1. IRB Reference No. *(For SJDIRB Use)*		• Initial Review	• Resubmission
2. Protocol Number *(For SJDIRB Use)*			
3. Protocol Title			
4. Principal Investigator			
5. Co-Investigator *(If Applicable)*			
6. Source Of Funds	• Institutional/ Investigator Funded • Institutional Grants • Corporate • Government • Others • No/Not Funded	**Name of the Funding Agency or Organization**	
7. Prior Technical Review	• Yes • No	**Name of the Research Committee/TRC that previously reviewed the protocol:**	
8. Prior Ethical Review	• Yes • No	**Name of the Research Ethics Committee/IRB that previously reviewed the protocol:**	

9. Site Study Personnel	**Name**	**Designation**	**Contact Number**	
			Tel. No.	
			Mobile No.	
			Email	
			Signature	
			Tel. No.	
			Mobile No.	
			Email	
			Signature	
			Tel. No.	
			Mobile No.	
			Email	
			Signature	
			Tel. No.	
			Mobile No.	
			Email	
			Signature	

<table>
<tr><td>10. CRO</td><td colspan="2"></td></tr>
<tr><td>11. Documents Submitted</td><td>

Basic Required Documents to be submitted for initial review

Application Form for Protocol Review (SJDIRB Form .5.1)
Protocol Assessment Form (SJDIRB Form 5.2)
ICF Assessment Form (SJDIRB Form 5.3)
Study Protocol/Thesis Manuscript Summary (SJDIRB Form 5.4)
Researcher/Investigator CoI Disclosure (SJDIRB Form 1.3.d) as applicable
Full Study Protocol or Thesis Manuscript
Informed Consent Form (English)
Informed Consent Form (in local language)
Child Assent Form in local language (for studies involving minors - from 7 years old to 17 years old)
Data collection forms in various formats, including printed surveys, digital forms, or online survey platforms/applications. If employing an online survey, please provide the hyperlink.
CV of Principal Investigator and study team members
GCP Certificate of Principal Investigator and study team members obtained within the last three (3) years
Advertisement for recruitment of participants
Proof of payment of IRB Review Fee (as applicable)
Gantt Chart
Budget

For Clinical Trials w/ SJREB Review

SJREB Form 1.2 - Protocol Summary Sheet
SJREB Form 2 - Protocol Assessment Form
SJREB Form 3 - Informed Consent Assessment Form
SJREB Form 6 – Notice of Approval

Additional Documents for Study Protocols requesting for Exempt from Review

Exemption Checklist & Assessment Form (SJDIRB Form 5.9)
Explicatory Letter for protocols requesting for exemption from review.

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Additional Specific Documents for Clinical Trials

Investigator’s Brochure (for clinical trials phase I, II, III) or Basic Product Information Document (for clinical trials phase IV)
Recruitment advertisements (as needed by the study protocol)
Clearance or permit from respective regulatory authorities (such as FDA approval for clinical trials and DENR local transport permit, as applicable)
Information for subjects
Clinical Trial Agreement
Protocol package will be based on the requirements provided by the Clinical Research Organization (CRO)
Additional SJDIRB Forms as needed
Catholic Guidance & Model Language for IRB Consent (SJDIRB FORM 5.5)
Recruitment Poster Guidance Checklist (SJDIRB Form 5.6)

Additional Specific Documents for Student Researchers and Investigator initiated study protocols/thesis

Certification that the Institution Doesn’t have Ethics Review Board
Active Institutional Memorandum of Agreement signed by the highest authority of the organization/institution.
Accomplished Individual Reliance Agreement (SJDIRB Form 5.7) signed by the Dean or Clinical Department Head of relying student researcher or medical resident, witnessed by the medical resident or student researcher.
Technical Approval Document/Certificate (For SJDEFI Community researchers, they may opt to use Form SJDIRB Form 5.8)
Recruitment Poster Guidance Checklist (SJDIRB Form 5.9)
Ethics Review certification if study/thesis is submitted to other IRB/REC
Steps/Scripts/Guidelines for Focus Group Discussions and Teleconference (Visual or Auditory) recordings
CV & GCP of Adviser and other Co-workers
Job Description and Responsibilities of adviser, co-workers, team members

</td></tr>
<tr><td>12. Duration</td><td>Start Date
End Date</td><td></td><td>Number of Study Participants</td><td></td></tr>
</table>

13. Submitted by		
	Principal Investigator	**Date of Submission**

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

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

NOTE TO APPLICANTS:

1. Please submit 3 copies of all documents
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.