

This Reliance Agreement ("Agreement") is made and entered into as of [DATE], by and between:

SAN JUAN DE DIOS EDUCATIONAL FOUNDATION, INC. INSTITUTIONAL REVIEW BOARD (SJDIRB), with a principal place of business at 2772 Roxas Boulevard, Pasay City, Philippines.

and

[Name of Researcher], residing at [RESEARCHER ADDRESS], affiliated with [Name of Researcher's Institution] (hereinafter "Researcher").

WHEREAS, SJDIRB is duly constituted and operates in accordance with the requirements of the Philippine Health Research Ethics Board (PHREB) and all applicable laws and regulations; and

WHEREAS, Researcher is engaged in human subject research and desires to rely on SJDIRB for the ethical review and continuing oversight of their research study, as Researcher's institution, [Name of Researcher's Institution], is [State the reason: "in the process of obtaining PHREB accreditation" or "not yet accredited by PHREB"].

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, the parties agree as follows:

- 1. **Designated Research.** This Agreement is limited to the following specific protocol:
 - a. SJDIRB Protocol Number: [INSERT PROTOCOL NUMBER]
 - b. Protocol Title: [INSERT PROTOCOL TITLE]
 - c. **Principal Investigator:** [INSERT RESEARCHER NAME], [RESEARCHER CONTACT INFORMATION]
 - d. **Sponsor/Funding Agency:** [INSERT SPONSOR/FUNDING AGENCY/COLLEGE/DEPARTMENT/UNIVERSITY/HOSPITAL/CENTER]
- 2. **Scope of Review.** SJDIRB agrees to serve as the Institutional Review Board of record ("Reviewing IRB") for the Designated Research and to:
 - a. Maintain a Board membership that satisfies the level-3 accreditation requirements of the Philippine Health Research Ethics Board (PHREB);
 - b. Make available to the Researcher, upon request, the SJDIRB Standard Operating Procedures;
 - c. Perform initial reviews, continuing reviews, reviews of submitted reportable events for the Designated Research that involve risks to subjects or others, amendments, incidents of serious or continuing noncompliance, and reviews of any other documents as needed to be consistent with applicable regulations;
 - d. Maintain and make accessible to the Researcher the SJDIRB application, protocol reviews, letters to the Principal Investigator, approvals and disapprovals, and minutes of the SJDIRB meetings relevant to the Designated Research;







- e. Notify the Researcher immediately in the event of a suspension or restriction of the SJDIRB's authorization to review studies; and
- f. Notify the Researcher of any SJDIRB policy decisions or regulatory matters that might affect the Researcher's reliance on SJDIRB reviews or the performance of the Designated Research.
- 3. Responsibilities of the Researcher. Researcher agrees to:
 - a. Provide the SJDIRB with current contact information and any changes in affiliation;
 - b. Ensure that they are appropriately qualified and meet the necessary standards to conduct the Designated Research;
 - c. Maintain policies regarding the disclosure and management of conflicts of interest related to the Designated Research and share those policies with the SJDIRB upon request;
 - d. Notify the SJDIRB immediately if there is any change in their ability to conduct the research, including any suspension or restriction imposed by their institution or any other entity;
 - e. Ensure the safe and appropriate performance of the Designated Research. This includes but is not limited to:
 - i. Monitoring study compliance;
 - ii. Reviewing major protocol deviations, and any unanticipated problems involving risk to subjects or others that occur in the conduct of the research;
 - iii. Ensuring a mechanism exists by which complaints about the research can be made by local study participants or others;
 - iv. Promptly reporting any unanticipated problems, adverse events, and non-compliance to the SJDIRB;
 - f. Maintain compliance with any additional state, local, or institutional requirements related to the protection of human subjects;
 - g. Provide SJDIRB with all documents and information necessary for SJDIRB to fulfill its responsibilities under this Agreement;
 - h. Cooperate with SJDIRB in any audits or inspections by regulatory authorities; and
 - i. Comply with all applicable laws, regulations, and guidelines related to the protection of human subjects in research.
- 4. **Financial Responsibilities.** The Researcher shall be responsible for the following financial obligations:
 - a. **Review Fee:** A non-refundable fee of Six Thousand Pesos (₱6,000.00) payable to SJDIRB for the review of the Designated Research.
 - b. **Documentation Costs:** All costs associated with the preparation and submission of documents, including transportation/delivery expenses, shall be borne by the Researcher.
 - c. **Site Visit Costs:** If SJDIRB deems it necessary to conduct site visits related to the Designated Research, the Researcher shall cover all associated costs. These costs may include, but are not limited to:
 - i. Travel expenses for SJDIRB personnel (e.g., airfare, ground transportation)
 - ii. Accommodation for SJDIRB personnel
 - iii. Per diem allowances for SJDIRB personnel
 - iv. Other reasonable expenses incurred during the site visit







- d. SJDIRB will provide the Researcher with a detailed estimate of anticipated site visit costs prior to the visit.
- 5. **Dispute Resolution.** Any dispute or controversy arising out of or relating to this Agreement, or the breach thereof, shall be settled amicably between the parties. If the parties are unable to reach an amicable settlement, the dispute shall be referred to the National Conciliation and Mediation Board (NCMB) for mediation.

6. Term and Termination.

- a. This Agreement shall commence on the Effective Date and shall remain in effect until terminated as provided herein.
- b. This Agreement may be terminated by either party upon **thirty (30) days written notice** to the other party.
- c. This Agreement may be terminated immediately by either party upon written notice to the other party if:
 - i. The other party breaches any material provision of this Agreement and fails to cure such breach within sixty (60) days after written notice of such breach.
 - ii. The Researcher becomes unable to conduct the Designated Research.
 - iii. The SJDIRB loses its accreditation or authorization to conduct IRB reviews.
- d. The Researcher may, at any time, choose to change their decision to cede review for the Designated Research. In such cases, the SJDIRB and Researcher will work together to facilitate the transfer of IRB oversight with the goal of limiting the potential disruption to the Designated Research. Until IRB oversight is transferred, the SJDIRB will continue to assume oversight.
- 7. **Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the Philippines.
- 8. Entire Agreement. This Agreement constitutes the entire agreement and understanding between the parties with respect to the subject matter herein and supersedes all prior or contemporaneous communications, representations, or agreements, whether oral or written.
- 9. **Severability.** If any provision of this Agreement is held to be invalid or unenforceable, such provision shall be struck from this Agreement and the remaining provisions shall remain in full force and effect.
- 10. **Notices.** All notices and other communications hereunder shall be in writing and shall be deemed to have been duly given when delivered in person, upon the first business day following deposit in the mail, postage prepaid, certified or registered, return receipt requested, addressed as follows:
 - a. If to SJDIRB:

Institutional Review Board Office Tel. (02) 8551-4385 loc. 2312 Monday – Wednesday 1:30 PM – 4:30 PM Email: irboffice@sjdefi.edu.ph







b. If to Researcher:

[RESEARCHER ADDRESS] or

to such other addresses as either party may designate in writing from time to time.

11. Amendments. This Agreement may be amended only by a writing signed by both parties.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

For SJDIRB

For Researcher/s

Signature: Printed Name: Chairperson, SJDIRB Date: Signature: Printed Name: Principal Investigator Date:

Signature: Printed Name: Principal Investigator Date:

Signature: Printed Name: Principal Investigator Date:

Signature: Printed Name: Research Adviser Date:



