

**IRB DISPOSITION -** WORKSHEET: STANDARD REVIEW

|  |  |
| --- | --- |
| **Research Title:**  |       |
|  |
| **Researcher(s):** |
| 1. |       |
| 2. |       |
| 3. |       |
| 4. |       |
| 5. |       |
| 6. |       |
|  |  |
| **Reviewer:** |       |

**APPROVAL CRITERIA**

|  |
| --- |
| **The study falls within the category below:** |
|[ ]  The research involving human subjects that the D’Youville IRB determines to be more than minimal risk. |

|  |
| --- |
| **Approval criteria: (Check the appropriate answers.)** |
|[ ]  Researchers have completed human subject protection training.  |
|[ ]  The research presents no more than Minimal Risk to subjects. |
|[ ]  Has obtained Site Permission Letter (An approval letter from an institution where research will be conducted).  |
|[ ]  The study is appropriate for the subjects being studied. |
|[ ]  Participants recruitment procedure appropriate. |
|[ ]  Risks to participants are reasonable in relation to anticipated benefits and the importance of the expected knowledge.  |
|[ ]  Participants selection procedure is fair and appropriate for the study. |
|[ ]  Informed consent will be obtained from each participant or their legal representative, documented according to federal regulations.  |
|[ ]  Adequate safeguards are in place to ensure participant safety during data collection. |
|[ ]  Participants' right to privacy and confidentiality is protected.  |

**(Check the appropriate answer)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** | **No** | **N/A** | **Criteria**  |
|[ ] [ ] [ ]  **Risks to subjects are minimized by using procedures which:** are consistent with sound research design. |
|[ ] [ ] [ ]  **Risks to subjects are minimized by using procedures which:**do not unnecessarily expose subjects to risk (pregnant women excluded from exercise). |
|[ ] [ ] [ ]  **Risks to subjects are minimized by using procedures which:**when appropriate, are already being performed for diagnostic or treatment purposes. |
|[ ] [ ] [ ]  Risks to subjects are reasonable in relation to anticipated benefits. |
|[ ] [ ] [ ]  Selection of subjects is equitable, and subjects will be selected from the least vulnerable population possible given the nature of the planned research. |
|[ ] [ ] [ ]  **Risk/benefit ratio of exposure to** deception is acceptable. |
|[ ] [ ] [ ]  **Risk/benefit ratio of exposure to** coercion is acceptable. |
|[ ] [ ] [ ]  Plan for desensitization and/or dehoaxing is acceptable. |
|[ ] [ ] [ ]  Subjects are protected from coercion related to researcher-subject relationship. |
|[ ] [ ] [ ]  Procedures for maintenance of subjects’ data are acceptable for the planned design. |
|[ ] [ ] [ ]  All subjects have equitable access to research findings. |

**(Check the appropriate answer)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** | **No** | **N/A** | **Required elements of INFORMED CONSENT:** |
|[ ] [ ] [ ]  Statement that the study involves research. |
|[ ] [ ] [ ]  Name of primary researcher. |
|[ ] [ ] [ ]  Title of research or general topic of research. |
|[ ] [ ] [ ]  Explanation of the purposes of the research. |
|[ ] [ ] [ ]  Expected duration of the subject’s participation. |
|[ ] [ ] [ ]  Description of the procedures to be followed. |
|[ ] [ ] [ ]  Identification of any experimental procedures to be used. |
|[ ] [ ] [ ]  Description of possible risks and/or discomforts. |
|[ ] [ ] [ ]  Description of realistic benefits to the subject or others. |
|[ ] [ ] [ ]  Disclosure of appropriate alternate procedures and/or treatments, if any, that might be advantageous to subjects. |
|[ ] [ ] [ ]  Extent to which confidentiality or anonymity will be maintained. |
|[ ] [ ] [ ]  Statement that participation is voluntary and refusal to participate will involve no penalty or loss of benefits to which subject is otherwise entitled. |
|[ ] [ ] [ ]  Statement that subject may withdraw participation and when and how subject can do that. |
|[ ] [ ] [ ]  Contact person for questions about research and subject’s rights. |
|[ ] [ ] [ ]  Explanation as to whether compensation is provided and what it consists of. |
|[ ] [ ] [ ]  Name, title, and phone number or address of contact person in event of research-related injury. |
|[ ] [ ] [ ]  Explanation as to whether medical treatments are available if injury occurs and what they consist of, or where further information may be obtained. |
|[ ] [ ] [ ]  Consent is documented/dated with signature of subject or subject’s legal representative. |

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** | **No** | **N/A** | **Required elements of IMPLIED CONSENT (when coding mechanisms are used):** |
|[ ] [ ] [ ]  Subjects are informed that coding is being used.  |
|[ ] [ ] [ ]  Researcher destroys coding mechanism at completion of data collection.  |
|[ ] [ ] [ ]  Subjects are informed of date on which coding mechanism is to be destroyed.  |

|  |
| --- |
| **Overall Comments and Recommendations:** |
| ***Please provide your written feedback and recommendations for improvement on each section of the protocol.*** |
|       |

|  |
| --- |
| **Disposition: (Check the appropriate disposition.)** |
|[ ]  Full Approval (no changes required)  |
|[ ]  Approval with recommendation: Proceed with Suggestions (minor improvements recommended)  |
|[ ]  Approval with Conditions: (There are severe and many concerns)  |
|[ ]  Disapproval (major revisions required) |
|[ ]  Approval ID (Administrator use only):  |