**FINAL REPORT (Form 3.4)**

**TO THE PRINCIPAL INVESTIGATOR:** *OBTAIN AN ELECTRONIC COPY OF THIS FORM AND ENCODE ALL INFORMATION REQUIRED IN THE SPACE PROVIDED. PRINT NAME, DATE AND SIGN THIS FORM BEFORE SUBMISSION. INDICATE WITH A (✓) CHECK MARK THE APPROPRIATE TICK BOX.*

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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 Number** |  |

|  |  |
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| **Protocol Title** |  |

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

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| **Study site(s):** |  | **No. of Study Arms** |  |

1. **CUMULATIVE SUMMARY OF SUBJECTS ENROLLED TO DATE**

*(For studies involving record and/or specimen review only, skip and complete Section B)*

*(For study designs utilizing multiple consent forms, this table may be replicated).*

|  |  |
| --- | --- |
| 1. **Number of subjects accrued** |  |

|  |  |
| --- | --- |
| 1. **Number of subjects currently active/ on study**   *(For example, subjects receiving study interventions/ interactions or long-term follow-up)* |  |

|  |  |
| --- | --- |
| 1. **Number of subjects completed**   *(Without events leading to early termination/ withdrawal from the study)* |  |

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| 1. **Number of subjects who voluntarily withdrew consent after enrolling**   *(For example, after signing the consent form, the subject changes his/her mind and decided not to participate or to stop participating after completing some of the study procedures)* |  |

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| **Explanation** |  |

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| 1. **Number of subjects terminated/ withdrawn from the study by the investigator due to adverse event(s)**   *For example, subject met toxicity drop point or experienced a serious adverse event.* |  |

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| **Explanation** |  |

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| 1. **Number of subjects terminated/ withdrawn from the study by the investigator due to other reasons**   *For example, non-compliance with the protocol, pregnancy, etc.* |  |

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| **Explanation** |  |

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| 1. **Number of subjects lost to follow-up** |  |

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| --- | --- |
| **Explanation** |  |

|  |  |
| --- | --- |
| 1. **Number of subjects who are no longer participating for reasons other than those above** |  |

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| --- | --- |
| **Explanation** |  |

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| 1. **Total of item nos. 2 to 8**   *(should be equal to item no. 1)* |  |

|  |  |
| --- | --- |
| 1. **Number of subjects approved at Makati Medical Center** |  |

1. **RECORDS AND SPECIMENS**

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| --- | --- |
| 1. **Number of specimens and/or records approved by the IRB:** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **Did you review medical records, patient charts, radiographs or other patient information for this study?** | **No**    **Yes** | **No. of records reviewed to date:** | dd |

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| 1. **Did you analyze specimens (e.g., archival tissue, blood, blood products, or body fluids) for this study?** | **No**    **Yes** | **No. of specimen analyzed to date:** |  |

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| --- | --- |
| **Duration of the Study (Date Initiated and Completed)**  **(MMM/DD/YYYY)** |  |

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| --- | --- |
| **Objectives** |  |

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| **Summary of Results:** |
|  |

**TO THE PRIMARY REVIEWER/ INDEPENDENT CONSULTANT:***INDICATE WITH A (✓) CHECK MARK THE APPROPRIATE TICK BOX. SPECIFY ON THE SPACE PROVIDED OTHER COMMENTS, IF APPLICABLE.*

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| **Comments/ Recommendations of the Primary Reviewer** |
| Acknowledged  Request for further information  \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_  Recommend further action  \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_  Others  \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ |

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| **Primary Reviewer’s Name** | **Signature** | **Date (MMM/DD/YYYY)** |
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| **Date of IRB meeting the report was presented**  **(MMM/DD/YYYY)** |  |