**PROGRESS REPORT**

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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. | **APPROVAL DATE** | Click or tap to enter a date. |

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| **1. Any amendments since the last review?** | No  Yes |
| (Describe briefly) | |

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| **2. Any changes in participant population, recruitment or selection criteria since the last review?** | No Yes |
| (Explain the changes) | |

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| **3. Any change in the Informed Consent process or documentation since the last review?** | No  Yes |
| (Please explain) | |

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| **4. Is there any new information in recent literature or similar research that may change the risk/benefit ratio for participants in the study?** | No  Yes |
| (Discuss and attach a copy of the literature) | |

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| **5. Any unexpected complication or side effect noted since the last review?** | No  Yes |
| (Discuss and attach a narrative) | |

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| **6. Did any participant withdraw from the study since the last review approval?** | No  Yes |
| (Reasons for withdrawal) | |

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| **7. Any new investigator that has been added to or removed from the research team since the last review?** | No  Yes |
| (Please identify them and submit the CVs of new investigators) | |

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| **8. Are there any new collaborating site/s that have been added or deleted since the last review?** | No  Yes |
| (Please identify the site/s and note the addition and deletion) | |

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| **9. Any other changes not mentioned above since the last review?** | No  Yes |
| (Describe briefly) | |

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| **10. Is the study site has been visited by FIERC, audited by the sponsor, or inspected by any regulatory authority?** | No  Yes |
| (Provide details regarding the visit/audit/inspection (when, where, etc.), findings and recommendations, and corrective action of the site, if any) | |

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| **11. Progress Status (\_\_\_\_\_Qtr. (Qtr. Period)** | | |
| Target Activity | % Completion and Actual Accomplishment | Remarks  (on target or reasons for delay) |
|  |  |  |

Click or tap here to enter text.

Signature over Printed Name of PI

Date: \_\_\_\_\_\_\_\_\_

**To be filled-up by FIERC**

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| **ASSESSMENT BY THE PRIMARY REVIEWER** | **YES** | **NO** | **COMMENTS** |
| 1. Do the risks to the study participants remain reasonable in relation to anticipated benefits? |  |  |  |
| 2. Are there new finding in the IB or literature that need to be included in the informed consent? |  |  |  |
| 3. Is there a need to revise the ICF? |  |  |  |
| 4. Is there a need to reconsent subjects enrolled in the study? |  |  |  |
| 5. Are there concerns about conduct of the research team (e.g. suspension of medical license, frequent protocol violation, patient or third-party complaints, etc.)or institutional commitment that may affect study participants safety? |  |  |  |
| 6. Are there concerns about participants safety, inability to comply with the protocol, high dropout rate that affect study termination? |  |  |  |

**FIERC RECOMMENDATIONS**

**Approved**

**Request an amendment to the protocol of the consent form**

**Request for further information**

**Suspend or terminate the study**

Click or tap here to enter text.

Signature over Printed Name of the Primary Reviewer

Click or tap here to enter text.

Date