estimated sample size.*** |
| ***C. Is the study being conducted (check all that apply):*** [ ]  i. online [ ]  ii. in person[ ]  iii. over the phone [ ] iv. By mail[ ]  v. Other, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 1. Complete section IV.C
2. Complete section IV.D and IV.E (if applicable)
3. Discuss in section III.F
4. Discuss in section III.F
5. Answer all relevant questions in Section IV, below
 |
| ***E. Briefly discuss how the anonymity or confidentiality of participants will be protected with respect to recruitment, data collection, data storage, and sharing of results. If video- or audio-taping will be used, be clear about how consent to tape will be secured as well as how it will be handled if not all participants consent to be taped. Please also discuss when and how the data/ video- or audiotapes will be destroyed.*** |
| ***F. Briefly describe how you will recruit your participants. If data collection will occur over the phone or by mail, please indicate the source of that information*** |
| ***G. Will participants be compensated for their time?*** [ ] YES [ ] NO*If yes, please describe how and when they will be compensated.* |
| ***H. Which of the following procedures will you be using (check all that apply):***[ ] i. Administration of surveys or questionnaires [ ]  ii. Administration of educational tests (i.e., aptitude, achievement, cognitive, diagnostic)[ ]  iii. Individual interviews[ ]  iv. Focus groups[ ]  v. An experimental manipulation[ ]  vi. Confederates[ ]  vii. Unobtrusive observation of public behavior[ ]  viii. Secondary research on existing data[ ]  ix, Other, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 1. Attach copies of all surveys/questionnaires OR describe in Section IV.A; Complete Section IV.D below
2. Attach copies of educational tests to be administered OR describe in Section IV.A; Complete Section IV.D, below
3. Include interview OR describe in Section IV.A; Complete Section IV.D, below
4. Include questions OR describe in Section IV.A; Complete Section IV.D, below
5. Complete Section IV.B; Complete Section IV.D, below
6. Complete Section IV.B; Complete Section IV.D, below
7. Complete Section IV.D and IV.E, below
8. Complete Section IV.F
9. Answer all relevant questions in Section IV, below.
 |

|  |
| --- |
| **IV. ADDITIONAL STUDY INFORMATION** |
| ***A. If measures are proprietary or cannot be included for some other reason, please provide a description (with sample items) of the measures to be used, or questions to be asked as part of interviews or focus groups.*** |
| ***B. If the study involves an experimental manipulation and/or confederates, briefly describe the manipulation and how it meets the criteria for a “benign behavioral intervention.” If confederates are involved, describe what role they play in the study.*** |
| ***C. Indicate the online platform to be used for the purposes of data collection.*** |
| ***D. Indicate where the study will be conducted. If not at the TU Main campus, include the name of the location and address. If appropriate, provide the name of the individual who will provide a letter indicating that the PI has permission to conduct the study at this site.*** |
| ***E. If the study involves unobtrusive observations, testing of educational practices and/or administration of surveys, questionnaires, or educational tests, briefly describe the study procedures.*** |
| ***F. If the study involves secondary research on existing data, please answer the following questions:**** Which of the following data will you be collecting/ studying?
* Were the data originally collected solely for research purposes?
* Please indicate the source of the data
* Are the data publicly available?
* How will the data be identified when you receive them?
 | [ ] Data [ ] Documents [ ] Records [ ] Biospecimens[ ] YES [ ] NO; If YES and available, please attach a copy of the IRB approval notice and the approved broad consent form[ ] YES [ ] NO[ ] Direct identifier (e.g., name, ssno) [ ] Indirect identifier (e.g., Unique ID number) [ ] No Identifier |
| ***G. Provide any other information that supports your request for an accelerated review.*** |

|  |
| --- |
| **V. ATTACHMENTS** |
| 1. ***Informed Consent Form/Information Sheet:*** *Please submit a copy of the informed consent form to be used in the study. If participation is fully anonymous, and the only link between participants and their involvement is the informed consent form, it is recommended that you make use of an information sheet instead. For online studies, please include the language you will be using to inform participants about the study. Please also include that you will have participants indicate their willingness to participate by clicking YES to continue or NO to end the survey.*

*I have attached:* [ ] *an informed consent form because participants are not anonymous*[ ]  *an information sheet because participants are anonymous*[ ] *content of an online consent form with information on how participants will indicate their willingness to participate*1. ***Advertisements****: Please include copies of any fliers or advertisements with this application. Please also include the content of any e-mails or letters that will be sent to participants.*

*I have attached (check all that apply):* [ ]  *flier(s)*[ ]  *content of an ad* [ ]  *content of an e-mail or letter. I have provided additional details about where and how these recruitment materials will be used in section III.F, above.*1. ***Copies of Surveys, Questionnaires, Interviews, Focus Group script/questions, etc.:*** *Please include copies of any data collection instruments that you will be using in this study. If you are unable to attach a copy of the instruments, explain why and describe the measures in Section IV.A*

*I have (check all that apply):*[ ]  Attached copies of data collection instruments[ ]  Described data collection instruments in Section IV.A, above1. ***Evidence of Human Subjects Protections Training****: Please attach copies of the CITI Training (or other NIH approved Human Subjects Protections training) certificate for all study personnel including the PI, Co-I’s, Faculty Advisor, and Research Assistants who will have contact with either participants or identifiable data.*
2. ***Other Supporting Documentation****: Please attach any other relevant supporting documentation such as letters of support from participating sites, IRB approval from another institution, etc.*
 |

|  |
| --- |
| **VI. INVESTIGATOR’S ASSURANCES** |
| By signing this form, I certify that1. The information provided in this application is complete and accurate
2. As PI, or Faculty Advisor for a student PI, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, and the protection of the rights and welfare of human subjects
3. I will contact the IRB if any of the following occurs:
	1. I need/want to modify the study procedures or consent document
	2. A participant complains about the study (regardless of the reason) or there is an adverse event
	3. I become aware of a protocol deviation/violation (e.g., anonymous participants become identifiable)
	4. New findings indicate that the study risks, or the risk/benefit ratio has changed
4. I agree that I will not implement any study procedures until either (a) legally effective informed consent has been obtained or (b) participants have been fully informed about the study via an information sheet and have had the opportunity to ask questions.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of PI Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of Faculty Advisor Date(If PI is a student) |