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**IRB DISPOSITION -** WORKSHEET: STANDARD REVIEW

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

**APPROVAL CRITERIA**

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

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| **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)**

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| **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)**

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| **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. |

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| **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. |

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