4. Initial Review Workflow

<table>
<tr><th colspan="4">ACTIVITY</th><th>RESPONSIBILITY</th></tr>
<tr><td colspan="4">Receive and manage study protocol submissions. Inquire whether protocol is to be under SJREB review.
↓</td><td>Secretariat</td></tr>
<tr><td colspan="4">Classify submission as Exempted, Expedited, Full Board or SJREB review
If exempted, IRB sends a letter of exemption.
↓ ↓</td><td>MDH IRB Chair</td></tr>
<tr><td>EXEMPT</td><td colspan="3">• For non-exempted protocols, Chair assigns 1 primary reviewer (may invite Content/Expert reviewer as needed), 1 secondary reviewer and 1 lay reviewer.
(Refer to SJREB Sub-Workflow for protocols included for SJREB review. SOP II Section 7)
↓</td><td>MDH IRB Chair</td></tr>
<tr><td rowspan="8">Send notification of exemption to PI with justification.</td><td colspan="3">Upload study protocol package with MDH IRB STUDY PROTOCOL ASSESSMENT FORM and MDH IRB INFORMED CONSENT ASSESSMENT FORM to MDH IRB OneDrive cloud storage.
↓</td><td>Secretariat</td></tr>
<tr><td colspan="3">Review the protocol and accomplish MDH IRB STUDY PROTOCOL ASSESSMENT FORM and MDH IRB INFORMED CONSENT ASSESSMENT FORM
↓</td><td>Primary Reviewers and Secondary Reviewers</td></tr>
<tr><td>FULL BOARD REVIEW</td><td>SJREB</td><td>EXPEDITED REVIEW</td><td></td></tr>
<tr><td>Include the protocol in the agenda of the next full board meeting
↓</td><td></td><td rowspan="3">↓</td><td>Secretariat</td></tr>
<tr><td>Present review findings during full board meeting
↓</td><td>Participate in protocol review during the SJREB meeting.
Present SJREB approved protocol during full board meeting.</td><td>Primary Reviewers</td></tr>
<tr><td>Deliberate on full board action on the protocol</td><td>Deliberate on site-related issues
↓</td><td>All MDH IRB Members</td></tr>
<tr><td>If Approved: Send approval notification of decision to PI.

If Minor modification, send notification with recommendations to PI; process resubmission by</td><td>If major or minor modification: Send notification with recommendations to PI then process resubmission by expedited review</td><td>If approved: Send approval notification to PI
If major or minor modification: Send notification with</td><td>Secretariat</td></tr>
</table>

	expedited review. **If Major modification**: Send notification with recommendations to PI; process resubmission by full board review. **If Disapproved**: Send notification of decision to PI with justification.		recommendations to PI then process resubmission by expedited review. **If disapproved:** Send to full board review and process accordingly	

DETAILED INSTRUCTIONS

4.1. Receipt and Management of Study Protocol Submission

4.1.1. A study protocol package for initial review must be received together with duly signed and accomplished forms and documents (as applicable) as enumerated in **MDH IRB FORM 2(A) 2021: REVIEW CHECKLIST**. All forms needed for review are available electronically and can be downloaded thru Manila Doctors Hospital website.

4.1.1.A. Basic Documents for All Studies

a. Review Checklist **[MDH IRB FORM 2(A)2021]**

b. Printed Registration and Application Form **[MDH IRB FORM 2(B) 2021]**

c. Study Protocol Assessment Form **[MDH IRB FORM 2(C) 2021]**

d. Study Protocol

e. Data collection forms (including CRFs)

f. CV of PI and study team members

g. Good Clinical Practice (GCP) Training Certificate of Principal Investigator (PI), Co-Investigator (Co-I) and the research coordinators of the study team (for clinical trials); On-line GCP is accepted if submission is for renewal

h. Electronic copy of study protocol **MDH IRB FORM 2(A) 2021, MDH IRB FORM 2(B) 2021, MDH IRB FORM 2(C) 2021**

4.1.1.A.1. Additional Documents for Clinical Trials and other Industry-Sponsored Studies

a. Receipt of payment of Review Fee

b. Investigator's Brochure (for clinical trials phase I, II, III) or Basic Product Information Document (for clinical trials phase IV)

c. Informed Consent Assessment Form (for studies with human participants) [MDH IRB FORM 2(D) 2021]

d. Informed Consent Form in English (for studies with human participants)

e. Informed Consent Form in local language (for studies with human participants)

f. Assent form in English (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)

g. Assent form in local language (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)

h. Certificate of Indemnity Insurance coverage for participants

i. Recruitment advertisements (as needed by the study protocol)

j Materials Transfer Agreement (MAT) (for any research involving transfer of biological specimens)

k. Significant Risk (SR) or Non-Significant Risk (NSR) classification for investigational device

l. Memorandum of Agreement (for collaborative studies)

m. Other information or documents for participants as needed.

4.1.1. A. 2. Additional Basic Documents for Studies initiated by Hospital and MDH Medical Staff, Fellows, Residents and Interns

a. Certification of **MDH Training Department Chairperson and Department Research Coordinator** of technical assessment

b. Copy of Letter of MDH Committee on Research (CORES) Endorsement to MDH IRB

c. Certification of Technical Approval by MDH Committee on Research (CORES) Chair

d. Informed Consent Assessment Form (for studies with human participants) [MDH IRB FORM 2(D) 2021]

e. Informed Consent Form in English (for studies with human participants)

f. Informed Consent Form in local language (for studies with human participants)

g. Assent form in English (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)

h. Assent form in local language (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)

i. Recruitment advertisements (as needed by the study protocol)

j. Materials Transfer Agreement (MTA) (for any research involving transfer of biological specimens)

k. Significant Risk (SR) or Non Significant Risk (NSR) classification for investigational device

l. Memorandum of Agreement (for collaborative studies)

m. Other information or documents for participants as needed.

4.1.2. Revised study protocol of Hospital and MDH medical staff: In case of major changes in the protocols deviating from the original, the PI should state that the research is a different version from the previous one and the new paper must be accompanied by all the documents required in the 4.1.1.A.2.

4.1.3. The Secretariat shall ensure completeness of submitted forms and documents using the above checklist. Incomplete submission will not be reviewed and will be sent back to the Principal Investigator for completion of requirements. One electronic and 1 hard copy must be submitted.

4.1.4. The Secretariat receiving the study protocol assigns a code to the package and stamps it onto all the forms and documents submitted. The Secretariat acknowledges receipt of study protocol and communicates to the PI the assigned code and date of full board meeting in which the study protocol will be reviewed using **MDH IRB FORM 2(G) 2021: ACKNOWLEDGEMENT LETTER.** The PI is informed that they cannot start the study without EC and FDA approval which is included in the acknowledgment letter.

4.1.5. The Secretariat signs **MDH IRB FORM 2(A) 2021: REVIEW CHECKLIST** to document the receipt of study protocol package and gives one copy of duly signed form to the PI or designated representative submitting the package and attaches another duly signed form to the study protocol package.

4.1.6. The PI or the designated representative manually logs the submission documents in the incoming logbook of the IRB and the Secretariat electronically logs the submission using **MDH IRB FORM 4(M) 2021: SUBMISSIONS LOG/ DATABASE.**