1. **POLICY STATEMENT**

The SJDIRB requires submission of pertinent documents (electronic/digital or hard copy) for ethical review. Preliminary evaluation determines exemption or need for review based on National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022.

2. **OBJECTIVE OF THE ACTIVITY**

This activity aims to ensure that submitted study documents (either digital or hardcopy) are complete, properly recorded, and properly evaluated to determine appropriate action or type of review.

3. **SCOPE**

The SJDIRB reviews research protocols from SJDEFI faculty, students, medical staff, residents, and trainees, as well as industry-sponsored studies. External protocols may be accepted under formal agreements or those reviewed by SJREB. The SOP covers Document Reception and Verification to Database Documentation and Management.

4. **WORKFLOW**

Steps	Activity	Responsibility	Timeline
1.	Guidelines on the submission of protocol packages for ethics review approval	PI/Researcher	Day 0
2.	Document Reception and Verification	Staff	Day 1
3.	Coding of study protocol	Staff	Day 1 – 2
4.	Study Classification and Determination of type of review	Staff, Panel Lead, Chair	Day 1 – 2
5.	Exempt Protocols	Panel Lead, Chair	Day 2 -7
6.	Communication to PI and	Staff & Panel Lead	Day 7
7.	Database Documentation and Management	Staff	Day 7

5. **DESCRIPTION OF PROCEDURES**

5.1. **Step 1, Guidelines on the submission of protocol packages for ethics review approval (SJDIRB - MC No. 1 s 2024)** All researchers (expedited, full board, exempt) are advised to follow the revised guidelines for online submissions, as follows:

5.1.1. Create a Google Folder where all documents will be submitted online. Name the folder under your name with the keyword topic of your research (i.e. REBALLOS Toxoplasmosis on Pregnant Women).

5.1.1.1. Inside the general folder, put the following: Application Form (SJDIRB Form 5.1), Protocol Assessment Form (SJDIRB Form

5.2), and ICF Assessment Form (SJDIRB Form 5.3). Then create a sub folder and label it as “Documents Submitted.”

5.1.1.1.1. IRB Application Form. Rename the file Application Form for Protocol Review to "2.1. Application Form_Surname of PI" (i.e. 2.1. Application Form_Reballos)

5.1.1.1.2. IRB Protocol Assessment Form. Rename the file to "2.3. Protocol Assessment Form_Surname of PI (i.e. 2.3. Protocol Assessment Form_Reballos.doc)

5.1.1.1.3. IRB ICF Assessment Form. Rename the file to "2.4 ICF Assessment Form_Surname of PI (i.e. 2.4 ICF Assessment Form_Reballos.doc).

5.1.1.2. In the folder Documents Submitted, submit all documents as follows:

5.1.1.2.1. Rename the file Protocol Summary to "1. Protocol Summary_Surname of PI and keyword topic of your research (i.e. 1. Protocol Summary_Reballos Toxoplasmosis on Pregnant Women).

5.1.1.2.2. Research Protocol. Rename file as "2. Protocol_Keywords of Research Title_Ver_No." (e.g. 2. Protocol_Toxoplasmosis of Pregnant Women_Ver_1).

5.1.1.2.3. Informed Consent/Assent Form. Rename file as "3.1. ICF_English Version_No." and "3.2. ICF_Tagalog Version_No." (e.g. 3.1. ICF_English Version_1 and 3.2. ICF_Tagalog Version_1)

5.1.1.2.4. Curriculum Vitae. Include all curriculum vitae of Principal Investigator (PI) and Co-Investigator (Co-I). Rename file name to "4.1. CV_Surname of PI or Co-Investigator (e.g. 4.1. CV_Reballos_PI or 4.2. CV_Reballos_CoI). Ensure that CV includes research, training or appropriate information related to the study.

5.1.1.2.5. GCP. Rename file to “5.1. GCP_Surname of PI_ (e.g. 5.1. GCP_Reballos_PI or 5.2. GCP_Reballos_CoI). Ensure that the GCP certificates are not expired. GCP certification has a 3-year duration.

5.1.1.2.6. Conflict of Interest Disclosure Form. Rename file as "6. CoI_Surname of Signatories" (e.g. 6. CoI_Reballos for single signatories or 6. CoI_Reballos/Gloriani for multiple signatories).

Ensure all members of the research team has signed the CoI form.

5.1.1.2.7. Job Description & Responsibilities. Rename file as "7. Job Descriptions and Responsibilities." Create a tabular form (in landscape format) indicating the name of the members of the team, their corresponding role (e.g. PI or CoI), job description and responsibilities.

5.1.1.2.8. Technical Approval Document/Certificate (for resident's research, student's thesis or dissertation). Rename file as "8. Technical Approval_Surname of PI (e.g. 8. Technical Approval_Reballos). This form should be signed by the Head/Research Coordinator of the Department (for residents) or Dean of the college (for students).

5.1.1.2.9. Data Collection Form. Rename file as it is with no. "9" before the file name (e.g. 9. Data Collection Form).

5.1.1.2.10. Budget. Rename file as it is with no. "10" before the file name (e.g. 10. Budget).

5.1.1.2.11. Gantt Chart. Rename file as it is with no. "11" before the file name (e.g. 11. Gantt chart). Create a tabular form (in landscape format) indicating all the steps indicated in the procedure.

5.1.1.2.12. Reliance Agreement. This document is only applicable to non-SJDEFI researchers. Rename file as it is, with number "12" before the file name (e.g. 12. Reliance Agreement). Ensure that the form is signed by the medical director for medical residents, or dean of the college department/graduate school.

5.1.1.2.13. Recruitment Poster (if applicable). Include the accomplished Recruitment Poster Guidance Checklist (renamed to "13. Recruitment Poster Guidance Checklist_Surname of PI, e.g. 13. Recruitment Poster Guidance Checklist_Reballos) and sample recruitment poster (renamed to "14. Poster_Surname of PI", e.g. 14. Poster_Reballos). Kindly check the format indicated in the checklist.

5.1.1.2.14. Payment. Rename the file to "15. Proof of Payment_Surname of PI_ Date of Payment" (e.g. 15. Proof of Payment_Reballos_01Jan24).

5.1.2. A letter of endorsement from the Institution's research ethics committee should also be submitted to the SJDIRB. In case the institution has no existing REC or IRB, the endorsement letter should be coming from the medical director. For academe, the letter should be from the school's research director.

5.1.3. For protocols that seem Exempted from Ethical Review, accomplish the form Exemption Checklist & Assessment (SJDIRB Form. 5.9.). Submit this document in the general folder, together with Application form and Protocol Summary.

5.1.4. Submit all documents in short bond paper size of 8x11 inches (216x279 cm). Convert all documents into pdf format except for the following: Protocol Assessment Form (SJDIRB Form 5.2), ICF Assessment Form (SJDIRB Form 5.3), Exemption Checklist & Assessment (SJDIRB Form. 5.9.)

5.1.5. There should be a separate file (as indicated) for the Informed Consent Forms, Budget, Gantt Chart, Data Collection Form, GCP, Job Description and other documents included in the Appendix of the Protocol. The protocol should only contain the Title Page, Table of Contents (if necessary), Body of the Protocol from Introduction to Data Analysis Plan, and References.

5.1.6. Share all contents of the folder to "irboffice@sjdefi.edu.ph" and change access to "editor". During submission through email, kindly add the link for easy access to the Secretariat.

5.2. **Step 2, Document Reception and Verification**.

5.2.1. Staff accept submissions electronically during office hours from 8:00 AM to 5:00 PM on weekdays. Please note that in-person submissions are not accepted except for San Juan de Dios Institutional Researchers.

5.2.2. The PI completes the Application Form for Protocol Review (SJDIRB Form 5.1) and ensures that all required study/protocol documents, as enumerated in the application form, are digitally prepared and submitted via email to irboffice@sjdefi.edu.ph

5.2.3. Upon successful submission, the staff will acknowledge receipt via email and log the digital activity using SJDIRB Form 25.

5.2.4. The staff assess document completeness using the SJDIRB FORM 5.1 checklist. Any missing documents prompt immediate notification to the proponent. The checklist includes:

5.2.4.1. **Basic Required Documents to be submitted for initial review**

5.1.3.1.1. Accomplished SJDIRB Forms, downloadable at https://sanjuandedios.org/healthministry_rev0_irb.htm

5.1.3.1.1.1. Application Form for Protocol Review (SJDIRB Form .5.1)

5.1.3.1.1.2. Protocol Assessment Form (SJDIRB Form 5.2)
5.1.3.1.1.3. ICF Assessment Form (SJDIRB Form 5.3)
5.1.3.1.1.4. Study Protocol/Thesis Manuscript Summary (SJDIRB Form 5.4)
5.1.3.1.1.5. Researcher/Investigator CoI Disclosure (SJDIRB Form 1.3.d) as applicable
5.1.3.1.2. Full Study Protocol or Thesis Manuscript
5.1.3.1.3. Informed Consent Form (English)
5.1.3.1.4. Informed Consent Form (in local language)
5.1.3.1.5. Child Assent Form in local language (for studies involving minors - from 7 years old to 17 years old)
5.1.3.1.6. 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.
5.1.3.1.7. CV of Principal Investigator and study team members
5.1.3.1.8. GCP Certificate of Principal Investigator and study team members obtained within the last three (3) years
5.1.3.1.9. Advertisement for recruitment of participants
5.1.3.1.10. Proof of payment of IRB Review Fee (as applicable)

5.1.3.2. **Additional Specific Documents for Clinical Trials**
5.1.3.2.1. Investigator's Brochure (for clinical trials phase I, II, III) or Basic Product Information Document (for clinical trials phase IV)
5.1.3.2.2. Recruitment advertisements (as needed by the study protocol)
5.1.3.2.3. Clearance or permit from respective regulatory authorities (such as FDA approval for clinical trials and DENR local transport permit, as applicable)
5.1.3.2.4. Information for subjects
5.1.3.2.5. Clinical Trial Agreement
5.1.3.2.6. Protocol package will be based on the requirements provided by the Clinical Research Organization (CRO)
5.1.3.2.7. Additional SJDIRB Forms as needed
5.1.3.2.7.1. Catholic Guidance & Model Language for IRB Consent (SJDIRB FORM 5.5)
5.1.3.2.7.2. Recruitment Poster Guidance Checklist (SJDIRB Form 5.6)
5.1.3.2.8. **For Clinical Trials with SJREB Review**

5.1.3.2.8.1. SJREB Form 1.2 - Protocol Summary Sheet
5.1.3.2.8.2. SJREB Form 2 - Protocol Assessment Form
5.1.3.2.8.3. SJREB Form 3 - Informed Consent Assessment Form
5.1.3.2.8.4. SJREB Form 6 – Notice of Approval

5.1.3.3. **Additional Specific Documents for Student Researchers and Investigator initiated study protocols/thesis**
5.1.3.3.1. **For Non SJDEFI-Researchers**
5.1.3.3.2. Certification that the Institution Doesn't have Ethics Review Board
5.1.3.3.3. Active Institutional Memorandum of Agreement signed by the highest authority of the organization/institution.
5.1.3.3.4. 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.
5.1.3.3.5. Technical Approval Document/Certificate (For SJDEFI Community researchers, they may opt to use Form SJDIRB Form 5.8)
5.1.3.3.6. Recruitment Poster Guidance Checklist (SJDIRB Form 5.9)
5.1.3.3.7. Ethics Review certification if study/thesis is submitted to other IRB/REC
5.1.3.3.8. Steps/Scripts/Guidelines for Focus Group Discussions and Teleconference (Visual or Auditory) recordings
5.1.3.3.9. CV & GCP of Adviser and other Co-workers
5.1.3.3.10. Job Description and Responsibilities of adviser, co-workers, team members
5.1.3.3.11. Gantt Chart
5.1.3.3.12. Budget
5.1.3.4. **Additional Documents for Study Protocols requesting for Exempt from Review**
5.1.3.4.1. Exemption Checklist & Assessment Form (SJDIRB Form 5.9)
5.1.3.4.2. Explicatory Letter for protocols requesting for exemption from review.
5.1.3.5. Others, Please Specify

5.1.4. For San Juan de Dios Community Researchers. The protocol submitted for review (either printed document or digital/electronic copy) should be in a long bond paper size (8" x 13").
5.1.5. The staff shall ensure completeness of submitted forms and documents using the checklist stated above.
5.1.6. Study protocols qualified for or under SJREB review are given instructions to submit to SJREB and endorsed to the SJREB Secretariat through email. A parallel submission with SJDIRB and SJREB will be observed for SJDIRB to facilitate processing of protocol submission. Refer to SOP 9: SJREB Protocol Review).
5.1.7. For Full Board (panel) Review, application shall be submitted at least fourteen (14) working days before the scheduled IRB meeting in order to be included in the agenda.
5.1.8. Date of submission will be based on completeness of the protocol package.
5.1.9. Incomplete submissions will not be reviewed and will be sent back to the PI for completion of requirements (refer to step 4 for the PI Notification process)

5.3. **Step 3, Coding of study protocol and entry into the database.** Coding a study protocol and entering data into a database involves several key steps to ensure accuracy, reliability, and compliance with ethical standards. Staff follows the detailed instructions for coding a study protocol and entering data into the database:
5.3.1. Number is assigned to the new study protocol which shall be used in subsequent communications with the PI. The IRB Reference Number shall follow the format SJDIRB-Year Code-Series Number/Source Code-Department Code, wherein:
5.3.1.1. **Year Code** – Refers to the year that the research and/or study protocol was submitted to the IRB.
5.3.1.2. **Series Number** – Refers to the sequential number of the research and/or study protocol submitted to the IRB. The series number shall be assigned four (4) digits after the Year Code.
5.3.1.3. **Source Code** – Refers to the origination of the research and/or study protocol.
a. **C** – study protocols for Collegiate Panel review
b. **H** – study protocols for Healthcare Panel review
c. **S** – study protocols with SJREB oversight
d. **E** – External research and/or study protocol.

5.3.1.4. **Department Code** – Refers to the endorsing body/unit/ of the research and/or study protocol and shall be composed of three (3) initials of the department or section.

a. ***MED*** Internal Medicine
b. ***SRG*** Surgery
c. ***PED*** Pediatrics
d. ***OBG*** Obstetrics and Gynecology
e. ***NRS*** Nursing
f. ***ANS*** Anesthesiology
g. ***EMS*** Emergency Medicine Section
h. ***FIM*** Family and Industrial Medicine
i. ***RHB*** Rehabilitation Medicine
j. ***RAD*** Radiology
k. ***AHE*** Allied Health Professions
l. ***MCS*** Medical Technology, Clinical Surgical Pathology
m. ***OTR*** Other Research Protocols (non-medical and non-health related

5.4. **Step 4, Study Classification and type of review.** SJDIRB classifies protocols into three (3) types to determine the appropriate type of review of protocols.

5.4.1. The staff in collaboration with the Panel Lead makes a preliminary assessment of protocols using the submitted application forms as well as other documents.

5.4.2. The following are the considerations in accordance to study classifications

5.4.2.1. **Exemption from Ethics Review;**

5.4.2.1.1. Protocols Without Human Participants or Identifiable Human Material (e.g. Meta-analysis):

5.4.2.1.1.1. No involvement of human participants or

5.4.2.1.1.2. No identifiable human tissue, biological samples, and data

5.4.2.1.2. Protocols Involving Minimal Risks or Harm:

5.4.2.1.2.1. Institutional quality assurance
5.4.2.1.2.2. Evaluation of public service programs
5.4.2.1.2.3. Public health surveillance
5.4.2.1.2.4. Educational evaluation activities
5.4.2.1.2.5. Consumer acceptability tests

5.4.2.1.3. Research with survey, interview, or observation interactions meeting specific criteria such as,

5.4.2.1.3.1. No disclosure of participant responses outside the research that could reasonably harm participants

5.4.2.1.3.2. No recorded information ensuring participant identity confidentiality
5.4.2.1.3.3. Protocols using publicly available data or information
5.4.2.1.3.4. Researches that falls under this classification are technically exempt from review, but will be subject to expedited review at the level of the Panel Lead or Chair using the Exemption Checklist & Assessment Form (SJDIRB Form 5.8)

5.4.2.2. **Expedited Review**
5.4.2.2.1. Does not involve more than minimal risks or harm but does not qualify for exemption
5.4.2.2.2. About a topic that should not result in causing social stigma
5.4.2.2.3. Does not involve vulnerable populations
5.4.2.2.4. Retrospective studies using anonymized data from medical records
5.4.2.2.5. Studies using simple questionnaires without identifiers
5.4.2.2.6. Proposals such as:
5.4.2.2.6.1. Chart review
5.4.2.2.6.2. Survey of non-sensitive nature
5.4.2.2.6.3. Use of anonymous or anonymized laboratory/pathology samples or stored tissue or data
5.4.2.2.7. Study protocols that do not meet the considerations for expedited review or exemption are classified under full board (panel) review.

5.4.2.3. **Full Board (Panel) Review**
5.4.2.3.1. Clinical trials about investigational new drugs, biologics or devices in various phases
5.4.2.3.2. Phase 4 interventional trials involving drugs, biologics, or devices
5.4.2.3.3. Protocols including questionnaires and social interventions that are confidential in nature that may cause psychological, legal, economic, and other social harm
5.4.2.3.4. Protocols involving vulnerable subjects that require additional protection from the IRB
5.4.2.3.5. Protocols that involve collection of identifiable biological specimens for research.

5.4.2.3.6. Protocols that involve complex or high-risk interventions, vulnerable populations, or sensitive topics that warrant a thorough review.
5.4.2.3.7. Informed consent process that involves unconventional procedures or if the population requires special considerations.
5.4.2.3.8. Study design, methodology, and data collection procedures that involve intricate or novel approaches.
5.4.2.3.9. Protocols that involve sensitive information and require rigorous measures to protect participant privacy and confidentiality.

5.5. **Step 5, Exempt Protocols:** The Panel Lead or Chair assesses qualification for exemption based on the listed criteria in 5.3.2.1 of this SOP.
5.5.1. Study protocols even if it is considered exempt may be assigned to an independent consultant if there are no available experts among the regular members. In these cases, a member or an alternate of the panel will serve as the other scientific reviewer.
5.5.2. Panel Lead will report the exempted protocols in the SJDIRB meeting.

5.6. **Step 6, Communication to PI and Reviewers.**
5.6.1. Communication to the PI
5.6.1.1. In the screening process, staff promptly informs the PI of the results through email. The email serves to address specific aspects:
5.6.1.1.1. Incomplete Submissions:
5.6.1.1.1.1. In cases of incomplete protocol submissions, the email details the reasons for the incompleteness.
5.6.1.1.1.2. The email provides study protocol-specific instructions on how the PI can rectify the issues, such as uploading required documents or revising specific sections.
5.6.1.1.1.3. Emphasizing that incomplete submissions will not proceed to the review stage, the email directs the PI to fulfill the requirements for a comprehensive submission.
5.6.1.1.2. If PI with Previous Studies :
5.6.1.1.2.1. Staff conducts a review of the PI's past studies and includes a reminder in the

email regarding any pending final reports for these studies.

5.6.1.1.2.2. This serves as a proactive measure to ensure that all necessary documentation for previous studies is complete and up to date.

5.6.1.1.3. Timely Response:

5.6.1.1.3.1. The email establishes a timeframe, allowing PIs a seven (7) calendar-day window to address and fulfill the screening requirements outlined in the communication.

5.6.1.1.3.2. This timeframe is set to ensure a prompt and efficient resolution to the screening process.

5.6.1.1.4. The Staff will issue a **Exempt Certification** (SJDIRB Form 5.10) within seven (7) days after the protocol qualifies for exemption, as determined by the panel lead. Accompanying the certificate is a notification email outlining the PI's associated responsibilities, which include:

5.6.1.1.4.1. Swift reporting of unanticipated problems or study violations.

5.6.1.1.4.2. Notification to the IRB within three days of voluntary suspension or termination, providing detailed reasons and safety measures.

5.6.1.1.4.3. Compliance with study sponsor directives, coupled with immediate notification to the IRB of sponsor-initiated suspension or termination.

5.6.1.1.4.4. Timely response to IRB terms and conditions arising from any occurrences.

5.6.1.1.4.5. Retention of the right to appeal the IRB's decision on research suspension or termination.

5.6.1.1.4.6. In the event of any significant protocol changes post the Exempt Certification issuance, the PI is required to submit an amendment to SJDIRB using the Protocol Amendment Form (SJDIRB

Form 11) for a decision regarding the change in classification.

5.6.1.1.4.7. Submission of the final report upon completion of the research.

5.6.1.2. Staff accomplishes the Email Communication Log (SJDIRB Form 26) to ensure proper documentation of online or digital actions

5.6.1.3. For the communication and specific process on Expedited and Full board review, refer to SOP 6 and 7 respectively.

5.6.2. Communication to the Reviewers

5.6.2.1. The Staff notifies the primary reviewers for protocol assignments in their **sjdefi.edu.ph email accounts, within three days from receipt of protocol submission**.

5.6.2.2. The Primary Reviewer confirms receiving the study protocol package and commits to reviewing it within the specified timeframe. **Failure to respond within three days results in reassignment to another primary reviewer.**

5.6.2.3. All digital communications staff accomplishes the email notification log (SJDIRB Form 26) to ensure proper documentation of online or digital actions.

5.7. **Step 7, Database Documentation and Management.** All submissions must be meticulously recorded by the staff in the protocol membership database (using SJDIRB Form 27) within five (5) days of receiving fully accomplished and comprehensive documents. This process adheres to the guidelines outlined in SOP-27 Management of Database, Active & Confidential Files.

6. **FORMS**

6.1.	Application Form for Protocol Review	SJDIRB Form 5.1
6.2.	Protocol Assessment Form	SJDIRB Form 5.2
6.3.	ICF Assessment Form	SJDIRB Form 5.3
6.4.	Protocol Summary Sheet	SJDIRB Form 5.4
6.5.	ICF Catholic Guidance	SJDIRB Form 5.5
6.6.	Recruitment Poster Guidance	SJDIRB Form 5.6
6.7.	Reliance Agreement	SJDIRB Form 5.7
6.8.	Technical Approval Endorsement	SJDIRB Form 5.8
6.9.	Exemption Checklist & Assessment	SJDIRB Form 5.9
6.10.	Exempt Certification	SJDIRB Form 5.10
6.11.	Email Communication Log	SJDIRB Form 26
6.12.	Protocol Database	SJDIRB Form 27
7.13.	Other External Forms	
	7.13.1.Protocol Summary Sheet	SJREB Form 1.2

7.13.2.Protocol Assessment Form	SJREB Form 2
7.13.3.Informed Consent Assessment Form	SJREB Form 3
7.13.4.Notice Of Protocol Modification	SJREB Form 5
7.13.5.Notice Of Approval	SJREB Form 6
7.13.6.Notice Of Post-Approval Modification	SJREB Form 10

7. HISTORY OF SOP

Version	Date	Main Change	Author	Approved By
00	04/27/2015	Origination	RDSPulido	
01	03/12/2016	● Changed SOP format ● Improved process	RDSPulido	
02	05/10/2017	Revision of History of SOP	RDSPulido	Sr.JBOnag,DC
03	9/25/2017	Correction of grammatical errors	RAArcangel	Sr.JBOnag,DC
04	02/22/2019	● Revision of section ● Inclusion of Table Title	CAFReballos	Sr.JBOnag,DC
05	09/05/2019	● Inclusion of Requirement Submission ● Revision of Continuous Coding System ● Deletion of References		
06	09/05/2019	● Reorganization of Appointment Process ● Inclusion of Definition of membership ● Deletion of References	CAFReballos	Sr.JBOnag,DC
07	01/28/2020	Deletion of SJIRB Forms 2.3 and 2.4 in section 6.1.2	CAFReballos	Sr.JBOnag,DC
08	11/16/2020	● Alignment with the 2020 SOP Workbook of PHREB ● Review exemptions based on NEGHHR 2017 The Research Ethics Review Process Guideline 3.1. and provision of Exempt	JVCorpusIII	Sr.JBOnag,DC

		Certification for protocols exempted from review ● Inclusion of electronic or digital submission and review process turn-around-time of pandemic related protocols (e.g. COVID-19) and clinical trials deemed by the governing agencies as urgent.		
09	04/07/2022	● Inclusion of SJDEFIIRB Forms 2.8, 2.9, 2.10, 2.11, 2.12 ● Decrease number of physical copies for submission from 8 to 3 ● Inclusion of timeline in the releasing of exemption certificate as well as the various responsibilities of PI	JVCorpusIII	Sr.JBOnag,DC
10	02/01/24	● Change of acronym SJDEFIIRB to SJDIRB for ease ● Inclusion of Panels & Email Communication Log ● Update References ● Updated SOP Number per PHREB/FERCAP Accreditors' recommendation. ● Included the following as prescribed by PHREB/FERCAP ○ Code of SJREB ○ Exempt Certification ○ Provisions of certificate of exempt from review ● Revision of forms ○ Under protocol Assessment	JVCorpusIII	Sr.JBOnag,DC

		▪ Delete sub sections of literature review as it applies only to clinical trials ▪ Add an item about data analysis plan to replace statistical treatments ▪ Add Outcomes such as scientific conclusions or sharing of information ▪ Data Privacy and Confidentiality, retain III and delete the rest ▪ Vulnerability- add a question “Are participants vulnerable? retain IV ▪ Risk-retain x about levels of risk, add an item about risk mitigation measures ▪ Add benefits that may be derived from the study, how are benefits maximized ▪ Recruitment procedures o ICF Assessment Form - add research procedures/interventions		

8. REFERENCES

8.1. W.H.O. Tool for Benchmarking Ethics Oversight of Health-Related Research Involving Human Participants. Geneva: World Health Organization; 2023. License: CC BY-NC-SA 3.0 IGO.
8.2. National Ethical Guidelines for Research Involving Human Participants 2022
8.3. UPM Research Ethics Board, SOPs and Forms 2022, https://reb.upm.edu.ph/sops-and-forms
8.4. SJREB, DOH 2021, https://doh.gov.ph/Single-Joint-Research-Ethics-Board
8.5. Philippine Health Research Ethics Board Standard Operating Procedures 2020
8.6. Department of Health Administrative Order No. 2020-010
8.7. WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks 2016

8.8. ICH guideline for good clinical practice E6(R2), 2016
8.9. CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
8.10. WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, 2013