**FINAL REPORT FORM**

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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. | **SPONSOR / FUNDING AGENCY** | 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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| **SPONSOR** | Click or tap here to enter text. | **SPONSOR ADDRESS** | 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. |

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| **TOTAL NUMBER OF PARTICIPANTS** | Click or tap to enter a date. | **NUMBER OF STUDY ARMS** | Click or tap here to enter text. |

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| **NUMBER OF STUDY PARTICIPANTS AT THE START OF THE STUDY** | **NUMBER OF PARTICIPANTS AT THE END OF THE STUDY** | **NUMBER OF PARTICIPANTS WHO RECEIVED THE ARTICLES** |
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| 1. **Summary of amendments to the original protocol (Include dates of approval)** | Click or tap here to enter text. |
| 1. **Summary of SAE reported** | Click or tap here to enter text. |
| 1. **Summary of SUSAR reported** | Click or tap here to enter text. |
| 1. **Summary of participants’ complaints, if applicable** | Click or tap here to enter text. |
| 1. **Summary of benefits documented** | Click or tap here to enter text. |
| 1. **Summary of indemnification, if applicable** | Click or tap here to enter text. |
| 1. **If terminated early, state the reason** | Click or tap here to enter text. |
| 1. **Progress report dates with corresponding FIERC Decision** | Click or tap here to enter text. |
| 1. **Continuing Review Application Submission dates with corresponding FIERC Action** (required for approval dates issued one year ago or earlier) | Click or tap here to enter text. |
| 1. **Summary of study materials used (for non-clinical research)** | Click or tap here to enter text. |
| 1. **Treatment or interventions** | Click or tap here to enter text. |
| 1. **Duration of the study** | Click or tap here to enter text. |
| 1. **Summary of Recruitment** | Click or tap here to enter text. |
| 1. **List of Informed Consent form used (version / date) and attach most recent version** | Click or tap here to enter text. |
| 1. **Study Objectives** | Click or tap here to enter text. |
| 1. **Dissemination Plan** | Click or tap here to enter text. |
| 1. **Summary of Results** | Click or tap here to enter text. |
| 1. **Recommendations of the researchers** | 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***   |  |  | | --- | --- | | **PRIMARY REVIEWER’S COMMENTS**  *(e.g. compliance with the terms of the approved protocol including post-approval review requirements, and overall assessment of risks against benefits in the conduct of study)* |  | | **RECOMMENDED ACTION** | **ACCEPTANCE OF THE FINAL REPORT**  **REQUIRE SUBMISSION WITH CORRECTIONS** |  |  |  | | --- | --- | | **PRIMARY REVIEWER:**  Click or tap here to enter text.  **Signature over Printed Name** | Click or tap to enter a date.  **Date:** | |