

**PROTOCOL REVIEW**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Date: | | | Reviewer: | | |
| IRB #: | | | Principal Investigator: | | |
| Review  Type: | Initial | Expedited | | Exempt | Continuing |

**Recommendation:**

|  |  |
| --- | --- |
| Full Approval | No changes needed; approved as is. |
| Pending Approval | Requires minimum clarifications, protocol modifications, or consent revisions. |
| Deferred | Requires substantive clarifications, protocol modifications, or consent revisions. |
| Disapproved |  |

**PROTOCOL CHECKLIST**

|  |  |  |
| --- | --- | --- |
| **Evaluation Area** |  | **Comments** |
| Is a sound purpose statement provided? | Yes  No |  |
| Does the rationale for the study include a brief description of the relevant literature to convey significance? | Yes  No |  |
| Are research questions or hypotheses researchable and consistent with the purpose statement? | Yes  No |  |
| Is selection of subjects equitable, given the purpose of the research and the setting in which the research will be conducted? | Yes  No |  |
| Are recruitment procedures adequately described and consistent with protection of human subjects? | Yes  No |  |
| Are procedures consistent with sound research design and include a step-by-step explanation of procedures that will be performed with human subjects? | Yes  No |  |
| Is data analysis (whether quantitative or qualitative) appropriate to answer the research questions or test the hypotheses? | Yes  No |  |
| Are research risks to subjects reasonable in relation to anticipated benefits? | Yes  No |  |
| Are risks to subjects and procedures for minimizing risks adequately described? | Yes  No |  |
| If there are vulnerable populations (minors, pregnant women, economically or educationally disadvantaged, intellectually disabled, prisoners) involved, are additional safeguards included in the study to protect these subjects? | Yes  No  N/A |  |
| Are potential benefits of the research to the individual and society adequately described? | Yes  No |  |
| Are there adequate provisions to protect the privacy of subjects and maintain confidentiality of data? | Yes  No |  |
| Are all instruments and protocols used for data collection described? | YesNo |  |
| Are Child Assent procedures described and consistent with federal regulations? | Yes  No  N/A |  |
| Are Informed Consent procedures described and consistent with federal regulations? | Yes  No |  |

**INFORMED CONSENT CHECKLIST**

|  |  |  |
| --- | --- | --- |
| **Does the informed consent:** |  | **Comments** |
| Include a statement that explains the purpose of the research? | Yes  No |  |
| Include a description of the procedures (what the participant is being asked to do or provide) and length of time subject is expected to participate? | Yes  No |  |
| Include a description of all potential risks to the subject (including physical, psychological, social harm, discomfort, or inconvenience)? | Yes  No |  |
| Include a description of any benefits of the research to the individual and society? | Yes  No |  |
| Include a description of compensation provided to participants (if any)? | Yes  No |  |
| Include a statement that participation is voluntary and refusal to participate will involve no penalty or loss of current benefits? | Yes  No |  |
| Include a statement that the subject may withdraw from the study at any time without penalty? | Yes  No |  |
| Include a description of how confidentiality of research records will be maintained? | Yes  No |  |
| Include who to contact (and how) for answers to questions or in the event of a research-related injury or emergency? | Yes  No |  |
| Include a statement that subjects may contact the Chair of the Institutional Review Board for answers to questions regarding their rights as research subjects? Contact information provided? | Yes  No |  |

**Other General Comments:**