Scientific Reviewer Form – Anesthesiology, Perioperative and Pain Medicine

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| --- | --- | --- | --- | --- |
| Principal Investigator |  | | Protocol # |  |
| Protocol Title |  | | | |
| Date of Review |  | Return Comments to PI by | |  |

|  |  |  |
| --- | --- | --- |
| Items | Assessment | **COMMENTS** |
| Scientific Review |  |  |
| Are the specific aims and corresponding hypotheses clearly stated? | **YES**  **NO** |  |
| Is the primary outcome (and secondary outcomes as appropriate) stated and defined? | **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** |  |
| Is the question or hypothesis being tested providing important knowledge to the field? | **YES**  **NO** |  |
| Are there adequate preliminary data in the literature (or from the investigator) to justify the research? | **YES**  **NO** |  |
| Is the sample size appropriate in order to accomplish the aims of the study? | **YES**  **NO** |  |
| If some participants begin but do not complete the study, does the sample size account for this possibility? | **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** |  |
| Is the data analysis plan appropriate, adequate, and sufficiently detailed? | **YES**  **NO** |  |
| Are the individuals who are conducting the trial properly qualified and trained to perform the procedures included in the protocol? | **YES**  **NO** |  |
| Does the research present risk to the subjects?    ⮡ If YES, is it acceptable? | **YES**  **NO** **YES**  **NO** |  |

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| **Items** | **Assessment** | | **COMMENTS** | |
| **Scientific Review** |  | |  | |
| How do the risks of the new treatment/therapy compare to standard treatment/therapies? | **Greater**  **About Same**  **Lower** | |  | |
| Is any standard of care denied as part of this study?  ⮡ If *YES*, specify. | **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?  ⮡ Have/Should other study designs been/be considered? | **YES**  **NO** **YES**  **NO** | |  | |
| Are there appropriate inclusion of gender, minorities and children? | | **YES**  **NO** |  |

# Reviewer’s overall assessment Reviewer’s overall score

Please check one of the following: Please check one of the following:

This protocol is acceptable in its present format.  1.0 – 1.5 Outstanding

This protocol is acceptable, pending clarifications  1.6 – 2.0 Excellent

from the Principal Investigator (list below)  2.1 – 2.5 Very Good

This protocol is NOT acceptable for the reasons  2.6 – 3.0 Good

stated below  3.1 – 3.5 Acceptable

Un-scored Unacceptable

##### Reviewer’s other comments/questions

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(optional)