**SCIENTIFIC REVEIWER FORM-DIVISION OF DEVELOPMENTAL MEDICINE**

**Principal Investigator:** Click here to enter text.

**Principal Investigator (Listed in CHeRP):** Click here to enter text.

**Protocol Title:** Click here to enter text.

**Protocol #:** Click here to enter text.

**Date of Review:** Click here to enter a date.

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| --- | --- |
| Items | INITIAL Assessment(SCROLL DOWN FOR COMMENTS) |
| Are the specific aims and corresponding hypotheses valid and testable? | [ ]  YES[ ]  NO[ ]  N/A |
| Is the primary outcome (and secondary outcomes if relevant) appropriate and evaluable? | [ ]  YES[ ]  NO |
| Has an appropriate literature search been performed such that that the rationale for the study has been adequately presented? *\*When risks to the subject are high, an extensive search is essential.* | [ ]  YES[ ]  NO |
| Are there adequate preliminary data in the literature (or from the investigator) to justify the research? | [ ]  YES[ ]  NO |
| Is the study design appropriate to test the study hypothesis(es)? | [ ]  YES[ ]  NO |
| If the protocol includes a placebo that might entail risk (even if not great), is the placebo essential for the conduct of the trial?  | [ ]  YES[ ]  NO[ ]  N/A |
| Is the data analysis plan adequate and appropriate to test the primary hypotheses? | [ ]  YES[ ]  NO |
| Does the study have sufficient power to test the primary hypotheses? | [ ]  YES[ ]  NO |
| Is it feasible or reasonable to achieve the results in the proposed timeframe, including the ability to recruit, retain, or follow subjects? | [ ]  YES[ ]  NO |
| Are the proposed tests or measurements appropriate to answer the scientific question? | [ ]  YES[ ]  NO |
| Are all the proposed tests or measurements requested necessary to answer the scientific question? | [ ]  YES[ ]  NO |
| Do the investigators have the appropriate expertise to carry out the protocol? | [ ]  YES[ ]  NO |
|  How do the risks of a new treatment (if proposed) compare to standard treatment/therapies? | [ ]  Greater[ ]  About Same[ ]  Lower [ ]  N/A |

# Reviewer’s overall assessment:

**Responses that must be addressed by the research team:**

**\*\*Please use tracked changes when making any changes to your protocol\*\***

Click here to enter text.

**Suggestions for the research team (no response necessary):**

**\*\*Please use tracked changes when making any changes to your protocol\*\***

Click here to enter text.