**What is the IRB?**

- An Institutional Review Board (IRB) is a committee established to review, approve, and monitor research involving human participants to ensure that their rights, welfare, and safety are protected. It operates in accordance with ethical principles, such as those outlined in the Belmont Report, and regulatory requirements like the Declaration of Helsinki, ICH-GCP, or national guidelines (e.g., the Philippine National Ethical Guidelines for Health and Health-Related Research).

**The IRB is responsible for:**

- Assessing research protocols for ethical compliance
- Ensuring informed consent is properly obtained
- Evaluating risk-to-benefit ratios
- Monitoring ongoing research for continued ethical compliance

It is sometimes referred to as a Research Ethics Committee (REC) in some countries.

1. **Who reviews the protocol?**

- Primary reviewers are selected on the basis of expertise related to the protocol. Research proposals are given to all members; both medical and non-medical or lay members, institutional and non-institutional members for review. The medical/ scientific members analyze the scientific and ethical procedures in the protocol while the lay/ non-institutional members focus their assessment on the informed consent form. The Informed Consent Form can be reviewed by both the lay and paramedical/ nurse/ pharmacist member. Review assignments should take into consideration the appropriate mix of old and new members.

2. **How long is the approval process for submitting a protocol/research until approval?**

- The turnaround time for submitting complete protocol submission until approval is 60 days?

3. **When is the timeline for review of the protocol?**

- The IRB regularly meets on every 3rd Tuesday of the month to review all protocols for full board. For under expedited review, the reviewers meet once a month and depending on their available schedule.

4. **Do you accept review of protocols outside MMC Institution?**

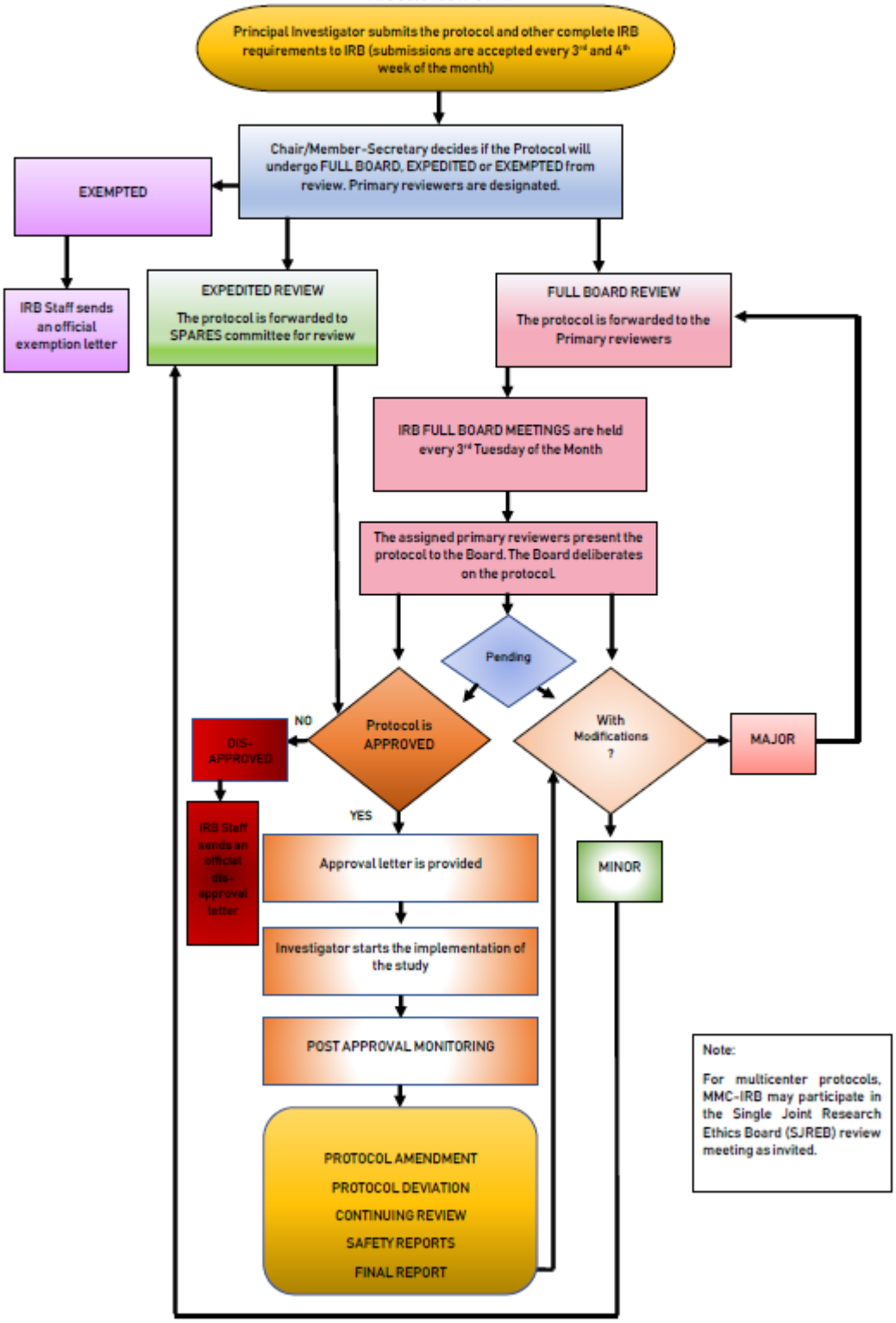
- Yes, we accept protocols, but it is for approval of the IRB Chair, If the IRB thinks that the review will be feasible, we will accept the review.

5. **What is the process for review in IRB?**

MAKATI MEDICAL CENTER

**INSTITUTIONAL REVIEW BOARD**

**PROCESS FLOW CHART**




Note:

For multicenter protocols, MMC-IRB may participate in the Single Joint Research Ethics Board (SJREB) review meeting as invited.

- The Principal Investigator submits the protocol and other complete IRB requirements to IRB (submissions are accepted every 3rd and 4th week of the month)
- The Chair/Member-Secretary determines the type of review the protocol will undergo: Full Board, Expedited, or Exempt. Primary reviewers are assigned accordingly.
- If the protocol is classified as “Exempt,” a Certificate of Exemption can be sent immediately to the Principal Investigator.
- If the protocol is designated for “Expedited Review,” it will be forwarded to the SPARES committee for review. The schedule for this review will depend on the availability of the SPARES committee, with reviews occurring monthly.
- For protocols requiring a Full Board Review, they will be forwarded to the primary reviewers. Full Board meetings are held on the third Tuesday of each month. If there are three or more protocols needing Full Board review, an additional meeting may be scheduled.
- Assigned primary reviewers will present the protocol to the Board, which will then deliberate on it.
- If the protocol is approved, an approval letter will be issued, allowing the Investigator to implement the study and proceed with submitting post-approval monitoring documents such as Protocol Amendments, Protocol Deviations, Continuing Reviews, Safety Reports, and Final Reports.
- If the protocol is disapproved, a disapproval letter will be sent to the Principal Investigator.
- Protocols that require “Minor Modifications” will be reviewed on an expedited basis, typically within approximately three days, without the need for a meeting.
- On the other hand, protocols deemed to require “Major Modifications” must be resubmitted and will be reviewed at the next scheduled Board meeting.
- For multicenter protocols, the MMC-IRB may participate in the Single Joint Research Ethics Board (SJREB) review meeting as invited.

**6. How much is the protocol review fees?**

- Please see the list of the review fees and post approval fee. https://irb.makatimed.net.ph/wp-content/uploads/2025/04/16.-InterOffice-Memo-IRB-Memo-Review-Fees-2024.pdf

**7. Will my protocol be classified as Expedited or Full Board or Exempted?**

| ISER | EXPEDITED REVIEW (SPARES) |
|---|---|
| **1** | Protocols of a non-confidential nature (not of a private character, e.g. relate to sexual preference etc., or not about a sensitive issue that may cause social stigma), not likely<br>to harm the status or interests of the study participants and not likely to offend the sensibilities nor cause psychological stress of the people involved. |

| | |
|---|---|
| **2** | Protocols not involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of refusal to participate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons,<br>nomads, refugees, minors and those incapable of giving consent). |
| **3** | Protocols that involve collection of anonymized biological specimens for research purposes by non-invasive means (e.g. collection of small amounts of blood, body fluids or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non- threatening manner). |
| **4** | Research involving data, documents or specimens that have been already collected or will be collected for ongoing medical treatment or diagnosis |

| **ISFB** | **FULL BOARD REVIEW** |
|---|---|
| **1** | Clinical trials about investigational new drugs, biologics or device in various phases (Phase 1, 2, 3) |
| **2** | Phase 4 intervention research involving drugs, biologics or device |
| **3** | Protocols including questionnaires and social interventions that are confidential in nature (about private behavior, e.g. related to sexual preferences etc., or about sensitive issues that may cause social stigma) that may cause psychological, legal, economic and other social harm |
| **4** | Protocols involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of refusal to participate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent) that require additional<br>protection from the IRB during review |
| **5** | Protocols that involve collection of identifiable biological specimens for research |

| **EX** | **EXEMPTION CRITERIA** |
|---|---|
| **1** | Study that does not involve human participants nor identifiable tissue, biological samples and data |
| **2** | Study design is meta-analysis and/or systemic with identifiable data |
| **3** | Case Reports |
| **4** | Study with less than minimal risk or harm |

| | |
|---|---|
| **5** | Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests |

**8. Do SJREB and MMC-IRB review the protocol at the same time?**

- It is the responsibility of the Makati Medical Center Institutional Review Board (MMC IRB) to participate in the SJREB review.

**9. What is the process for obtaining informed consent?**

- The guidelines for obtaining informed consent are included in the 2.8 Informed Consent Assessment Forms, accessible through the "MMCIRB Informed Consent Guidelines" template.

**10. What are the potential risks to participants, both physical and psychological?**

- In research involving human participants, risks can vary widely depending on the nature of the study. These risks may be physical, psychological, social, legal, or economic. Below are the most common physical and psychological risks:

**10.1. Physical Risks**

- These involve potential harm or discomfort to the body, which may range from mild to severe:

  - **Side effects of drugs or interventions** (e.g., nausea, dizziness, allergic reactions)
  - **Injury from procedures** (e.g., blood draws, biopsies, exercise testing)
  - **Invasive techniques** that cause pain or bodily harm
  - **Device malfunction** or unexpected adverse effects from medical equipment
  - **Radiation exposure** (e.g., in imaging studies)
  - **Infections** due to breaches in sterile technique
  - **Fatigue** or **discomfort** due to long procedures or frequent hospital visits

**10.2. Psychological Risks**

These relate to emotional or mental distress a participant may experience during or after the study:

- **Anxiety or stress** related to sensitive questions (e.g., about trauma, abuse, mental health, or sexual behavior)
- **Depression or emotional distress** triggered by study topics or assessments
- **Feelings of shame, guilt, or embarrassment** from self-disclosure or perceived judgment
- **Cognitive overload or fatigue** from extensive questionnaires or tasks
- **Unwanted self-awareness** (e.g., realizing a potential health issue through participation)

**10.3. Strategies to Minimize Risks**

- Researchers and IRBs must implement safeguards, including:
- Proper **risk assessment** in study design
- Use of **trained professionals** during procedures
- Clear **informed consent** processes
- **Psychological support** or referrals, if needed
- Ensuring **confidentiality** and **data protection**

**11. How do I submit the initial requirements to the Institutional Review Board (IRB)?**

- Make sure the initial submission forms are readily available on your end. You can access all forms at the website https://irb.makatimed.net.ph/forms/
- All requirements are outlined in the 2.1A Application Form for Initial Submission. Please submit the completed requirements via email to irbmmc.admin@makatimed.net.ph.

**12. Where can I find the submission forms?**

- The forms for both Initial and Post Approval can be downloaded from the IRB website. https://irb.makatimed.net.ph/forms/

**13. When can we expect to receive the decision letter following our initial and post-approval protocol review, regardless of whether it is an Expedited or Full Board Review?**

- You will receive the decision letter three days after the review.

## AMENDMENT

1. **Can the amendment be applied in the protocol even prior to approval?**

- No. Any change in the protocol submitted for amendment cannot be applied or implemented yet until it has been reviewed and approved by the IRB.

2. **What is considered as an amendment submission?**

- Any change or revision in the protocol or study team after the Initial submission approval is considered an amendment submission.

3. **Can I use my new amended study title in my amendment requirements even prior to approval?**

- No. The amended title can only be applied to the study after the amendment is reviewed and approved by the IRB.

4. **Is it considered an Amendment submission if there is a change in sponsor in the clinical trial?**

- Yes, this is considered an amendment.

5. **Can I file for an Amendment prior to the approval of my Initial submission?**

- No. Any change in the protocol prior to its Initial approval is amended through Resubmission. However, if the protocol was already approved by the IRB (ie. If the protocol already received a Certificate of Approval/ COA) and there are revisions to be made, then amendment submission is applicable.

6. **Can I proceed with my data collection if I have an Amendment that is yet to be reviewed by the board/ if my Amendment is not yet approved?**

- Yes, you can proceed if the amendment is unrelated to the data collection. However, if it is related then the data collection cannot commence until the amendment approval for it has been given by the IRB.

7. **In form 3.2, what is "Original Version" and "New Version"?**

- Under the Original Version column, the previous version of the document must be specified while under the New Version column, the new version of the document is indicated.

## PROGRESS REPORT

1. **Can we proceed with our site monitoring activities prior to the Progress Report approval?**

- Yes, site activities or monitoring are allowed if the Progress Report has not been approved yet.

2. **What are not considered allowed while the Progress Report approval is not yet given by the IRB?**

- Recruitment is not allowed while the PI is waiting for their Progress Report approval.

3. **Are SUSAR line listings required to be submitted during Progress Report?**

- Yes. These are submitted as supporting documents if they are available.

4. **Are SUSAR line listings only submitted during Progress Report?**

- No. While these are considered supporting documents alongside the Progress Report requirements, SUSARS can also be submitted every six months or whenever needed, but as a Notification report only.

5. **When is the considered expiration date of my study?**

- The date of approval of your protocol is also considered as the date of expiry of your protocol which occurs every year.

6. **When should I submit for a Progress Report?**

- It is preferrable to submit all Progress Report requirements to IRB one month prior to the expiration of the protocol. However, one must also take note of the IRB submission cut-off dates in the IRB website, to ensure that their submission will be included in the next scheduled full board meeting.

7. **Is there a specific form to submit if I have failed to renew my study for x number of years/ failed to renew it on time?**

- The PI is required to accomplish the Form 3.9 Expired Study Report if they have not renewed their protocol on time.

8. **Why are updated CVs and GCPs needed for Progress Report?**

- Updated CVs are required because the IRB must be updated with the current/ updated qualifications or credentials of the PI. Updated GCP certificate is required because it ensures that the PIs are knowledgeable about the ethical and scientific standards required for conducting clinical research and are updated regarding any updates on GCP.

9. **What happens if I am unable to renew my protocol on time/ If I renew my protocol way past its expiration date?**

- There is a grace period of 12 working days post expiration that is given to the PI to submit their complete Progress Report requirements. Failure to submit the Progress Report on time will automatically inactivate the status of the study.

10. **Can I submit for other post-approval submissions (Amendment, SAE, Protocol Deviation, Notification, etc…) if my study is considered inactive/ expired?**

- No. Other post-approval submissions can only be considered if the PI submitted for a Progress Report at the same time.

## Serious Adverse Event (SAE)

1. **What are the requirements for submitting an SAE report?**

- The PI is required to submit the following documents (see below).
    - Cover letter
    - Accomplished Form 3.1A (in copiable PDF file)
    - Death certificate (if the participant expired)
    - COVID vaccination dates of the participant if the protocol is a vaccine study (the dates can be included in the cover letter)

2. **What vaccination dates of the study participant are needed, when reporting an SAE submission?**

- If the study/ protocol is a vaccine study, then the PI must provide the COVID-19 vaccination dates of the participant (if they received any).

3. **Are pregnancy reports considered as a safety report?**

- No, unless there is a pregnancy anomaly that occurred to the pregnant study participant.

4. **When should SAEs be reported to the IRB?**

- See below the SAE Reporting Time Frame as per the MMC-IRB SOP.

**a.** Fatal or life threatening unexpected ADRs occurring in clinical investigation qualify for very rapid reporting. Regulatory agencies should be notified reporting (e.g., by telephone, facsimile, e-mail) not later than seven (7) calendar days after the first knowledge by the sponsor of that case followed by complete written report within eight (8) calendar days.

**b.** All other SAEs, SUSARs that are not fatal or life threatening must be filed by the IRB Secretariat as soon as possible but not later that fifteen (15) calendar days after the first knowledge by the sponsor that the case meets the minimum criteria for expedited reporting.

**c.** All the other adverse events, SUSARs, and DSURs will be reported as part of the annual progress report.

**d.** All Adverse Events reports to the IRB should be reported to the appropriate entities of the hospital if applicable or necessary (e.g., Therapeutics Committee, Quality Management Division, Medication Safety Subcommittee, etc.).

5. **What if a participant expired but the death or safety report is not reportable as per our study protocol/ Sponsor?**

- As per the ICH-GCP E6 guideline, any adverse events resulting in death must still be reported to the IRB and is required to be reviewed and approved by the board.

6. **What if the death certificate of the deceased participant is not yet available?**

- This can be submitted to-follow/ submitted as soon as available. Kindly ensure as well that all personal information regarding the participant will be redacted in the certificate.

7. **What happens if the participant has a succeeding SAE report after the first report/ Initial report?**

- This must be submitted as a separate SAE submission. In the SAE form 3.1 form, the type of report should be Follow-Up Report 1.

8. **What are the correct order of SAE report types?**

- Initial Report, Follow-up Report 1, Follow-up Report 2…3,4, and so on, then Final Report (if either the participant recovered or expired due to the serious adverse event).

9. **Can SAE submissions be expedited?**

- No. SAE submissions are reported and reviewed during the IRB's monthly full board meeting.

10. **What does it mean if the decision point we received for the SAE is "Take note and continue monitoring"?**

- Take note and continue monitoring means that the SAE report has been acknowledged/ noted by the board, and necessary monitoring for the participant is advised. However, if the participant recovered/ is deceased, then this decision point is considered as "Approval", so long as the PI submitted the complete requirements for the SAE.

## Other Queries for Post Approvals

### General:

- Post approval guidelines are sent to along with the Certificate of Approval (COA)
- All submissions require a cover letter and endorsement (if applicable)
- Do not leave any blank fields behind, the submission will be considered incomplete, put N/A or not applicable

### Deviation

1. **What does 'Continue Study and Monitor Compliance' mean in the decision letter?**

- This is also considered to be an approval of the Protocol Deviation that was submitted.

### Final Report

1. **When do I submit a final report?**

- You may submit final report once you have the result or final clinical study report is available.

2. **When the study has already concluded, when can we send a Final Report?**

- You may submit a Final Report submission as soon as the Clinical Study Report (CSR) is available.

3. Can we publish the study protocol prior to the Final Report approval?

- You must have an approval of your Final Report submission first before publishing the study protocol.

### Notification

1. What are considered to be sent as a Notification submission?

- Pregnancy Reports
- Investigational Brochure
- DSMB
- DSURs
- Safety Reports/SUSARs/CIOMs
- Site Close Out
- Synopsis

### Early Study Termination:

1. If we have already sent an Early Study Termination but we have a CSR, can we still submit this?

- You may submit it but it will be considered as a Notification submission.