

SC 502-D

01/01/07

STUDY: _____

IRB TRACKING # _____

| | Yes | No |
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| The protocol is under a separate investigational new drug application (IND) or investigational device exemption (IDE). | <input type="checkbox"/> | <input type="checkbox"/> |
| The protocol clearly identifies that the research may include subjects who are unable to give informed consent. | <input type="checkbox"/> | <input type="checkbox"/> |
| The human subjects are in a life-threatening situation that requires intervention, and | <input type="checkbox"/> | <input type="checkbox"/> |
| Available treatments are unproven or unsatisfactory, and | <input type="checkbox"/> | <input type="checkbox"/> |
| The collection of valid scientific evidence is necessary to determine the safety and effectiveness of particular interventions, and | <input type="checkbox"/> | <input type="checkbox"/> |
| The clinical investigation could not practicably be carried out without the waiver of informed consent: | <input type="checkbox"/> | <input type="checkbox"/> |
| The intervention under investigation must be administered before consent from the subjects' legally authorized representatives is feasible; and | <input type="checkbox"/> | <input type="checkbox"/> |
| There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation. | <input type="checkbox"/> | <input type="checkbox"/> |
| There is evidence that participation in the research holds out the prospect of direct benefit to the subjects: | <input type="checkbox"/> | <input type="checkbox"/> |
| Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects; and | <input type="checkbox"/> | <input type="checkbox"/> |
| Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity. | <input type="checkbox"/> | <input type="checkbox"/> |
| The protocol defines the length of the potential therapeutic window based on scientific evidence. | <input type="checkbox"/> | <input type="checkbox"/> |
| The IRB has reviewed and approved informed consent procedures and an informed consent document to be used with subjects or their legally authorized representatives in situations where use of such procedures and documents is feasible. | <input type="checkbox"/> | <input type="checkbox"/> |
| The protocol includes documentation that the Investigator will make every reasonable effort to obtain informed consent within the therapeutic window by: | <input type="checkbox"/> | <input type="checkbox"/> |
| Attempting to contact a legally authorized representative for each subject and obtain consent within the therapeutic window. | <input type="checkbox"/> | <input type="checkbox"/> |
| If a legally authorized representative is not reasonably available, attempting to contact, within the therapeutic window, the subject's family member who is not a legally authorized representative, and asking whether he or she objects to the subject's participation in the clinical investigation. | <input type="checkbox"/> | <input type="checkbox"/> |

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| Procedures are in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, of the subject's inclusion in the clinical investigation, the details of the investigation and other information contained in the informed consent document. | <input type="checkbox"/> | | |
| That he or she may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. | <input type="checkbox"/> | | |
| | | | |
| If a subject is entered into a clinical investigation with waived consent and the subject dies before a legally authorized representative or family member can be contacted, information about the clinical investigation is to be provided to the subject's legally authorized representative or family member, if feasible. | <input type="checkbox"/> | | |
| Procedures and information to be used when providing an opportunity for a family member to object to a subject's participation in the clinical investigation consistent with regulations are acceptable. | <input type="checkbox"/> | | |
| <i>The Investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.</i> | | | |
| If a legally authorized representative or family member is told about the clinical investigation and the subject's condition improves, the subject is also to be informed as soon as feasible. | <input type="checkbox"/> | | <input type="checkbox"/> |
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| Community disclosure and consultation will be carried out. | | <input type="checkbox"/> | <input type="checkbox"/> |
| Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn will be carried out. | <input type="checkbox"/> | | |
| Public disclosure to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn, prior to initiation of the clinical investigation, of plans for the investigation and its risks and expected benefits. | <input type="checkbox"/> | | |
| Public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results. | <input type="checkbox"/> | | |
| An independent data monitoring committee to exercise oversight of the clinical investigation will be established. | | <input type="checkbox"/> | <input type="checkbox"/> |

 Primary Reviewer

 Date