**CONTINUING REVIEW APPLICATION FORM**

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| **APPLICATION SUBMISSION DATE**  *(To be filled out by FIERC)* | 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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| **DATE APPROVAL** | Click or tap to enter a date. | **EXPIRY OF ETHICAL CLEARANCE** | Click or tap to enter a date. |

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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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| **EMAIL** | Click or tap here to enter text. | **TELEPHONE NO.** | Click or tap here to enter text. | **MOBILE NO.** | Click or tap here to enter text. |

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| **STUDY SITE** | Click or tap here to enter text. | **STUDY SITE ADDRESS** | Click or tap here to enter text. |

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| **SPONSOR** | Click or tap here to enter text. | **SPONSOR CONTACT PERSON** | Click or tap here to enter text. |

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| **EMAIL** | Click or tap here to enter text. | **TELEPHONE NO.** | Click or tap here to enter text. | **MOBILE NO.** | Click or tap here to enter text. |

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| 1. **START DATE:** | Date of research site initialization  Click or tap to enter a date. | Explanation, if not yet initialized as of date of this application: *(reason/s)* Click or tap here to enter text. |

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| 1. **ACTION REQUESTED:** | Renewal: New participant accural to continue |
| Renewal: Enrolled participant follow-up only |
| Renewal: Data analysis only |
| Renewal: *(Specify)* |

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| 1. **HAVE THERE BEEN ANY AMENDMENTS SINCE THE LAST REVIEW / APPROVAL?** | |
| **No** | **Yes** (Describe briefly and indicate date/s of Study Protocol Amendment Submission/s)  Click or tap here to enter text. |

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| 1. **HAVE THERE BEEN ANY DEVIATION / VIOLATION REPORTS SINCE THE LAST REVIEW / APPROVAL?** | |
| **No** | **Yes** (Describe briefly and indicate date/s of Study Protocol Deviation /Violation Submission/s)  Click or tap here to enter text. |

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| 1. **HAVE THERE BEEN ANY CHANGES IN THE PARTICIPANT POPULATION, RECRUITMENT OR SELECTION CRITERIA SINCE THE LAST REVIEW / APPROVAL?** | |
| **No** | **Yes** (Explain changes and indicate date/s Study Protocol Amendment Submission/s)  Click or tap here to enter text. |

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| 1. **HAVE THERE BEEN ANY CHANGES IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST REVIEW / APPROVAL? Attach latest version of participant informed consent form /document** | |
| **No** | **Yes** (Explain changes and indicate date/s Study Protocol Amendment Submission/s)  Click or tap here to enter text. |

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| 1. **HAS ANY INFORMATION APPEARED IN THE LITERATURE, OR EVOLVE FROM THIS OR SIMILAR RESEARCH THAT MIGHT AFFECT THE PANEL’S EVALUTATION OF THE RISK / BENEFIT ASSESSMENT OF HUMAN PARTICIPANTS INVOLVED IN THE STUDY PROTOCOL?** | |
| **No** | **Yes** (Describe briefly and provide copy of literature cited)  Click or tap here to enter text. |

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| 1. **HAVE THERE BEEN ANY UPDATES OR MEASURES IN THE PROTOCOL TO GUARANTEE PROTECTION OF PRIVACY AND CONFIDENTIALITY OF PARTICIPANT INFORMATION IN COMPLIANCE WITH LOCAL REGULATIONS (e.g. Data Privacy Act of 2012)?** | |
| **No** | **Yes (**Describe briefly these provision)  Click or tap here to enter text. |

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| 1. **IS A BIOBANK BEING MAINTAINED FOR THIS STUDY?** | |
| **No** | **Yes** (Describe governance and custodianship, access to data and transfer of materials, and measures protecting privacy and confidentiality)  Click or tap here to enter text. |

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| 1. **HAVE ANY UNEXPECTED DISCOMFORTS, COMPLICATIONS, OR SIDE EFFECTS BEEN NOTED SINCE LAST REVIEW / APPROVAL?** | |
| **No** | **Yes** (Summarize and indicate date/s of Reportable Negative Events / SUSAR report submission/s)  Click or tap here to enter text. |

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| 1. **HAVE ANY PARTICIPANTS WITHDRAWN FROM THIS STUDY SINCE THE LAST REVIEW / APPROVAL?** | |
| **No** | **Yes** (Explain context surrounding withdrawal and documenting due  diligence exerted by the study team in managing these withdrawals)  Click or tap here to enter text. |

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| 1. **HAVE THERE BEEN ANY INTERVENTION(S) OR METHODS IN THE CONDUCT OF STUDY THAT IS / ARE NOT IN THE APPROVED PROTOOCOL?** | |
| **No** | **Yes** ((Describe use and indicate date/s of Study Protocol Deviation /  Violation Report Submission/s)  Click or tap here to enter text. |

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| 1. **HAVE ANY INVESTIGATORS BEEN ADDED OR DELETED SINCE LAST REVIEW / APPROVAL?** | |
| **No** | **Yes** (Enumerate personnel and indicate date/s of Study Protocol  Amendment Submission/s. Append CV if not yet submitted to the FIERC)  Click or tap here to enter text. |

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| **14. HAVE ANY NEW COLLABORATING SITES (INSTITUTIONS) BEEN ADDED OR DELETED SINCE**  **THE LAST REVIEW APPROVAL?** | |
| **No** | **Yes** (Enumerate sites and indicate date/s of Study Protocol Amendment Submission/s)  Click or tap here to enter text. |

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| **15. HAVE ANY INVESTIGATORS DEVELOPED EQUITY OR CONSULTATIVE RELATIONSHIP WITH A PARTY RELATED TO THIS STUDY PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST SINCE THE LAST REVIEW /APPROVAL?** | |
| **No** | **Yes** (Append a statement of disclosure)  Click or tap here to enter text. |

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| **16. HAVE THERE BEEN CHANGES IN STUDY PERSONNEL SINCE THE LAST REVIEW / APPROVAL?** | | |
| **No** | **Deleted** (Enumerate and indicate  date/s Study Protocol Amendment  Submission/s)  Click or tap here to enter text. | **Added** (Enumerate and indicate  date/s Study Protocol Amendment  Submission/s)  Click or tap here to enter text. |

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| **17. HAVE THERE BEEN OTHER CHANGES NOT MENTIONED ABOVE SINCE THE LAST REVIEW**  **APPROVAL? Attach protocol synopsis** | |
| **No** | **Yes** (Provide details regarding the visit / audit / inspection (when, where, etc.) findings and recommendations, and corrective action of the site, if any)  Click or tap here to enter text. |

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| **18. HAS THE STUDY SITE BEEN VISITED BY FIERC or ANOTHER ETHICS COMMITTEE, AUDITED BY**  **SPONSOR, OR INSPECTED BY AN ANY REGULATORY AGENCY?** | |
| **No** | **Yes** (Provide details regarding the visit / audit / inspection (when, where, etc.) findings and recommendations, and corrective action of the site, if any)  Click or tap here to enter text. |

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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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| ***To be filled-out by FIERC***   |  |  |  | | --- | --- | --- | | **ASSESSMENT BY THE PRIMARY REVIEWERS** | | | | 1. Does the continuing review application change in risk, change in benefits, and change in benefit-risk ratio? | Yes | No | | 1. Does the continuing review application required to revise the ICF? | Yes | No | | 1. Does the continuing review application required to re-consent? | Yes | No |  |  | | --- | | **RECOMMENDED ACTION:**  **APPROVE**  **REQUEST INFORMATION: (INDICATE INFORMATION)** Click or tap here to enter text.  **RECOMMENDED FURTHER ACTION: (INDICATE ATION)** Click or tap here to enter text.  **PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE** |  |  |  | | --- | --- | | **PRIMARY REVIEWER:**  Click or tap here to enter text.  **Signature over Printed Name** | Click or tap to enter a date.  **Date:** | |