**Instructions:**  Please type detailed responses in the gray boxes below. Do not leave any boxes blank. This completed form must be submitted to the TBR IRB ([IRB@tbr.edu](mailto:IRB@tbr.edu)) along with a cover sheet (Form A), Form C, copies of informed consent forms, surveys, interview protocols, and any other supporting information. Consolidate all supporting documentation into a single PDF document, but please submit Form B as a signed PDF document separately.

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| **NOTE: Subject recruitment and data collection may not be initiated prior to formal approval from the TBR IRB.** |

**Anticipated Review Category:**

A. Expedited Review

B. Full Board Review

A principal investigator who believes that Expedited Review is appropriate should review the criteria for Expedited Review in Section VI.A.2 of the TBR IRB Procedures and be sure to include information in the answers below that supports Expedited Review.

**1. Statement of Purpose and Background**

In one or two paragraphs, state the purpose of the research and relevant background information to provide a rationale for the proposed research. Provide a justification for the use of humans in the research if the project could conceivably use some other source of data.

**2. Research Design and Methods**

Discuss the data collection methods, the research activities and any devices, tests, questionnaires, interview guides, or other instruments that will be used. If applicable, include information such as the number of groups, types of groups, number of participants in each group, and other relevant information. **Attach** copies of interview questions and a copy of any survey instruments that will be administered. Study Location: Identify the location and setting where subjects will participate in this research and address any special considerations.

**3. Subjects**

***3.a.*** Characteristics of the subjects: How many, their gender, age range, ethnicity, etc. Use the list on Form A, page 2 to remind you of the main categories. If you will use special or vulnerable populations where ability to provide informed consent may be limited, provide a rationale for including them. Examples of special populations include children, pregnant women, prisoners, cognitively impaired individuals, frail elderly persons, etc.

***3.b.*** If recruiting human subjects, provide a listing of the selection criteria that will be used, discuss the methods of recruitment, and provide details on the recruitment source. Selection Criteria: How will you determine who is included or excluded? Who makes the decision? Recruitment Methods: Describe how you will identify and recruit subjects. Submit a copy of the flyer or advertisement if you will be advertising for subjects. (If subjects will be identified through private records, the holder of the records must make the initial contact with the subject.) Include a statement about how the recruitment will ensure voluntary participation and not single out or embarrass individuals who choose not to participate. Recruitment source: Identify the institutions from which you will recruit subjects. If appropriate, include a letter from that institution/organization indicating support of the study.

**4. Informed Consent Process**

Describe who will make the initial contact with potential subjects and how the research will be explained to them. Include information about how the informed consent agreement will be introduced and note any other measures to be used to assess the potential subjects’ understanding of what will be asked of them as well as steps taken to ensure that they understand the voluntary nature of their participation. Be sure to build in adequate time for prospective subjects to reflect on whether or not they want to participate. **Attach** a copy of the informed consent form.

DO NOT PASTE THE INFORMED CONSENT FORM BELOW.

**5. Project Management and Risks**

***5.a.1. Risks and Potential Problems:*** Identify potential or known physical, psychological, social, and economic or legal risks that might be associated with participation in the research. These might be direct risks or the result of a subject’s name accidentally being linked to his/her responses. Discuss whether the risks are minimal (no greater than normal daily risks) or significant. Assessment of Risk: Assess whether the risks and inconveniences associated with a subject’s participation in the research are reasonable in relation to the anticipated benefits to the subjects or in relation to the knowledge that may reasonably be expected to result from the research.

***5.a.2. Management of Risks:*** Describe precautions, safeguards, or other steps incorporated into the research activity to reduce or limit the severity or likelihood of harm. These might include extra precautions in storing data or coding personal identifiers.

***5.b. Deception or Incomplete Disclosure:*** If applicable, fully describe and justify the use of deception in this research. Include a description of the debriefing practices that are proposed.

***5.c. Confidentiality:*** Describe provisions made to maintain confidentiality of data. Who will have access to the collected data, where will it be stored, and for how long?

**6. Potential Benefits**

Describe the anticipated benefits to (a) the subject, (b) the population from which the subject is drawn, and (c) society/science expected to result from this research. (Do not include compensation or incentives that might be offered to subjects.)

**7. Costs, Compensation and Incentives**

Describe any costs that the subject may incur as a result of participation (charges for tests, travel, lost work time, etc.). If compensation or an incentive is offered for participation, provide details of this payment. Indicate whether the subject is compensated for the number of procedures, the time involved, or some other basis for payment. Indicate whether payment is made by check, cash, or money order, and whether the amount is prorated if the subject decides to discontinue participation. Indicate how the value of the incentive was determined. Compensation/incentives should be appropriate but not excessive to a degree that would unduly influence a potential subject’s decision to participate.

**A. EXPEDITED REVIEW DECISION**

**This Section to be Completed by the TBR IRB Subcommittee**

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| Category(s) for Expedited Review (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **This Application Has Been Approved by an Expedited Review:**  Approved By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name / Signature / Date  Approved By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name / Signature / Date  Approved By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name / Signature / Date  **TBR IRB Approval Number:** **tbr\_**  **This Application Requires a Full Board Review:**  Lead Reviewer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name / Signature / Date  TBR IRB (Co-)Chair: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name / Signature / Date |

**B. FULL BOARD REVIEW DECISION**

**This Section to be Completed by the TBR IRB Chair (co-Chair)**

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| Full Board Review Convened on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, 20\_\_\_\_\_\_.  Number of participating TBR IRB Members: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_ **This application has been approved by the TBR IRB.**  \_\_\_\_\_ **This application requires modification in order to be approved.** (See attached explanation.)  \_\_\_\_\_ **This application has been rejected by the TBR IRB.** (See attached explanation and opportunity to respond.)  **TBR IRB Approval Number: tbr\_**  TBR IRB Chair (co-Chair): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name / Signature / Date |