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

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

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| **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):** |

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|       |
| **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) |