**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** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
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 *Add more rows if necessary*

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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***

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| **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 |

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| **RECOMMENDED ACTION**[ ]  **APPROVE**[ ]  **REQUEST FOR ADDITIONAL JUSTIFICATION / INFORMATION**[ ]  **REQUIRE SPECIFIC ACTIONS** [ ]  **DISAPPROVE** | **JUSTIFICATION FOR RECOMMENDED ACTION:** |

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| **PRIMARY REVIEWER:**Click or tap here to enter text.**Signature over Printed Name** | Click or tap to enter a date.**Date:**  |

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