**CONTINUING REVIEW APPLICATION**

**(Form 3.3A)**

*\*If IRB approval of your study has expired, you must also complete the Expired Study Report Form.*

*\*Please ensure that this form is accomplished in accordance with your study's Continuing Renewal/Progress Report, as it is necessary that your study is "Active" before submitting for Final Report. Otherwise, you cannot submit a Final Report if your study is "Inactive" from not being able to renew your study prior to the study's expiration.*

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

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

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

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| **Expiration Date of Study Approval (MMM/DD/YYYY)** |  |

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

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| **Principal Investigator** |  |

|  |  |
| --- | --- |
| **Department** |  |

|  |  |  |
| --- | --- | --- |
| **Telephone Number/ Messaging App** | **Mobile Number** | **Email Address** |
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| **Additional Contact: If additional information is needed, specify the contact person if other than the PI (e.g., study coordinator)** |  | **Email Address/**  **Contact Number** |  |

**STUDY PERSONNEL**

|  |  |
| --- | --- |
| **Co-Investigator(s):** |  |

|  |  |
| --- | --- |
| **Other Study Personnel (i.e., research coordinators, data managers, etc.)** |  |

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| --- |
| **Have there been any changes in study personnel not previously reported to the IRB? Indicate the changes below and when:** |
|  |

**PROTOCOL SUMMARY**

**Summary of Study: Attach current protocol with version date.**

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| 1. **What is you research question (hypothesis?)** |
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| 1. **Describe the Design** |
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| --- |
| 1. **What will the subjects be asked to do? What will be done to the subjects?** |
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| --- |
| 1. **Describe the risks to the subjects:** |
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| --- |
| 1. **Describe the potential benefits to subjects or others, if any:** |
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**PROJECT STATUS (Check all that apply)**

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| --- |
| **A. Active – Open to Enrolment** |
| No enrolment to date  Participant enrolment has begun  Specimen collection or chart review occurring |

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| --- |
| **B. Active – Closed to Enrolment** |
| Treatment and/or active follow-up continues  Long term follow-up of subjects as patients (e.g., following for survival)  Data analysis only |

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| **C. Study Closed Prior to Completion**  ***Do not complete this form. Please complete the Final Study Report/ Study Closure Form*** |

|  |
| --- |
| **D. Study Completed (*Enrolment, treatment, data collection, follow-up, and data analysis are complete.)***  ***Do not complete this form. Please complete the Final Study Report/ Study Closure Form.*** |

**SPONSOR/ FUNDING SOURCE**

|  |  |
| --- | --- |
| **Is this research funded at this time?** | **No  Yes** |

|  |  |
| --- | --- |
| **Has the sponsor/ funding source changed since the last review?** | **No  Yes** *\*If YES, please attach the Sponsor/ Funding Information* |

**DRUG AND DEVICE STUDIES**

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| --- | --- |
| 1. **Since the last continuing review, has your study site been inspected by the FDA?** | **No  Yes** |

|  |  |
| --- | --- |
| **If YES, did the site receive Inspectional Observations?** | **No  Yes** *\*If YES, please attach a copy of Inspectional Observations and*  *your response to FDA* |

|  |  |
| --- | --- |
| 1. **Is the Principal Investigator the holder of the IND or IDE?** | **No  Yes** *\*If YES, provide a copy of the most recent IND/ IDE report*  *submitted to the FDA.* |

**ENROLLMENT**

|  |  |  |  |
| --- | --- | --- | --- |
| **Has enrolment been lower than anticipated?** | **No**  **Yes** | **If YES, explain the reasons for low or no enrolment and, if relevant, what steps were or will be taken to increase enrolment:** |  |

**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).***

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

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

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

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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** |  |

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

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

**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:** |  |

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

**PROGRES REPORT: (Complete all sections in sufficient detail to assess current risk/ benefit)**

The primary purpose of continuing review is to re-assess the risk-benefit ratio at intervals appropriate to the degree of risk associated with the study procedures, but not less than once per year. At the time of continuing review, the IRB must ensure that the regulatory criteria for IRB approval continue to be satisfied. Please answer the following questions so that both you and the IRB can determine whether any new information has emerged, either from the research itself or from other sources that could alter the IRB's previous determinations, particularly with respect to risk to subjects.

1. **Unanticipated problems**

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| --- | --- |
| 1. **Since the last IRB review, have any serious, unexpected adverse events occurred that were considered related to participation in the research that have not been previously reported to the IRB?** | **No  Yes** *\*If YES, please attach Unanticipated Problem*  *Report describing any previously unreported unanticipated event.* |

|  |  |
| --- | --- |
| 1. **Since the last IRB review, have any other unanticipated problems involving risks to subjects or others occurred, for example, medication or laboratory errors, loss or unintended disclosure of confidential information, investigator suspension or termination?** | **No  Yes** *\*If YES, please attach Unanticipated Problem Report describing any previously unreported unanticipated event.* |

1. **PROTOCOL DEVIATIONS/ VIOLATIONS**

|  |  |
| --- | --- |
| **Since the last IRB review, have any protocol deviations/ violations involving risks to subjects or others occurred that have not been previously reported to the IRB?** | **No  Yes** *\*If YES, please attach the IRB Protocol Deviation/ Violations Report Form (Form 3.5)* |

1. **COMPLAINTS ABOUT THE RESEARCH**

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| --- | --- |
| **Since the last IRB review, have any subjects or others complained about the research?** | **No  Yes** *\*If YES, please provide a summary of the complaints and how they were resolved.* |

1. **PROGRESS REPORT AND INTERIM FINDINGS**

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| --- |
| 1. **Provide a brief general summary of the progress of the study.** |
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| 1. **Has there been an interim analysis or are there any interim findings to report?** | **No  Yes** *\*If YES, please provide results of interim analysis or a summary of any findings to date.* |

1. **DATA AND SAFETY MONITORING**

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| --- | --- |
| **Is this a trial subject oversight by a Data Safety and Monitoring Board (DSMB), Data Monitoring Committee (DMC), other similar body (e.g., coordinating or statistical center), or group whose responsibilities include review of adverse events and interim findings?** | **No  Yes** *\*If YES, indicate the type of monitoring plan*  *below, and attach a copy of the most recent report or communication.*  *DSMB/ DMC/ DSMC*  *Monitor/ monitoring group*  *Coordinating or statistical center* |

1. **OTHER INFORMATION RELEVANT**

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| --- | --- |
| **Since the last IRB review, have there been major advances, changes in standards or care, drug approvals, device recall, new black box warning, or key publications in major peer-reviewed journals which would alter the risk/ benefit assessment of this study?** | **No  Yes** *\*If YES, please provide a summary of relevant information. Provide the key references and interpretation/ commentary.* |

1. **INVESTIGATOR'S ASSESSMENT OF RISKS AND BENEFITS**

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| --- | --- |
| 1. **Since the last IRB review, have the risks to subjects changed?** | **No  Yes** *\*If YES, please provide a summary of the*  *changes in the risks to subjects.* |

|  |  |
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| 1. **Since the last IRB review, has the magnitude of benefit or likelihood of benefit to subjects changed?** | **No  Yes** *\*If YES, please provide a summary of the*  *changes in the anticipated benefits.* |

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| 1. **Do the risks to subjects continue to be reasonable in relation to anticipated benefits, if any, to subjects and to the importance of the knowledge that may reasonably be expected to result?** | **No  Yes** *\*If NO, explain below:* |

1. **PROPOSED MODIFICATIONS/AMENDMENTS/ CHANGES TO THE RESEARCH**

|  |  |
| --- | --- |
| **Are any changes to the research being proposed at this time?** | **No  Yes** *\*If YES, please attach the Protocol Amendment Review Form (Form 3.2) detailing proposed changes. \*\** |

***\*\*NB: The IRB must approve all changes to protocols and consent forms and other study documents (e.g., questionnaires, recruitment letters, advertisements, etc.) prior to implementation.***

**ATTACHMENTS:**

**Attach the following:**

**Research Protocol**: Current dated version of the protocol (Provide highlighted or strikeout copy of any changes proposed with this continuing review submission, if applicable.)

**Investigator Financial & Other Personal Interests Disclosure Form** for each investigator and key study personnel

**Research Consent Forms**: Copy of most recent IRB-approved consent forms showing the IRB- approval stamp

**Research Consent Forms**: Consent forms for re-approval without IRB-approval stamp (if changes are proposed, include one copy with proposed changes highlighted and one copy without proposed changes highlighted).

**For multi-center trials -** Please attach any relevant multi-center reports

**PRINCIPAL INVESTIGATOR'S ASSURANCES**

* I have followed all applicable policies and procedures of Makati Medical Center, national and local laws regarding the protection of human subjects in research, including, but not limited to, the following:
* The research was performed as approved by the IRB under the direction of the Principal Investigator by appropriately trained and qualified personnel;
* Unanticipated problems were promptly reported to the IRB, as well as any other information necessary for appropriate oversight of the research;
* Research-related records (and source documents) will be maintained in a manner that documents the validity of the study and integrity of the data collected, while protecting the confidentiality of the data and privacy of participants;
* Study-related records will be retained and available for audit for a period of 15 years after the study has ended (or longer, according to sponsor or publication requirements) even if I leave the Makati Medical Center;
* IRB approval or exemption will be obtained before initiating any new research activities involving human subjects; and
* All co-investigators, research staff, employees, and students assisting in the conduct of the research will be informed of their obligations in meeting the above commitments.

I verify that the information provided in this Continuing Review Application is accurate and complete.

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| **Name of the Principal Investigator** |  | **Signature** |  | **Date (MMM/DD/YYYY)** |
|  |  |  |  |  |