**Institutional Review Board**

**Criteria for Approval**

|  |  |
| --- | --- |
| Protocol ID |  |
| Title of Protocol |  |
| PI/Researcher(s) |  |

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| --- | --- |
| **General Considerations** | |
|  | Review Type: Choose an item. |
|  | Review Level: Choose an item. |
|  | Level of Risk: Choose an item. |
|  | Adequate expertise has been obtained for the review, whether through the Reviewer, the convened IRB, or consultation |

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| **Criteria for IRB Approval (all must be checked) (Applies to Initial Review, Continuing Review, Amendments)** | |
|  | Risks to subjects are minimized by using procedures consistent with sound research design and do not unnecessarily expose subjects to risk  Comments: Click or tap here to enter text. |
|  | Risks to subjects are minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes  Comments: Click or tap here to enter text. |
|  | Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result  Comments: Click or tap here to enter text. |
|  | Selection of subjects is equitable (taking into account the purposes of the research, the setting of the research, category of subjects who are vulnerable to coercion or undue influence)  Comments: Click or tap here to enter text. |
|  | Informed consent is sought from each prospective subject or the subject’s legally authorized representative  Comments: Click or tap here to enter text. |
|  | Informed consent is appropriately documented or appropriately waived (see the Consent Process worksheet for more information)  Comments: Click or tap here to enter text. |
|  | The research plan makes adequate provision for monitoring the data collected to ensure safety of subjects  Comments: Click or tap here to enter text. |
|  | There are adequate provisions to protect the privacy of subjects  Comments: Click or tap here to enter text. |
|  | There are adequate provisions to maintain the confidentiality of data  Comments: Click or tap here to enter text. |
|  | Additional safeguards have been included in the study to protect the rights and welfare of subjects likely to be vulnerable to coercion or undue influence  Comments: Click or tap here to enter text. |