**TOWSON UNIVERSITY**

**INSTITUTIONAL REVIEW BOARD**

**APPLICATION FOR STANDARD OR FULL BOARD REVIEW**

|  |  |  |
| --- | --- | --- |
| *This form should be used for research that does not qualify for accelerated review. The research must also meet the criteria for one of the standard or full board 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, 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 with individual identifiers or from voice, video, digital, or image recordings (this excludes secondary research of existing data or recordings of public observation)? * Include children and/or legal minors as participants?   ***Proceed to Sections II, III, or IV. Please choose one or more of the categories that best fit your research in either Standard Review or Full Board Review below.*** | | YES NO  YES NO  YES NO  YES NO  YES NO  YES NO  YES NO  YES NO  YES NO |

**Continued on the Next Page**

|  |  |  |  |
| --- | --- | --- | --- |
| **II. STANDARD REVIEW CATEGORIES – “Expedited” Research** | | | |
| *Place a check mark next to the appropriate category that applies to your research.* | | | |
|  | 1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling. | | |
|  | 1. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children2, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week. | | |
|  | 1. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra‐ and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;   (j) sputum collected after saline mist nebulization. | | |
|  | 1. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x‐rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) | | |
|  | 1. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.) | | |
|  | 1. Collection of data from voice, video, digital, or image recordings made for research purposes. | | |
|  | 1. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies | | |
|  | 1. Not applicable – category for continuing review | | |
|  | 1. Not applicable – category for continuing review | | |
| **III. STANDARD REVIEW CATEGORIES – “Exempt” Research** | | | |
| *Place a check mark next to the appropriate category that applies to your research.* | | | |
|  | 1. Not applicable – this is an accelerated review category | | |
|  | 1. 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) **AND** the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained either directly or through identifiers linked to the subjects. The PI must make appropriate provisions for ensuring the privacy of subjects and for maintaining the confidentiality of the data. | | |
|  | 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.The PI must make appropriate provisions for ensuring the privacy of subjects and for maintaining the confidentiality of the data. | | |
|  | 1. Not applicable – this is an accelerated review category | | |
|  | 1. Not applicable – this is an accelerated review category | | |
|  | 1. Taste and food quality evaluation and consumer acceptance studies: (i) If wholesome foods without additives are consumed, or (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency and Inspection Service of the U.S. Department of Agriculture. | | |
|  | 1. 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 the IRB conducts determines   that the Broad consent for storage, maintenance, and secondary research or identifiable private information or identifiable biospecimens is obtained in accordance with the requirements for Broad consent, Broad consent is appropriately documented or waiver of documentation is appropriate (See What are the Requirements for Informed Consent section of the PI manual), AND if there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. | | |
|  | 1. 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 procedures for obtaining Broad Consent conformed with those requirements discussed in What are the Requirements for Informed Consent section of the PI manual and the IRB determines that documentation, or waiver, of informed consent conforms with the requirements discussed in What are the Requirements for Informed Consent section and that the proposed research falls within the scope of the Broad Consent obtained. Furthermore, 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. | | |
| **IV. FULL BOARD REVIEW CRITERIA AND CATEGORIES** | | | |
| *Place a check mark next to the appropriate category that applies to your research.* | | | |
|  | 1. Studies which have been determined by the IRB Chairperson to be MORE THAN MINIMAL RISK. | | |
|  | 1. Studies involving elements, procedures, or interventions that require additional provisions or safeguards, such as (a) involving vulnerable or sensitive populations (e.g., prisoners); (b) studies taking place in foreign countries with few or no provisions for the protection of human subjects and in which the procedures pose more than minimal risk to subjects; (c) studies where information may be disclosed that could require reporting, such as child or elder abuse; illegal activities, etc; or (d) studies involving behavioral interventions that do not meet the criteria for “Benign.” | | |
|  | 1. Studies requiring an Investigational New Drug or Investigational Device Exemption Application. | | |
|  | 1. Studies involving procedures that are personally intrusive, stressful, or potentially traumatic (Stress can be physical, psychological, social, financial or legal). | | |
|  | 1. Studies assessing sensitive topics and data collected are not anonymous, such as the following: (a) sexual orientation, attitudes, preferences, or practices; (b) illegal or punishable conduct, including use of alcohol, drugs, or other addictive products; (c) information that could damage the individual’s financial standing, employability, or reputation; (d) information that could lead to social stigmatization or discrimination; (e) psychological well-being or mental health; (f) incest, rape, date rape, or sexual molestation, veteran or war-time experiences. | | |
| **V. STUDY INFORMATION** | | | |
| *In this section, you are being asked to provide information about your study that will help support your selection of the standard or full board review category, above. Please provide as much detail as possible in your descriptions.* | | | |
| ***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, age(s), and inclusion/exclusion criteria.*** | | | |
| ***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 |
| ***D. Briefly describe who will conduct the consent process and how consent will be obtained.*** | | | |
| ***E. Briefly discuss how the 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. Voice, video, digital, or image recordings  ix. Collection of biological specimens (e.g. blood samples, saliva, etc)  x, Other, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | 1. Attach copies of all surveys/questionnaires OR describe in Section VI.A; Complete Section VI.D below 2. Attach copies of educational tests to be administered OR describe in Section VI.A; Complete Section VI.D, below 3. Include interview OR describe in Section VI.A; Complete Section VI.D, below 4. Include questions OR describe in Section VI.A; Complete Section VI.D, below 5. Complete Section VI.B; Complete Section VI.D, below 6. Complete Section VI.B; Complete Section VI.D, below 7. Complete Section VI.D and VI.E, below 8. Complete Section VI.A, D, E, and F, below 9. Complete Section VI. D and VI. G, below 10. Answer all relevant questions in Section VI, below. | |
| ***I. Please provide detail for your study’s procedures.*** | |  | |

|  |  |
| --- | --- |
| **VI. ADDITIONAL STUDY INFORMATION** | |
| ***A. Please provide a brief description or list (with sample items) of the measures to be used, or questions to be asked as part of interviews or focus groups. Make sure to attach all copies of surveys, questionnaires, etc with your complete application package.*** | |
| ***B. If the study involves an experimental manipulation and/or accomplices, briefly describe the manipulation and how it meets the criteria for a “benign behavioral intervention.” If accomplices 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 the collection of data from voice, video, digital, or image recordings, 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, SSN) Indirect identifier (e.g., Unique ID number) No Identifier |
| ***G. If collecting biological specimens, please detail procedures for collection and testing below.*** | |
| ***H. Provide any other information that supports your request for a standard or full board review.*** | |

|  |
| --- |
| **VII. 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, 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.* |

|  |
| --- |
| **VIII. 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) |