



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

Philippine Health Research Ethics Board (PHREB) Level 3 Accreditation No. L3-2020-035-03  
 SIDCER (Strategic Initiative for Developing Capacity in Ethical Review)-Forum for Ethical Review Committees  
 in Asia and the Western Pacific Region (FERCAP) Recognition



**APPLICATION FORM FOR PROTOCOL REVIEW (SJDEFIIRB FORM 2.1)**

1. IRB Reference No. (For SJDEFIIRB Use)		<input type="checkbox"/> Initial Review	<input type="checkbox"/> Resubmission
2. Protocol Number			
3. Protocol Title			
4. Principal Investigator			
5. Co-Investigator (If Applicable)			
6. Source of Funds	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
	<input type="checkbox"/> Institutional/ Investigator Funded _____		
	<input type="checkbox"/> Institutional Grants _____		
	<input type="checkbox"/> Corporate _____		
	<input type="checkbox"/> Government _____		
	<input type="checkbox"/> Others _____		
7. Prior Technical Review	<input type="checkbox"/> Yes Research Committee/TRC that previously reviewed the protocol: _____ _____	<input type="checkbox"/> No	
8. Prior Ethical Review	<input type="checkbox"/> Yes Research Committee/TRC that previously reviewed the protocol: _____ _____	<input type="checkbox"/> No	



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	Name	Designation	Contact Number	
			Tel. No.	
9. Site Study Personnel	1.		Tel. No.	
			Mobile No.	
			Email	
			<b>Signature</b>	
	2.		Tel. No.	
			Mobile No.	
			Email	
			<b>Signature</b>	
	3.		Tel. No.	
			Mobile No.	
			Email	
			<b>Signature</b>	
4.		Tel. No.		
		Mobile No.		
		Email		
		<b>Signature</b>		

10. CRO

11. Documents Submitted	<input type="checkbox"/> Application Form for Protocol Review <input type="checkbox"/> Protocol Assessment Form <input type="checkbox"/> Informed Consent Assessment Form Full Protocol Version _____ <input type="checkbox"/> Research Project Proposal Format <input type="checkbox"/> Protocol Summary <input type="checkbox"/> Declaration of No Conflict of Interest <input type="checkbox"/> Data Collection Forms (electronic and/or hardcopy) <input type="checkbox"/> Informed Consent Form (English) Version _____ <input type="checkbox"/> Informed Consent Form (Local Dialect) Version _____ <input type="checkbox"/> Child Assent Form in local language (for studies involving minors - from 7 years old to 17 years old) version _____ <input type="checkbox"/> Budget <input type="checkbox"/> CV of Principal Investigator and other site staff <input type="checkbox"/> GCP Certificate of Principal Investigator and other site staff <input type="checkbox"/> Job Description & responsibilities of co-workers	<input type="checkbox"/> Technical Approval Document <input type="checkbox"/> GANTT Chart <input type="checkbox"/> Ads for recruitment of participants, if applicable <input type="checkbox"/> Information for subjects <input type="checkbox"/> Case Report Forms (CRF) <input type="checkbox"/> Investigators' Brochure <input type="checkbox"/> Continuing Review/ Progress Report <input type="checkbox"/> Protocol Amendment _____ <input type="checkbox"/> Protocol Violation/Deviation <input type="checkbox"/> SUSAR(s) <input type="checkbox"/> SAE(s) <input type="checkbox"/> Final Report <input type="checkbox"/> Early Termination Report <input type="checkbox"/> Reliance Agreement <input type="checkbox"/> FDA approval for clinical trials <input type="checkbox"/> Clinical Trial Agreement <input type="checkbox"/> Payment Schedule Agreement <input type="checkbox"/> Explicatory Letter for protocols requesting for exemption from review. <input type="checkbox"/> Others; Specify _____
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12. Duration	Start Date		Number of Study Participants	
	End Date			
13. Submitted by				
	Principal Investigator		Date of Submission	

**--- TO BE FILLED OUT BY SJDEFIIRB SECRETARIAT ---**

14. Completeness of Document	<input type="checkbox"/> Complete	<input type="checkbox"/> Incomplete
15. Remarks		
16. Type of Study	<input type="checkbox"/> Clinical Trial (Sponsored Initiated)	<input type="checkbox"/> Multicenter (International)
	<input type="checkbox"/> Clinical Trial (Research Initiated)	<input type="checkbox"/> Multicenter (National)
	<input type="checkbox"/> Health Operations Research	<input type="checkbox"/> Submitted to SJ REB
	<input type="checkbox"/> Social or Behavioral Research	<input type="checkbox"/> Single Site
	<input type="checkbox"/> Public Health or Epidemiologic	<input type="checkbox"/> Others, Specify: _____
	<input type="checkbox"/> Biomedical Research (Retrospective, Prospective and Diagnostic Studies)	
17. Received by		
	Signature over Printed Name	Date

**NOTE TO APPLICANTS:**

1. Please submit 1 hard copy of all documents at the IRB office (3<sup>rd</sup> Floor, Fray Juan Clemente Holistic Center) and email all digital documents at [irboffice@sjdefi.edu.ph](mailto:irboffice@sjdefi.edu.ph)
2. Please make sure that you have a copy of this form duly signed by the person who received the application
3. In recognition of SJDH being a Catholic institution, the subjects should be given a choice as to the method used to avoid pregnancy for the duration of the study in accordance with their moral beliefs (e.g. total abstinence). This statement should be reflected in the protocol.

