SAN JUAN DE DIOS EDUCATIONAL FOUNDATION, INC.
INSTITUTIONAL REVIEW BOARD

APPROVAL LETTER (SJDEFIIRB FORM 6.2)

<DATE>

<Principal Investigator's Name>
Principal Investigator
<Site Address>

RE: **IRB Action on Submitted Protocol**

IRB Reference Number:

Protocol Number:

Protocol Title:

Dear <Investigator>,

We wish to inform you that the Institutional Review Board had reviewed your research protocol on <date>, and hereby granted **APPROVAL**, and subjected for implementation at the San Juan De Dios Educational Foundation, Inc. (Hospital). Your study had been assigned the **IRB Reference No. <IRB No.>.** The approval granted is valid for one (1) year, subject to annual review for continuing approval.

The following documents have been approved for use in the study. <Include any additional form submitted by the primary investigator>

DOCUMENTS
1.
2.
3.
4.
5.
6.
7.
8.

While the study is in progress, may we request you to submit to us the following document(s):

1. Annual Report one (1) month before the expiration of the approval and Progress Report after six (6) months, together with the Continuing Review/Progress Report Form (SJDEFIIRB Form 3.3). The report should include the following: *(Note: In view of active ethical clearance, this report is mandatory even if the study has not been started or is still awaiting release of funds.)*
    a. Date(s) covered by the report.
    b. Protocol summary and status report on the progress of the research.
    c. Number of participants accrued
    d. Withdrawal or termination of participants.
    e. Complaints on the research since the last IRB review.
    f. Summary of relevant recent research literature, interim findings and amendments since the last IRB review.
    g. Any relevant multi-center research reports.
    h. Any relevant information especially about risks associated with the research.
    i. A copy of the informed consent document.
2. Any changes in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, must be submitted or reported using the attached Protocol Amendment Submission Form (SJDEFIIRB Form 3.2).
3. Revisions in the informed consent form
4. Reports of adverse events.
5. Serious Adverse Events (SAE's) at SJDEFIH site: **As soon as possible, but no later than five (5) working days after first awareness of the problem.** SAE from other sites: within ten (10) working days of notification.
6. SUSARs (Suspected Unexpected Serious Adverse Reaction) must be reported as SAEs.
7. All non-significant adverse events occurring in the research and judged by the research team to be related/possibly related to the research protocol should be recorded in a summary form, and included in the six (6)-months Progress Report and at the closure of the study.
8. Notice of termination of the study and reasons for such.
9. Any event which may have ethical significance.
10. Any information which is needed by the IRB to do on-going review
11. Notice of time of completion of the study

My signature below also verifies that the **Institutional Review Board of San Juan De Dios Educational Foundation (Hospital)** operates in accordance with applicable nation/local and institutional regulations and guidelines which govern **Good Clinical Practices** and **IRB/EC Operations.**

For any concerns or other forms that may require your research protocol, you may reach us through the following:

Institutional Review Board Office

Tel. (02) 8551-4384 / 85 loc. 2312
Monday – Wednesday 1:30 PM – 4:30 PM
Email: irb.sanjuandedios@gmail.com

Thank you for choosing our hospital as one of your sites.

Very truly yours,

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Chairman
Institutional Review Board