Scientific Reviewer Form – Anesthesiology, Perioperative and Pain Medicine

|  |  |  |  |
| --- | --- | --- | --- |
| 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** |       |

|  |  |  |
| --- | --- | --- |
| **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)