**PROTOCOL AMENDMENT APPLICATION**

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| **DATE SUBMITTED** | Click or tap to enter a date. | **FIERC PROTOCOL CODE** | Click or tap here to enter text. |

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| **PROTOCOL TITLE** | Click or tap here to enter text. |

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| **PRINCIPAL INVESTIGATOR** | Click or tap here to enter text. | **CO-INVESTIGATOR /S** | Click or tap here to enter text. |

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| **DATE OF INITIAL APPROVAL** | Click or tap to enter a date. | **SPONSOR / SOURCE OF FUND** | Click or tap here to enter text. |

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| **PAGE and LINE NO.** | **ORIGINAL** | **AMENDMENT** | **REASON** | ***FOR REVIEWER’S ONLY*** | |
| **APPROVAL** | **COMMENTS** |
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| **Note:**   1. Approval should be obtained from FIERC prior to implementation of an amendment. 2. Amendment should be integrated into a revised Study Protocol. Modified part should be highlighted and include a footer (in all pages) that indicates both the DATE and VERSION NUMBER of the resubmitted study protocol. 3. Summarized the amendment in a cover letter indicating in which page of the revised study protocol the respective revision may be found. |

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| Click or tap here to enter text. |
| **Principal Investigator’s Signature over Printed Name** |
| **DATE:** Click or tap to enter a date. |

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| **RECEIVED BY:** | Click or tap here to enter text.  Signature over Printed Name | **DATE:**  Click or tap to enter a date. |

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| ***To be filled-out by FIERC***   |  |  |  | | --- | --- | --- | | **ASSESSMENT BY THE PRIMARY REVIEWERS** | | | | 1. Type of Review | Minor | Major | | 2. Does the amendment increase the risks to participants? | Yes | No | | 3. Does the amendment increase the benefits to the  participants? | Yes | No | | 4. Does the amendment required to revise the ICF? | Yes | No | | 5. Does the amendment required to re-consent? | Yes | No |  |  |  | | --- | --- | | **RECOMMENDED ACTION**  **APPROVE**  **REQUEST FOR ADDITIONAL JUSTIFICATION / INFORMATION**  **REQUIRE SPECIFIC ACTIONS**  **DISAPPROVE** | **JUSTIFICATION FOR RECOMMENDED ACTION:** |  |  |  | | --- | --- | | **PRIMARY REVIEWER:**  Click or tap here to enter text.  **Signature over Printed Name** | Click or tap to enter a date.  **Date:** | |