**A. RAPID REVIEW OF RESEARCH DURING PUBLIC HEALTH EMERGENCIES**

# OBJECTIVES

1. This SOP describes how MMMC-RERC will accept protocol submissions during public health emergencies.
2. This SOP will also describe how MMMC-RERC will conduct board meetings and review clinical trial protocols using the MMMC-RERC’s Official ZOOM Account during public health emergencies.
3. The MMMC-RERC may participate in Single Joint Review Ethics Board (SJREB) deliberations to act on public health emergency protocols.

# SCOPE

MMMC-RERC will accept clinical trial protocols related to the use of new medications or vaccines during public health emergencies.

# RESPONSIBILITIES

1. It is the responsibility of the Administrative Staff to process clinical trials submitted electronically.
2. It is the responsibility of selected/identified members of MMMC-RERC and subject experts to do rapid review of clinical trials submitted electronically to them without compromising ethical issues.
3. It is the responsibility of the selected/identified members MMMC-RERC and subject expert to check the completeness of the study protocol package sent electronically to them. Systematically review the study protocol, write their comments after each item listed in the study protocol assessment forms and informed consent checklist, include consideration of relevant guidelines when doing the review, and present their findings during the review.

# SUBMISSION OF PROTOCOLS

1. Protocol submission to MMMC-RERC may be done electronically. A hard copy of the protocol can be sent later.
2. Principal Investigators should contact MMMC-RERC as soon as possible to communicate their intention to submit research protocols related to public health emergencies.
3. Electronic communication with Principal Investigators should be initiated to seek clarifications.
4. All electronic communications should be printed for documentation purposes and archived.
5. In addition to the ethics review form, a checklist including the following items should be submitted:
   * Identification of the research as public health emergency related.
   * A monitoring and safety management plan provided by the study sponsor.
6. The Chair or the Member-Secretary will assign or identify selected members of MMMC-RERC who will do rapid review of the clinical trial protocol. The subject expert will help in the review process. These members should have specialized training in reviewing research during public health emergencies to be able to rapidly review research protocols without compromising ethical considerations.
7. Protocols should be sent to reviewers and subject expert electronically within 24 hours of submission.
8. The assigned/identified reviewers will check the completeness of research protocols sent to them electronically. Systematically review the study protocol, write their comments after each item listed in the study protocol assessment forms and informed consent checklist, include consideration of relevant guidelines when doing the review, and present their findings during the review.
9. Reviewers and subject expert should complete their review within 3 days.
10. The Chair or Member-Secretary will schedule a meeting to review these protocols and inform also the assigned/identified members of this assigned schedule.

# WORKFLOW

|  |  |
| --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** |
| Protocol submission done electronically | Principal Investigator |
| Receives the submitted documents and checks for completeness of the study  protocol package | Administrative Staff |
| Assigns an MMMC-RERC code | Administrative Staff |
| Logs the submission in the Submission log/logbook | Administrative Staff |
| Assigns identified members of MMMC-RERC who will review the protocol | Chair |
| Identifies subject experts to help in the review process | Chair or Member-Secretary |
| Sends submitted protocol to assigned/identified members of MMMC-  RERC and subject expert | Administrative Staff |

# BOARD MEETING AND REVIEW OF PROTOCOLS

1. The Member-Secretary determines quorum and informs the Chair to indicate readiness to call the meeting to order. A quorum shall consist of 1/3 of all members of MMMC-RERC.
2. The review meetings of MMMC-RERC could be done virtually especially if a face-to-face meeting represents a health risk to committee members. Video recording of virtual meetings will be taken and filed in a secure folder.
3. If a pre-identified member of the committee submits their review but is unable to join the meeting, they should be considered as part of the quorum requirement.
4. Meetings with the Principal Investigators may be done virtually also.

1. The consolidated review and suggestions should be communicated to the principal investigators within 5 working days.
2. Communication with the principal investigators to seek clarifications may be done electronically.
3. The principal investigator should respond to the review within 3 days.
4. All communications should be documented and archived.

# MEETING WORKFLOW

|  |  |
| --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** |
| Schedules date of meeting | Chair / Vice-Chair/ Member-Secretary/  Members |
| Informs assigned/identified members of  MMMC-RERC and the expert of the scheduled meeting | Administrative Staff |
| Determines quorum and informs the Chair to indicate readiness to call the meeting to  order | Member-Secretary/Administrative staff |
| Approval of Meeting Agenda | Chair / Vice-Chair/ Member-Secretary/  Members |
| Reviews initial study protocol submissions and resubmissions | Chair / Vice-Chair/ Member-Secretary/  Members |
| Conducts clarificatory interview | Chair / Vice-Chair/ Member-Secretary/  Members |
| Adjourns meeting | Chair |
| Collects, stores, and disposes meeting materials | Administrative Staff |

**B. CONDUCT OF ONLINE REVIEW PROCEDURES**

1. **Objectives**

This SOP will also describe how MMMC-RERC will conduct board meetings and review clinical trial protocols using the MMMC-RERC’s Official ZOOM Account.

It is the responsibility of the Administrative Staff to accept and manage online protocol/document submissions during public health emergencies, send the protocol documents to the primary reviewers and include the protocol/document in the full board meeting agenda for discussion and decision. It is also the responsibility of the administrative staff to communicate the online review results to the Principal Investigator, keep the softcopies of the documents in the protocol files and update the protocol entry in the MMMC-RERC database.

The MMMC-RERC may also participate in Single Joint Review Ethics Board (SJREB) deliberations to act on public health emergency protocols.

# SCOPE

MMMC-RERC will accept clinical trial protocols related to the use of new medications, devices and vaccines during public health emergencies conducted by consultants of MMMC involving MMMC patients. It also reviews researches submitted virtually by MMMC residents or fellows in training as well as protocol submitted by non MMMC residents, fellow and consultants in the Southern Tagalog Region including but not limited to Investigator initiated researches and clinical trials.

# RESPONSIBILITIES

1. It is the responsibility of the Administrative Staff to process clinical trials submitted electronically.
2. It is the responsibility of selected/identified members of MMMC-RERC and subject experts to review clinical trials submitted electronically.
3. It is the responsibility of assigned primary reviewers of MMMC-RERC and subject experts for regular submissions to systematically review the study protocol, write their comments after each item listed in the study protocol assessment forms and informed consent checklist, include consideration of relevant guidelines when doing the review, and present their findings during the meeting.
4. It is the responsibility of the Administrative Staff to check the completeness of the study protocol package sent electronically.

# SUBMISSION OF PROTOCOLS

1. Protocol submission to MMMC-RERC may be done electronically. One (1) hard copy of the protocol can be sent within six months after the initial submission.
2. Principal Investigators should contact MMMC-RERC as soon as possible to communicate their intention to submit research protocols.
3. The Administrative Staff may send electronic communication to the Principal Investigators to seek clarifications.
4. All electronic communications should be printed for documentation purposes.
5. The Chair or the Member-Secretary will assign or identify primary reviewer who will review the clinical trial protocol. The subject expert, if needed will help in the review process. These members should review the research protocol without compromising ethical considerations.
6. Protocols should be sent to reviewers and subject expert electronically within 15 calendar days prior to the scheduled full board meeting.
7. The assigned/identified reviewers will check the completeness of research protocols sent to them electronically and systematically review the study protocol, write their comments after each item listed in the study protocol assessment forms and informed consent checklist, include consideration of relevant guidelines when doing the review, and present their findings during the meeting.
8. Reviewers and subject expert should complete their review within 7 days.
9. The Chair or Member-Secretary will schedule a meeting to review these protocols and inform also the assigned primary reviewer.

# WORKFLOW

|  |  |
| --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** |
| Protocol submission done electronically | Principal Investigator |
| Receives the submitted documents and checks for completeness of the study  protocol package | Administrative Staff |
| Assigns an MMMC-RERC code | Administrative Staff |
| Logs the submission in the Submission log/logbook | Administrative Staff |
| Assigns primary reviewers who will review the protocol | Chair |
| Identifies subject experts to help in the review process | Chair or Member-Secretary |
| Sends submitted protocol to primary reviewers of MMMC-RERC and subject  expert | Administrative Staff |

# BOARD MEETING AND REVIEW OF PROTOCOLS

1. The Member-Secretary determines quorum and informs the Chair to indicate readiness to call the meeting to order. A quorum shall consist of 50% +1 of all members of MMMC-RERC.
2. The review meetings of MMMC-RERC could be done virtually especially if a face-to face meeting represents a health risk to committee members.
3. Meetings with the Principal Investigators/Sub-Investigators may be done virtually also.
4. The consolidated review and suggestions should be communicated to the Principal Investigators within 7 working days.
5. Communication with the principal investigators to seek clarifications may be done electronically.
6. The principal investigator should respond to the review within 7 days.
7. All communications should be documented.

# MEETING WORKFLOW FOR INITIAL REVIEW

|  |  |
| --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** |
| Schedules date of meeting | Chair or Member-Secretary |
| Informs assigned/identified members of  MMMC-RERC and the expert of the scheduled meeting | Administrative Staff |
| Determines quorum and informs the Chair to indicate readiness to call the meeting to  order | Member-Secretary |
| Approval of Meeting Agenda | Chair and Member-Secretary |
| Reviews initial study protocol submissions and resubmissions | Assigned primary reviewers |
| Presents the summary of protocol submitted to members during meeting | Assigned primary reviewers |
| Conducts clarificatory interview | All members |
| Approves /Disapproves/ Request for  Information | All Members |
| Adjourns meeting | Chair |
| Saves soft copies of all documents | Administrative Staff |

# MEETING WORKFLOW FOR POST APPROVAL SUBMISSION

|  |  |
| --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** |
| Schedules date of meeting | Chair or Member-Secretary |
| Informs assigned/identified members of  MMMC-RERC and the expert of the scheduled meeting | Administrative Staff |
| Determines quorum and informs the Chair to indicate readiness to call the meeting to  order | Member-Secretary |
| Approval of Meeting Agenda | Chair and Member-Secretary |
| Reviews post approval submissions    (Resubmission or Study Protocol  Modification, Withdrawal, Amendment  Application, Continuing Review, Progress  Reports, Study Protocol Non-Compliance  Report, Early Study Termination, Queries,  Notifications and Complaints, SAE, SUSAR Reports, Site Visit Report, Final Report) | Assigned primary reviewers |
| Decision | All Members |
| Adjourns meeting | Chair |
| Saves soft copies of all documents | Administrative Staff |