



SJD Institutional Review Board

Title: Application Form for Protocol Review

Code: SJDIRB Form 3.1

Version: 09

1. Protocol Number			2. SJREB Code: (N/A if not applicable)		
3. IRB Reference No. (For SJDIRB Use)			<input type="radio"/> Initial Review	<input type="radio"/> Resubmission	
4. Protocol Title					
5. Principal Investigator					
6. Co-Investigator (If Applicable)					
7. Source Of Funds	<input type="radio"/> Institutional/ Investigator Funded <input type="radio"/> Institutional Grants <input type="radio"/> Corporate <input type="radio"/> Government <input type="radio"/> Others <input type="radio"/> No/Not Funded		Name of the Funding Agency or Organization		
8. Prior Technical Review	<input type="radio"/> Yes <input type="radio"/> No		Name of the Research Committee/TRC that previously reviewed the protocol:		
9. Prior Ethical Review	<input type="radio"/> Yes <input type="radio"/> No		Name of the Research Ethics Committee/IRB that previously reviewed the protocol:		
10. Site Study Personnel (If more than 3 Use the Back of this form)	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					

10. CRO



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11. Documents Submitted	Basic Required Documents to be submitted for Initial Review OApplication Form for Protocol Review (SJDIRB Form 3.1) OProtocol Assessment Form (SJDIRB Form 3.2) OICF Assessment Form (SJDIRB Form 3.3) OStudy Protocol/Thesis Manuscript Summary (SJDIRB Form 3.4) OResearcher/Investigator Col Disclosure (SJDIRB Form 1.3c) as applicable OFull Study Protocol or Thesis Manuscript OInformed Consent Form (English) OInformed Consent Form (local language) OChild Assent Form in local language (for studies involving minors - from 7 years old to 17 years old) OData collection forms in various formats, including printed surveys, digital forms, or online survey platforms/applications. If employing an online survey, please provide the hyperlink. ORecruitment Plan (SJDIRB Form 6.6) OCV of Principal Investigator and study team members OGCP Certificate of Principal Investigator and study team members obtained within the last three (3) years OResearch Team Matrix: Role & Job Description (SJDIRB Form 6.11) OStaff Screening Criteria (SJDIRB Form 6.12) OProof of payment of IRB Review Fee OGantt Chart OBudget		Additional Specific Documents for Clinical Trials OInvestigator's Brochure (for clinical trials phase I, II, III) or Basic Product Information Document (for clinical trials phase IV) OClearance or permit from respective regulatory authorities (such as FDA approval for clinical trials and DENR local transport permit, as applicable) OInformation for subjects OClinical Trial Agreement OProtocol package will be based on the requirements provided by the Clinical Research Organization (CRO) OCatholic Guidance: Informed Consent and Unexpected Pregnancy (SJDIRB Form 6.5) OProof of Clinical Trial Registration at https://registry.healthresearch.ph/index.php/about-the-registry	
	For Clinical Trials w/ SJREB Review OSJREB Form 1.2 -Protocol Summary Sheet OSJREB Form 2 - Protocol Assessment Form OSJREB Form 3 - Informed Consent Assessment Form OSJREB Form 6 – Notice of Approval Additional Documents for Study Protocols requesting for Exempt from Review OExemption Checklist & Assessment Form (SJDIRB Form 6.9) OExplanatory Letter for protocols requesting for exemption from review.		Additional Specific Documents for Student Researchers and Investigator initiated study protocols/thesis OCertification that the Institution Doesn't have Ethics Review Board OEthics Review certification if study/thesis is submitted to other IRB/REC OActive Institutional Memorandum of Agreement signed by the highest authority of the organization/institution. OIndividual Reliance Agreement (SJDIRB Form 6.7) signed by the Dean or Clinical Department Head of relying student researcher or medical resident, witnessed by the medical resident or student researcher. OTechnical Approval Document/Certificate (For SJDEFI Community researchers, they may opt to use Form SJDIRB Form 6.8) OSteps/Scripts/Guidelines for Focus Group Discussions and Teleconference (Visual or Auditory) recordings OCV & GCP of Adviser and other Co-workers OJob Description and Responsibilities of adviser, co-workers, team members OProof of Research Registration at https://www.herdin.ph/index.php	
12. Duration	Start Date		Number of Study Participants	
	End Date			
13. Submitted by				
	Name & Signature of Principal Investigator (PI)		Date of Submission	



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--- TO BE FILLED OUT BY SJDIRB SECRETARIAT ---

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

NOTE TO APPLICANTS

- Before you start:
 - Submit one copy of your application. Keep a signed copy for your records.
 - If your research involves pregnancy, give participants a choice of methods to avoid it, including abstinence. State this clearly in your protocol.
- WMA Declaration of Helsinki: Register your research BEFORE enrolling anyone:
 - Clinical Trials: <https://registry.healthresearch.ph/index.php/about-the-registry>
 - Student (Undergraduate/Postgraduate) or Medical Resident Research: <https://www.herdin.ph/index.php>
 - send proof of registration at irboffice@sjdefi.edu.ph
- SJDEFI-Hospital Research Registration. Registration Offices:
 - Medical/Clinical: Medical Service Division Office (Ground Floor, Main Building)
 - Nursing: NSD-Training Office (5th Floor, JCLS Building)
 - Allied Health: Instituto De Marillac, HR Office (4th Floor, Annex Building)