|  |  |
| --- | --- |
| **PI Name:** | **Submission #:** |
| **Protocol Title:** | |

**Reviewer Instructions:** Please check applicable boxes and provide explanation, rationale, etc. as necessary in the form below.

|  |
| --- |
| **Documents reviewed with this submission (check all that apply):** |
| Revised protocol  Current approved protocol, for comparison  Revised consent(s)  Current approved informed consent(s) for comparison  Other relevant documents, as applicable—specify here: |
| **The amendment includes the following changes (check all that apply):** |
| Increase or decrease in accrual (impacts statistical design)  Addition, deletion or change in either a treatment group or study arm  Addition or deletion of a study drug  Change in treatment period/intervention period/intervention design/study design  Change in informed consent documents  Editorial and/or administrative changes  Other, specify here: |
| **Provide a brief summary of the current approved protocol (note: if the only change involve editorial or administrative edits, this section is not required):** |
|  |
| **Provide a rationale for the amendment (note: if the only change involve editorial or administrative edits, this section is not required):** |

|  |
| --- |
|  |
| **Do the changes in the amendment alter the risk/benefit ratio to the participants?**  Yes  No |
| **Explain:** |
| **In your judgment, do the benefits of this study continue to outweigh the risks?**  Yes  No |
| **Are the approval criteria at** [**46.111**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/regulatory-text/index.html#46.111) **still met as a result of this amendment/revision?**  Yes  No |
| **Does this amendment/revision contain any significant new findings that might impact a subject’s willingness to continue participation in this study?**  Yes (Confirm that plans to re-consent subjects, revised consent documents and/or additional documents are provided with this amendment)  Confirmed  No |
| **Please provide your comments and/or concerns regarding the amendment:** |
| **Please provide your recommendation for action on this amendment/revision:**  Approved as submitted  Modifications required/conditional approval, explain in detail:  Send to Full Committee (if this review is being conducted by expedited review)  Tabled (For Full Committee only; not permitted at expedited level)  Disapproved (For Full Committee only; not permitted at expedited level) |