**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.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Date of Submission (MMM/DD/YYYY)** |  | **IRB Protocol Number** |  |

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

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Principal Investigator’s Signature** |  | **Principal Investigator’s Contact Number** |  |

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

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

|  |  |  |  |
| --- | --- | --- | --- |
| **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)* |  |

|  |  |
| --- | --- |
| 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)* |  |

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

|  |  |
| --- | --- |
| 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 **Number of subjects terminated/ withdrawn from the study by the investigator due to adverse event(s)**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.*  |  |

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

|  |  |
| --- | --- |
| 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 **Number of subjects terminated/ withdrawn from the study by the investigator due to other reasons**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.*  |  |

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

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

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

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

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

|  |  |
| --- | --- |
| 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**

|  |  |
| --- | --- |
| 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 |

|  |  |  |  |
| --- | --- | --- | --- |
| 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:** |  |

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

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

|  |
| --- |
| **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.*

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

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

|  |  |
| --- | --- |
| **Date of IRB meeting the report was presented****(MMM/DD/YYYY)** |  |