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**Greater than Minimal Risk Reviewer Evaluation Form**

Please complete the following checklist after you have completed a comprehensive review of the study documentation. This checklist will serve as your official evaluation regarding the proposed research study. As a reviewer, your evaluation must be inclusion of all components of the research. Subjects should not be asked to participate in research that is flawed by design, methodology, outcomes measurement or that which promises benefits which cannot reasonably be delivered.

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| **IRB #:** Click or tap here to enter text. | **PI:** Click or tap here to enter text. |
| **Title of Study:** Click or tap here to enter text. | |
| **Primary Reviewer:** Click or tap here to enter text. | **Secondary Reviewer:** Click or tap here to enter text. |

**Protocol Review**

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| **STUDY BACKGROUND, RATIONALE, & AIMS** | **YES** | **NO** | **N/A** |
| 1. Statement of purpose is adequate |  |  |  |
| 2. Study rationale is adequate |  |  |  |
| 3. Aims and objectives are clearly stated |  |  |  |
| 4. Historical Background information is adequate with relevant and current literature which supports the proposed research |  |  |  |
| 5. Results from previous pre-clinical or clinical studies justify the proposed research |  |  |  |
| 6. The proposed research compares to the local standard of care treatment for the condition or is theorized to possible be more beneficial |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **STUDY DESIGN** | **YES** | **NO** | **N/A** |
| 1. The proposed research design is sound |  |  |  |
| 2. The design is adequate to address research question/objectives |  |  |  |
| 3. Justification for the use of placebo is appropriate |  |  |  |
| 4. Justification for any “wash-out” period is appropriate |  |  |  |
| 5. Study has sufficient power to yield evaluable results |  |  |  |
| 6. Study endpoints are well defined |  |  |  |
| 7. There is a statistical plan to evaluate the stated outcomes |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **INCLUSION/EXCLUSION CRITERIA FOR SUBJECTS** | **YES** | **NO** | **N/A** |
| 1. Inclusion/exclusion criteria are clearly specified and appropriate |  |  |  |
| 2. Choice of subjects is appropriate for the question being asked |  |  |  |
| 3. Selection of subjects is equitable based upon the setting of the research |  |  |  |
| 4. Selection of subjects is equitable among gender, ethnicity and age |  |  |  |
| 5. If the study is limited to a certain population? If so, does the study provided regarding why other are not being considered for participation? |  |  |  |
| 6. Inclusion or exclusion of women, minorities or children is justified |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **RECRUITMENT OF SUBJECTS** | **YES** | **NO** | **N/A** |
| 1. The Principal Investigator and/or Sub-Investigators have access to a population that will allow recruitment of the necessary number of subjects |  |  |  |
| 2. Methods for recruiting potential subjects are well defined |  |  |  |
| 3. Location and timing of the recruitment process is acceptable |  |  |  |
| 4. All recruitment materials are submitted and appropriate |  |  |  |
| 5. Methods for identifying potential subjects for recruitment are acceptable |  |  |  |
| 6. The amount or type of compensation or reimbursement is reasonable and not coercive/unduly influential |  |  |  |
| 7. Any coercion/undue influence to participate is avoided or minimized |  |  |  |
| 8. Vulnerable subject populations are identified and adequately protected, and additional safeguards are provided where needed to protect subjects’ rights and welfare and minimize coercion or undue influence |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **STUDY PROCEDURES** | **YES** | **NO** | **N/A** |
| 1. Rationale and details of the study procedures are adequately described and acceptable |  |  |  |
| 2. Study utilizes procedures already performed for diagnosis/treatment |  |  |  |
| 3. Frequency and duration of study visits/procedures/assessments are stated |  |  |  |
| 4. Duration of the study drug intervention is limited appropriately to that which is minimally necessary to evaluate efficacy |  |  |  |
| 5. There are clearly defined stopping rules ( or early termination) to withdraw the subject in case he/she does not improve and before the advent of severe disease progression |  |  |  |
| 6. Research procedures are clearly differentiated from standard of care |  |  |  |
| 7. Procedures for detection, treating, documentation and reporting of adverse events, serious adverse events and unanticipated problems are adequate |  |  |  |
| 8. Tissue collection and/or genetic analysis is justified |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **DRUGS, BIOLOGICS, & DEVICES** | **YES** | **NO** | **N/A** |
| 1. The status of the drug is described and appropriate (investigational, new use of an FDA-approved drug, or an FDA-approved drug within approved indications) |  |  |  |
| 2. The drug dosage and route of administration are appropriate |  |  |  |
| 3. The drug or device safety and efficacy data are sufficient to warrant the proposed phase of testing |  |  |  |
| 4. The risk status (significant risk or non-significant risk) of the device is described and appropriate |  |  |  |
| 5. IND or IDE is provided, or meets exemption |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **DATA COLLECTION, ANALYSIS, AND OVERSIGHT** | **YES** | **NO** | **N/A** |
| 1. Rationale for the proposed number of subjects is reasonable |  |  |  |
| 2. Plan for data collection/assessments is appropriate |  |  |  |
| 3. Plans for data/statistical analyses are defined and justified |  |  |  |
| 4. Provisions for monitoring data are adequate to ensure the safety of participants (a Data Safety Monitoring Plan is required but does not necessarily have to include an independent DSMB) |  |  |  |
| 5. For Multi-site trials where PI is the lead Researcher provisions for communicating risks and material protocol changes between sites are adequate |  |  |  |
| 6. Plan for communication or disclosure of study results is adequate |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **INFORMED CONSENT PROCEDURE** | **YES** | **NO** | **N/A** |
| 1. Consent will be sought from each prospective participant or their legal representative (surrogate consent) |  |  |  |
| 2. If surrogate consent is allowed, does the Principal Investigator provide justification for this kind of informed consent |  |  |  |
| 3. Is there a description of the procedure that would be followed for obtaining and documenting informed consent from those subjects who subsequently become capable of consenting for themselves during the course of the trial? |  |  |  |
| 4. The consent process minimizes the possibility of coercion or undue influence |  |  |  |
| 5. The procedure for obtaining consent is fully described; sufficient time is allowed |  |  |  |
| 6. If those who do not use English as a primary language will be enrolled, application indicates whether translated consent forms or short form consent will be used |  |  |  |
| 7. Communications with the participant, both written and verbal, will be in language understandable to the participant or representative |  |  |  |
| 8. All translated consent documents are included with application |  |  |  |
| 9. Information communicated during the consent process will not include exculpatory language through which the participant or representative is made to waive or appear to waive legal rights or release or appear to release the investigator, sponsor, institution, or their agents from liability for negligence. |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **POTENTIAL RISKS, DISCOMFORTS & BENEFITS FOR SUBJECTS** | **YES** | **NO** | **N/A** |
| 1. Risks (including physical, psychological, social, legal, or economic risks) and benefits are adequately identified, evaluated and described |  |  |  |
| 2. Risks are minimized and the likelihood of benefits maximized |  |  |  |
| 3. Subjects are being evaluated at intervals that are sufficiently frequent to identify and prevent untreated problems |  |  |  |
| 4. Injury/illness due to research is addressed |  |  |  |
| 5. Criteria for discontinuation/withdrawal of a subject are specified and appropriate |  |  |  |
| 6. Risks are reasonable in relation to potential benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result; the risk/benefit ratio is acceptable for proceeding with the research |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **QUALIFICATIONS OF INVESTIGATORS & STUDY RESOURCES** | **YES** | **NO** | **N/A** |
| 1. The Principal Investigator and Co-Investigator(s) have the appropriate academic, clinical credentials, and experience for the study |  |  |  |
| 2. Study personnel are sufficient in numbers, qualifications, experience and time dedicated for research |  |  |  |
| 3. Research is performed at acceptable facilities with appropriate equipment |  |  |  |
| 4. Medical or psychological resources that subjects may need as a consequence of the research are available |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |

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| **PRIVACY AND CONFIDENTIALITY** | **YES** | **NO** | **N/A** |
| 1. Privacy protection measures are adequate |  |  |  |
| 2. Confidentiality of identifiable data measures are adequate |  |  |  |
| 3. For FDA regulated research, disclosure that FDA may inspect records |  |  |  |
| 4. Certificate of Confidentiality is warranted |  |  |  |
| ***Comments/Deficiencies:*** Click or tap here to enter text. | | | |