**TOWSON UNIVERSITY**

**INSTITUTIONAL REVIEW BOARD**

**APPLICATION FOR ACCELERATED REVIEW – STUDIES INVOLVING MINORS/LEGAL MINORS**

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| *This form should be used for any research that includes minors/legal minors alone or minors/legal minors AND adults. Minors are any individuals who under the age of majority (i.e., 18 in the state of Maryland) or are not emancipated minors. Legal Minors are anyone over the age of 18 who are not legally capable of consenting to medical treatment or research on their own behalf. Such individuals will have a legal guardian appointed for them, unless they are wards of the state. 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. Age of Participants** | **Age of Minors to be included:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Age of Legal Minors to be included:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Are Minors/Legal minors capable of providing informed assent? YES NO**   * **If yes,**  attach Informed Assent form for Approval * **If no**¸ explain why, in Section III.E, below.   **Will adult participants be included? YES NO** | |
| ***I. Do you intend to collect information on the following topics?***   * Information that could place the person at risk for criminal or civil liability such as illicit drug use, underage drinking, or criminal behavior, etc. * Information that could cause the participant significant distress such as past sexual abuse/assault, prior traumatic experiences, etc. * Sensitive medical or mental health information such as history of STDs, HIV, abortions, schizophrenia, etc. * 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) * Information that could damage the participants’ financial standing, employability, educational advancement, or reputation * Collect data with individual identifiers or from voice, video, digital, or image recordings (this excludes secondary research of existing data or recordings of public observation)?   ***\*\*Note: YES to any of these items, Complete the Application for Standard or Full Board Review***  ***NO, to all items, Proceed to Section II. ACCLERATED REVIEW CATEGORIES*** | | YES NO  YES NO  YES NO  YES NO  YES NO  YES NO |

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| **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 (a) The study involves the use of educational tests OR observation of public behavior only **AND** (b) The Investigator **WILL NOT** participate in the activities being observed **AND (Check the one’s that apply to your study):**   (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 |
|  | (3) Not Applicable |
|  | 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 (Also, Answer questions in section III.I, below) **AND** (*check the appropriate criteria 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) |
|  | **If your study meets category (5)**, 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. |

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| **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.B and IV.D 2. Complete section IV.C and IV.D (if applicable) 3. Discuss in section III.G and IV.D 4. Discuss in section III.G and IV.D 5. Answer all relevant questions in Section IV, below |

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| **III. STUDY INFORMATION (continued)** |

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| ***D. 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.*** |
| ***E. If you indicated that minor/legal minor participants are unable to provide informed assent, please explain why, below. Acceptable reasons include but are not limited to: (a) participants are too young or lack the cognitive capacity to provide assent on their own behalf; (b) data collection involves unobtrusive observation of participant behavior Also explain how the rights of minor/legal minor participants will be protected if informed assent is not required.*** |

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| ***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. Unobtrusive observation of public behavior (answer H, below)  iv. Secondary research on existing data (answer I, below)  v. Other, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 1. Attach copies of all surveys/questionnaires OR describe in Section IV.A, below; Complete Section IV.D, below 2. Attach copies of educational tests to be administered OR describe in Section IV.A, below; Complete Section IV.D, below 3. Complete Section IV.C and IV.D, below 4. Complete Section IV.E, below 5. Answer all relevant questions in Section IV, below. |

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| **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. Indicate the online platform to be used for the purposes of data collection.*** |
| ***C. 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.*** |
| ***D. If the study involves unobtrusive observations, testing of educational practices and/or administration of surveys, questionnaires, or educational tests, briefly describe the study procedures.*** |

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| **IV. ADDITIONAL STUDY INFORMATION** | |
| ***E. 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 |
| ***F. Provide any other information that supports your request for an accelerated review.*** | |

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| **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. ***Informed Assent Form:*** *Please submit a copy of the informed assent 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. If you believe that participants are unable to provide assent, please justify this position in Section III.E above.*   *I have attached:*  *an informed assent 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*  *explained why it is not possible obtained informed assent, above*   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.G, 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, above*   1. ***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.* |

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| **VI. INVESTIGATOR’S ASSURANCES** |
| By signing this form, I certify that   1. 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) |