**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)** |  | **IRB Protocol Number** |  |

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| **Sponsor** |  | **Sponsor’s Protocol Number** |  |

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| **Principal Investigator** |  | **Co-investigator(s)** **(if any)** |  |

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| **Principal Investigator’s Signature** |  | **Principal Investigator’s Contact No.** |  |

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| **Protocol Title**  |  |

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| **Date of Initial Approval of Protocol (MMM/DD/YYYY)** |  |

**TO THE PRINCIPAL INVESTIGATOR:***PLEASE INDICATE YOUR RESPONSE FOR EACH ASSESSMENT POINT IN THE SECOND COLUMN. IF A POINT IS NOT APPLICABLE, PLEASE WRITE “N/A” OR “NONE” AS APPROPRIATE.*

**TO THE PRIMARY REVIEWER/ INDEPENDENT CONSULTANT:***IF YOU HAVE NO FURTHER COMMENTS, PUT AN (X) MARK ON “APPROVE”. OTHERWISE, PUT AN (X) MARK ON “REQUEST FURTHER INFORMATION” AND SPECIFY THE ISSUES IN THE SPACE PROVIDED.*

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| **ASSESSMENT POINT** | **PI’S RESPONSE** | RECOMMENDATIONS |
| 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. Summary of reasons for withdrawal at local site
 |  |  | Approve |  | Request further information |
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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.
 |  |  | Approve |  | Request further information |
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| 1. Any new and relevant information, published or unpublished, since the last IRB review, especially information about risks associated with the research
 |  |  | Approve |  | Request further information |
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| 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);
 |  |  | Approve |  | Request further information |
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| 1. A summary of any subject withdrawals from the research since the last IRB review, and the reasons for withdrawal, if known;
 |  |  | Approve |  | Request further information |
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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;
 |  |  | Approve |  | Request further information |
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| 1. The latest versions of the protocol and sample informed consent document(s) in use at the site;
 |  |  | Approve |  | Request further information |
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| 1. Any proposed modifications to the informed consent document or protocol;
 |  |  | Approve |  | Request further information |
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| 1. The current Investigator’s Brochure, if any, including any modifications;
 |  |  | Approve |  | Request further information |
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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);
 |  |  | Approve |  | Request further information |
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| 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.)
 |  |  | Approve |  | Request further information |
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| 1. Drug Safety Update Report (DSUR) Executive Summary, if available.
 |  |  | Approve |  | Request further information |
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| 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.)
 |  |  | Approve |  | Request further information |
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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.
 |  |  | Approve |  | Request further information |
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| 1. Study start data and expected duration
 |  |  | Approve |  | Request further information |
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| 1. Summary of SAEs/SUSARS

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

Description of ViolationCorrective Action TakenDate Reported to IRBType of Protocol Deviation |  |  | Approve |  | Request further information |
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**TO THE PRIMARY REVIEWER/ INDEPENDENT CONSULTANT:***PRINT NAME, SIGN AND DATE THIS FORM. INDICATE WITH AN (X) MARK THE APPROPRIATE TICK BOX.*

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| **Reviewer’s Recommendation:**  |  | Renew approval with no further action |  | Termination of approval |
|  | Approval pending[ ]  Request additional information[ ]  Recommend modification |  | Others (specify): |
|  | Recommend suspension of:[ ]  Enrolment of new subjects[ ]  Research procedures in currently enrolled subjects[ ]  The entire study |  |  |
| **Other comments (if any):** |

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| **Primary Reviewer’s Name** | **Signature** | **Date (MMM/DD/YYYY)** |
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