**PROGRESS REPORT EVALUATION FORM**

**(Form 3.3B)**

**TO THE PRINCIPAL INVESTIGATOR:** *OBTAIN AN ELECTRONIC COPY OF THIS FORM AND ENCODE ALL INFORMATION REQUIRED ON THE SPACE PROVIDED. PRINT NAME, DATE AND SIGN THIS FORM BEFORE SUBMISSION.*

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| **Date of Submission (MMM/DD/YYYY)** | Click here to enter text. | **IRB Protocol Number** | Click here to enter text. |

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| **Sponsor** | Click here to enter text. | **Sponsor’s Protocol Number** | Click here to enter text. |

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| **Principal Investigator** | Click here to enter text. | **Co-investigator(s)** **(if any)** | Click here to enter text. |

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| **Principal Investigator’s Signature** | Click here to enter text. | **Principal Investigator’s Contact No.** | Click here to enter text. |

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| **Protocol Title**  | Click here to enter text. |

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| **Date of Initial Approval of Protocol (MMM/DD/YYYY)** | Click here to enter text. |

**TO THE PRINCIPAL INVESTIGATOR:***INDICATE THE LOCATION OF THE ASSESSMENT POINT (E.G. PAGE NO.) IN THE SECOND COLUMN. INDICATE* ***N/A*** *IF NOT APPLICABLE*

**TO THE PRIMARY REVIEWER/ INDEPENDENT CONSULTANT:***IF YOU HAVE NO FURTHER COMMENTS, PUT A (√) MARK ON THE SPACE PROVIDED.OTHERWISE, SPECIFY THE ISSUES IN THE SPACE PROVIDED.PLEASE DO NOT USE PENCIL IN ACCOMPLISHING THIS FORM.*

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| **ASSESSMENT POINT** | ***LOCATION*** | **REVIEWER’S COMMENTS** |
| APPROVE/SUFFICIENT/NO FURTHER COMMENT**(put a check √ mark)** | FOR REVISION (specify issues) |
| 1. The number of subjects accrued; (For multi-site studies, the number of subjects accrued at the local site and the number accrued study-wide, if available)
2. Expected enrollment rate
3. Actual enrollment rate
4. Reason for the difference between the expected and actual enrolment rate
5. Enrollment issues
6. Number of subjects who withdrew
7. Summary of reasons for withdrawal at local site
 | Click here to enter text. |  |  |

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| 1. A brief summary of any amendments to the research approved by the IRB since the IRB’s initial review or the last continuing review.
 | Click here to enter text. |  |  |
| 1. Any new and relevant information, published or unpublished, since the last IRB review, especially information about risks associated with the research
 | Click here to enter text. |  |  |
| 1. A summary of any unanticipated problems. In many cases, such a summary could be a brief statement that there have been no unanticipated problems (i.e., adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document and Investigator’s Brochure (if applicable);
 | Click here to enter text. |  |  |
| 1. A summary of any subject withdrawals from the research since the last IRB review, and the reasons for withdrawal, if known;
 | Click here to enter text. |  |  |

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| 1. A summary of any complaints about the research from subjects enrolled at the local site since the last IRB review;
 | Click here to enter text. |  |  |
| 1. The latest versions of the protocol and sample informed consent document(s) in use at the site;
 | Click here to enter text. |  |  |
| 1. Any proposed modifications to the informed consent document or protocol;
 | Click here to enter text. |  |  |
| 1. The current Investigator’s Brochure, if any, including any modifications;
 | Click here to enter text. |  |  |

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| 1. Any other significant information related to subject risks, such as the most recent report, if any, from data safety monitoring board (DSMBs); (Additionally, it may be useful for sponsors to ensure that IRBs are informed when DSMBs have met, even when no problems have been identified and the DSMBs has recommended continuation of the study as designed. This information can be transmitted either by the investigator or directly by the sponsor);
 | Click here to enter text. |  |  |
| 1. Aggregate information about relevant regulatory actions occurring since the last review that could affect safety and risk assessments (e.g., withdrawal or suspension from marketing in any country on the basis of safety, reports of recalls and device disposition.)
 | Click here to enter text. |  |  |
| 1. Drug Safety Update Report (DSUR) Executive Summary, if available.
 | Click here to enter text. |  |  |
| 1. Changes in the investigator’s situation or qualifications (e.g., suspension of hospital privileges, medical license, involvement in numerous clinical trials, renewal of GCP training, etc.)
 | Click here to enter text. |  |  |

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| 1. Changes in the acceptability of the proposed research in terms of institutional commitments (e.g., personnel and financial resources, adequacy of facilities) and regulations, applicable state and local law, or standards of professional conduct of practice.
 | Click here to enter text. |  |  |
| 1. Study start data and expected duration
 | Click here to enter text. |  |  |
| 1. Summary of SAEs/SUSARS

For Onsite: AE reportedCausalityDate Reported to IRB For Offsite: AE reportedCount |  |  |  |
| 1. Summary of Protocol Deviations

Description of ViolationCorrective Action TakenDate Reported to IRBType of Protocol Deviation |  |  |  |

**TO THE PRIMARY REVIEWER/ INDEPENDENT CONSULTANT:***PRINT NAME, SIGN AND DATE THIS FORM.PLEASE DO NOT USE PENCIL IN ACCOMPLISHING THIS FORM. INDICATE WITH A (✓) CHECK MARK THE APPROPRIATE TICK BOX.*

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| **Reviewer’s Recommendation:**  |
| * Renew approval with no further action
* Approval pending
* Request additional information
* Recommend modification
* Recommend suspension of:
* Enrolment of new subjects
* Research procedures in currently enrolled subjects
* The entire study
* Termination of approval
* Others (specify): \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_
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| **Primary Reviewer’s Name** | **Signature** | **Date (MMM/DD/YYYY)** |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |