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| **IRB#**: |  |
| **IRB Reviewer(s):** |  |
| **Date of Review**: |  |

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| **INFORMATION FOR THE REVIEWER:** This is a word document, so you may download it to your computer to complete. Each of the components below must be adequately addressed within the application in order to be approved by the IRB. Please indicate whether the PI has given adequate consideration and safeguards to the following areas of concern. Note any concerns, recommendations or questions in the reviewer’s comment section for each component.  For expedited reviews save completed reviews as a *WORD* document and return to the committee chair. For a full committee review, email a copy to the chair and bring a copy to the committee meeting. The chair will summarize and compile the reviews. Copies of the reviewer checklist will be made available to applications, institutional officials, or federal officials upon request.  Concerns and questions noted by reviewer(s) must be satisfactorily addressed by the applicant prior to final project approval. | | | |
| 1. **RESEARCHER INFORMATION** | **YES** | **NO** | **NA** |
| 1. PI is a faculty member or student with a faculty supervisor. |  |  |  |
| 1. CITI human subjects certification is current. |  |  |  |
| 1. This project requires additional training beyond the basic/required CITI modules. If any optional modules or additional training is needed please note in the comments. |  |  |  |
| 1. Potential conflicts of interest are identified and if present, managed. |  |  |  |
| Reviewer Comments: | | | |
| Applicant Response: | | | |
| 1. **GENERAL DESCRIPTION OF THE PROPOSED RESEARCH** | **YES** | **NO** | **NA** |
| 1. Research question/problem statement and project goals/purpose are clearly stated |  |  |  |
| 1. Summary includes a brief description of the population, sample, setting, methods and procedure, dissemination/sharing of results. |  |  |  |
| 1. Variables (quantitative) or phenomenon of interest (qualitative) are adequately described. |  |  |  |
| 1. Necessary approvals, agreements, and/or contracts with partners have been obtained and are attached. |  |  |  |
| Reviewer Comments: | | | |
| Applicant Response: | | | |
| 1. **PARTICIPANTS AND RECRUITMENT** | **YES** | **NO** | **NA** |
| 1. Criteria for inclusion/exclusion are equitable. |  |  |  |
| 1. Recruitment procedures are clearly described. |  |  |  |
| 1. Role of human subjects and what they will be told about the research are clearly described. |  |  |  |
| 1. Participation of protected or vulnerable populations (including children, facility residents, etc.) is justified. |  |  |  |
| If protected or vulnerable populations are included please identify those populations here: |  |  |  |
| 1. Additional issues related to protected populations have been adequately addressed (e.g., setting, privacy, rights, etc.) |  |  |  |
| 1. Recruitment materials (letters of initiation, recruiting scripts, etc.) are attached and appropriate. |  |  |  |
| 1. Appropriate procedures for obtaining and documenting informed consent from participants are described. |  |  |  |
| 1. **The informed consent document(s) covers the necessary elements for the level of risk and the subject group involved (see below).** | **YES** | **NO** | **NA** |
| 1. An understandable explanation of research purpose |  |  |  |
| 1. Statement of why subject was selected |  |  |  |
| 1. Disclosure of the identity and all relevant roles of researcher (e.g., PhD candidate, faculty member, facility owner) |  |  |  |
| 1. An understandable description of procedures |  |  |  |
| 1. Expected duration of subject’s participation |  |  |  |
| 1. Statement that participation is voluntary |  |  |  |
| 1. Statement that refusing or discontinuing participation involves no penalty or loss of benefit |  |  |  |
| 1. Description of reasonably foreseeable risks or discomforts |  |  |  |
| 1. Information on compensation for participation |  |  |  |
| 1. Description of how confidentiality will be maintained |  |  |  |
| 1. Contact info for questions about the research (including researcher, faculty supervisor, and research participant advocate) |  |  |  |
| 1. Includes Austin College IRB# |  |  |  |
| 1. Includes contact information for the IRB |  |  |  |
| 1. Statement that subject should keep/print a copy of the informed consent form |  |  |  |
| 1. Disclosure of all potential conflicts of interest |  |  |  |
| 1. Understandable lay person language used throughout consent document and process |  |  |  |
| 1. Consent document is worded so that participants are not asked to waive their legal rights |  |  |  |
| 1. If appropriate, indicates that a procedure is experimental (i.e., not a standard treatment or procedure) |  |  |  |
| 1. If appropriate, disclosure of alternative procedures/treatment |  |  |  |
| 1. Of appropriate, additional costs to subject resulting from research participation |  |  |  |
| Reviewer Comments: |  |  |  |
| Applicant Response: |  |  |  |
| 1. **RESEARCH PROCEDURES** | **YES** | **NO** | **NA** |
| 1. Data collection procedures are adequately described |  |  |  |
| 1. Data collection procedures are adequately described and include provisions for the protection of participants’ identities and contact information. |  |  |  |
| 1. Adequate provisions to maintain the confidentiality of the collected data are described. |  |  |  |
| 1. Copies of data collection tools (surveys, questionnaires, interview protocols, spreadsheets, etc.) are provided as they will be seen by participants. |  |  |  |
| 1. Content of data collection tool(s) is appropriate. |  |  |  |
| 1. Authorship of data collection tools is appropriately recognized. |  |  |  |
| Reviewer Comments: |  |  |  |
| Applicant Response: |  |  |  |
| 1. **POTENTIAL RISKS and BENEFITS** | **YES** | **NO** | **NA** |
| 1. Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk. |  |  |  |
| 1. Deception is necessary and appropriate debriefing is included. |  |  |  |
| 1. Risks are reasonable relative to anticipated direct benefits to subjects. |  |  |  |
| 1. Risks are reasonable relative to the importance of the knowledge that may reasonably be expected to result. |  |  |  |
| Reviewer Comments: |  |  |  |
| Applicant Response: |  |  |  |

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| |  | | --- | | Other comments related to this proposal: |   **WAIVERS:**  Does the application contain a request for the committee to waive any aspects of consent or other standard IRB guidelines?  \_\_\_\_\_ No  \_\_\_\_\_ Yes – If yes describe request and if request is appropriate:  **RISK LEVEL:** | |
|  | Minimal risk |
|  | Greater than minimal risk |
|  |  |
| **RECOMMENDATION:** | |
|  | Table proposal (provide rationale): |
|  | Approve |
|  | Disapprove |
|  | Approve with the following stipulations/changes: |
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| **HOW OFTEN THIS STUDY SHOUD BE REVIEWED:** | |
|  | 6 months |
|  | 12 months |
|  | Other: |

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Reviewer Signature (Full Committee Only) Date