**II. MANAGEMENT OF PROTOCOL SUBMISSIONS**

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|  |  |
| --- | --- |
| Supersedes | Standard Operating Procedure Version 4.0 |
| Version | 5.0 |
| Authored By | Dr. Narcisa Sonia Comia  Dr. Mary Warren Ilaga  Dr. Von Andre Medina |
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| Approved By | **Dr. Robert Magsino**  President and CEO |
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**2.1 OBJECTIVES/SCOPE/RESPONSIBILITIES**

**2.1.1 OBJECTIVES**

The objective of this chapter is to classify the submissions received by the MMMC-RERC to qualify either for Full Board Review, Expedited Review or Exempt from review.

The SOP describes how the MMMC-RERC manages initial submission of study protocol packages. The SOP also aims to provide guidance as to how the reviewers evaluate a study protocol submitted to the MMMC-RERC for the first time (initial submission).

**2.1.2. SCOPE**

MMMC- RERC reviews clinical trials conducted by consultants of MMMC involving MMMC patients. It also reviews researches done by MMMC residents or fellows in training and residents and fellows in training of other institutions in the Southern Tagalog region. MMMC RERC also reviews researches done by undergraduate students enrolled in schools in the Southern Tagalog region if the research involves human subjects. It may also review protocols submitted by practicing physicians outside MMMC and protocols done by social scientists.

The SOP applies to MMMC - RERC actions from the time of initial submission to preparation of copies of the package for distribution to the reviewers, deliberation during board meeting and filing of the protocol package in the Active File cabinet.

**2.1.3 RESPONSIBILITIES**

It is the responsibility of the Administrative Staff to manage study protocol package submission and process the submission.

It is the responsibility of the MMMC-RERC Chair to decide whether the study protocol is for full board review, for expedited review or for exemption from review .The MMMC-RERC Chair or Member-Secretary is responsible for assigning primary reviewers. It is the responsibility of the Administrative Staff under the supervision of the Member Secretary to ensure that the deliberations and discussions during board meeting are adequately documented.

It is the responsibility of the assigned reviewers to check the completeness of the study protocol package delivered 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 findings in the full board meeting (for full board review study protocols).

The Principal Investigator (PI) is responsible for submitting a complete set of documents to the MMMC-RERC.

**2.2 TYPES OF REVIEW**

**2.2.1 FULL BOARD REVIEW**

**2.2.1.1 OBJECTIVE/SCOPE/RESPONSIBITY**

This SOP applies to the review and approval of study protocols and amendments which poses medium to high risk to the study participants. Major revisions in the protocol or informed consent are also included.

It is the responsibility of the administrative staff to manage the document submission, send the protocol documents to the primary reviewers and include the protocol in the full board meeting agenda for discussion and decision. It is also the responsibility of the administrative staff to communicate the review results to the Principal Investigator, keep the copies of the documents in the protocol files and update the protocol entry in the MMMC-RERC database.

It is the responsibility of the primary reviewers to review the protocol and related documents by using the assessment forms and make recommendation for appropriate action.

**2.2.1.2 Full Board Review Workflow**

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| --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** |
| Receives the submitted documents and checks for completeness of the study protocol package | Administrative staff |
| Assigns an MMMC-RERC code ***(for new protocol submission only)*** based on SOP 5.5.2.1 | Administrative staff |
| Logs the submission in the Submission log/logbook | Administrative staff |
| Determines that the protocol is for full board review | Chair |
| Assigns reviewers for full board review | Chair/ Member-Secretary |
| Prepares and distribute the Notice of Review to Primary Reviewers | Administrative staff |
| Review and answer the assessment forms and submit to decision to the Administrative Staff | Primary Reviewers |
| Includes the full board protocol/documents in the agenda of the next Full Board Meeting | Administrative staff |
| Files the properly coded study protocol in the Active Study File Cabinet and updates Protocol Database. | Administrative staff |

**2.2.1.3 Detailed Instructions**

a. Full board review of study protocol and study protocol-related submissions typically includes seven (7) copies of protocol synopsis and five (5) copies of the following:

* Initial Study Protocol Submissions
* Resubmission or Study Protocols for Modification
* Withdrawal of Study Protocol Applications
* Study Protocol Amendment Applications
* Continuing Review Applications
* Progress Reports
* Final Reports
* Serious Adverse Event Reports (onsite)
* Site Visit Reports
* Study Protocol Noncompliance (Deviation or Violation) Reports
* Early Study Termination Applications
* Queries from Various Stakeholders

b. The Administrative Staff ensures completeness of submitted forms and documents using the review checklist.

c. The Administrative Staff receiving the study protocol assigns the MMMC-RERC code to the package and writes in onto all the forms and documents submitted. Assignment of the MMMC RERC code is based on SOP 5.5.2.1.

d. The Administrative Staff logs the submission using ***MMMC-RERC F-5-H: SUBMISSIONS LOG and GENERAL SUBMISSION LOGBOOK.***

e. The MMMC-RERC Chair classifies the study protocol for Full Board Review.

f. The Chair or the Member-Secretary assigns one (1) scientific reviewer and one (1) non-scientific member as primary reviewers of the study protocol. Reviewers are selected on the basis of their expertise. The scientific/medical reviewer is tasked to focus more on technical soundness and related ethical issues while the non-scientific reviewer is tasked to focus on the informed consent process and forms.

g. The Administrative Staff prepares a letter using ***MMMC-RERC F-2-E: NOTICE OF REVIEW*** and sends the study protocol package to the assigned primary reviewers**.**

h. The Administrative Staff files the study protocol package in a properly coded Study protocol file folder and places it in the Active Study File cabinet.

i. The assigned primary reviewers review and answer the assessment forms and submit the decision to the Administrative Staff.

j. Studies that qualify for full board review and received by the Administrative Staff **fifteen (15)** calendar days before the scheduled full board meeting are included in the agenda.

**2.2.2 EXPEDITED REVIEW**

**2.2.2.1 Objectives/Scope/Responsibility**

The objective of this SOP is to describe how MMMC-RERC manages study protocols for expedited review.

This SOP applies to the review and approval of study protocols or amendments with minimal risk to study participants. Minor revisions in the protocol or informed consent may also be classified under expedited review. The submission procedures are the same as a first time submission.

It is the responsibility of the MMMC-Chair and the primary reviewers to assess any protocol that qualifies for the expedited review process. The same assessment forms used for full board review will be used to evaluate the scientific and ethical merits of the protocol.

**2.2.2.2 Types of Protocols Subjected to Expedited Review after Initial Submission**

* + - * 1. The research poses low risk.
        2. The study does not involve vulnerable populations.
        3. The study does not involve the collection of stigmatizing information.
        4. The study uses anonymized or archived samples.
        5. Continuing review of clinical trials that do not involve further recruitment of participants.
        6. Research involving data, documents or specimens that have already been collected or will be collected for ongoing treatment or diagnosis.
        7. Continuing reviews, protocol amendments and end of the study reports that have minor modifications and no significant risk to study participants.
        8. Continuing review of studies previously classified under expedited review.
        9. Study protocol amendments that are administrative in nature and do not affect the study protocol.

**2.2.2.3 Expedited Review of Resubmissions/Amendments/Reports (4 copies)**

1. Administrative revisions, such as correction of typing errors.
2. Addition or deletion of non-procedural items, such as the addition of study personnel names, laboratories, etc.
3. The research activity includes only minor changes from previously approved protocol.
4. Minor protocol amendments that do not change the risk/benefit assessment.
5. Progress/Final reports that do not deviate from approval given by MMMC-RERC.

**2.2.2.4 Expedited Review Workflow**

|  |  |
| --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** |
| Receives the submitted documents and checks for completeness of the study protocol package | Administrative staff |
| Assigns an MMMC-RERC code based on SOP 5.5.2.1 ***(for new protocol submission only)*** | Administrative staff |
| Logs the submission in the Submission log/logbook | Administrative staff |
| Determines that the protocol is for expedited review | Chair |
| Assigns reviewers for the expedited review | Chair/ Member-Secretary |
| Prepares the Notice of Review for Primary Reviewers | Administrative staff |
| Do the expedited review, answer the assessment forms and submit decision to the Administrative Staff | Primary Reviewers |
| Communicates the decisions of the chair according to the primary reviewers’ assessments. | Administrative staff |
| Communicates the decisions of MMMC-RERC to the Principal Investigator | Administrative staff |
| Includes the expedited protocol/documents in the agenda of the next Full Board Meeting | Administrative staff |
| Files the properly coded study protocol in the Active Study File Cabinet and updates Protocol Database. | Administrative staff |

**2.2.2.5 Detailed Instructions**

1. The Administrative Staff ensures completeness of submitted forms.
2. The Administrative Staff receives the study protocol and assigns the MMMC-RERC code to the package and writes in onto all the forms and documents submitted. Assignment of the MMMC RERC code is based on SOP 5.5.2.1.
3. The Administrative Staff logs the submission using ***MMMC-RERC F-5-H: SUBMISSIONS LOG and GENERAL SUBMISSION LOGBOOK.***
4. The Administrative Staff sends the Study Protocol Submission Package to the RERC Chair immediately for classification of review as expedited.
5. The RERC Chair and/or Member-Secretary will assign at least two (2) primary reviewers for the submission package.
6. The Administrative Staff prepares a letter using ***MMMC-RERC F-2-E: NOTICE OF REVIEW*** and sends the study protocol package to the assigned primary reviewers**.**
7. The Administrative Staff files the study protocol package in a properly coded Study protocol file folder and places it in the Active Study File cabinet.
8. The submission packages will be sent to the Primary Reviewers together with the originally approved protocol and assessment forms.
9. The Primary Reviewers accomplish the review and return the signed assessment form to the Administrative Staff.
10. The Administrative Staff communicates the decision of the Primary Reviewer to the RERC Chair within **7 calendar days**.
11. For submissions under expedited review, the action is finalized at the level of the Chair within seven **(7) calendar days.**
12. The Administrative Staff communicates the decision to the Principal Investigator within fifteen **(15) calendar days.**
13. The Administrative Staff includes the expedited protocol/documents in the agenda for the next RERC meeting.

**2.2.3 EXEMPT FROM REVIEW**

**2.2.3.1 Scope/Responsibility**

This SOP applies to the management of study protocols submitted to MMMC-RERC which may qualify for “exempt from review”.

Exempt from review protocols are protocols that do not need to undergo either full board or expedited review after a preliminary assessment by the Primary reviewers. “Exempt from review” is a decision made by the MMMC-RERC Chair.

The following may be considered “Exempt from review”:

1. Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols).
2. Protocol for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests;
3. Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met:
   * There will no disclosure of the human participants’ responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation; and
   * The information obtained is recorded by the investigator in such a manner that the human participant cannot readily be ascertained, directly or through identifiers linked to the participants.

d. Protocol that involves the use of publicly available data or information.

It is the responsibility of the administrative staff to manage the document submission, send the protocol to the primary reviewers and refer the protocol to the RERC Chair if the study protocol qualifies for “exempt from review”.

**2.2.3.2 Exempt from Review Workflow**

|  |  |
| --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** |
| Receives the submitted documents and checks for completeness of the study protocol package | Administrative staff |
| Assigns an MMMC-RERC code based on SOP 5.5.2.1 ***(for new protocol submission only)*** | Administrative staff |
| Logs the submission in the Submission log/logbook | Administrative staff |
| Determines that the protocol is exempt from review | Chair |
| Communicates the decision of the Chair and Primary reviewers to the PI. | Administrative staff |
| Files the properly coded study protocol in the Active Study File Cabinet and updates Protocol Database. | Administrative staff |

**2.2.3.3 Detailed Instructions**

1. The Administrative Staff receiving the study protocol assigns the MMMC-RERC code to the package and writes in onto all the forms and documents submitted. Assignment of the MMMC RERC code is based on SOP 5.5.2.1.
2. The Administrative Staff logs the submission using ***MMMC-RERC F-5-H: SUBMISSIONS LOG*** *and* ***GENERAL SUBMISSION LOGBOOK.***
3. The Administrative Staff sends the Study Protocol Submission Package to the RERC Chair and/or Member-Secretary who will assign at least two (2) primary reviewers for the submission package.
4. The Administrative Staff prepares a letter using ***MMMC-RERC F-2-E: NOTICE OF REVIEW*** and sends the study protocol package to the assigned primary reviewers**.**
5. The Administrative Staff files the study protocol package in a properly coded Study protocol file folder and places it in the Active Study File cabinet.
6. The submission packages will be sent to the Primary Reviewers who may recommend “exempt from review”.

1. The Administrative Staff communicates the decision of the Primary Reviewers to the RERC Chair within seven (**7) calendar days**.
2. For submissions that qualify under “exempt from review”, the action is finalized at the level of the Chair within seven (**7) calendar days.**
3. The Administrative Staff communicates the decision to the Principal Investigator within fifteen **(15) calendar days.**
4. The Administrative Staff files the study protocol package in a properly coded Study protocol file folder and places it in the Active Study File cabinet.

**2.2.4 REVIEW OF A MEDICAL DEVICE PROTOCOL**

**2.2.4.1 Objective/Scope/Responsibility**

The purpose of this SOP is to describe procedures in the review of medical device protocols submitted to the MMMC-RERC.

## This SOP provides instructions for review and approval of medical device protocols intended for human participants submitted to the MMMC-RERC. Medical device protocols are reviewed through the same expedited or full board procedures depending on the level of risk involved in the study. An investigational new device is given a Significant Risk (SR) or Non-Significant Risk (NSR) classification by the regulators in the sponsor country. This information should be provided by the sponsor to the MMMC-RERC. The MMMC-RERC should make provisions to minimize the risks to human participants during review of the protocol and related documents.

## It is the responsibility of the MMMC-RERC members to review medical device protocols in accordance with international and national guidelines and regulations.

**2.2.4.2 Review of Medical Device Workflow**

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| --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** |
| Receives the submitted documents, checks for completeness, and forwards to the Chair or Member-Secretary | Administrative Staff |
| Determines if the protocol is for Expedited or Full Board review | Chair / Member-Secretary |
| Assigns primary reviewers | Chair /Member-Secretary |
| Conduct the review using the assessment forms and submit the decision/ recommendation to the Administrative Staff. | Primary Reviewers |
| Expedited Review: Communicates the decision from expedited reviewers to the Principal Investigator. | Administrative Staff |
| Full Board Review: Includes the protocol in the meeting agenda | Administrative Staff |
| Communicates decision of MMMC-  RERC to PI | Administrative Staff |
| Files the properly coded study protocol in the Active Study File Cabinet and updates Protocol Database. | Administrative staff |

# **2.2.4.3 Detailed Instructions:**

**a.** The Administrative Staff receives the submitted documents and forward to the Chair or Member-Secretary together with accomplished  ***MMMC-RERC F-2-A: Review Checklist*, MMMC-RERC F-2-B: *Registration and Application for I*nitial Review and Resubmission form, *MMMC-RERC F-2-C2*: *Medical Device Assessment* *form, MMMC-RERC F-2-D Informed Consent Assessment Form***

**b.** Member - Secretary and Chair check the information/communication from the principal investigator related to the Significant Risk (SR) or Non-Significant Risk (NSR) determination by regulators (FDA) from the sponsor country. The protocol is assigned to expedited review or full board review depending on the risk assessment.

**c.** Unless the FDA has already made a risk determination for the study, MMMC-RERC must review the sponsor’s Significant Risk or Non-Significant risk determination for every investigational medical device study reviewed and modify the determination if MMMC-RERC disagrees with the sponsor.

**d.** For a device study to be eligible for expedited review, it must either be:

* exempt from IDE requirements
* previously determined to be an NSR study by the FDA

**e.** Primary reviewers with appropriate expertise are assigned to review the protocol and related documents. It is advisable that a bioengineer with appropriate experience related to the medical device together with a medical doctor with related clinical experience are assigned to review the protocol while a lay person/ non-medical member reviews the consent form.

**f.** When reviewing a medical device protocol, the Primary Reviewers must use the following forms:

* **MMMC-RERC F-2-C2**
* **MMMC-RERC F-2-D**

**g.** The Primary reviewers must review the following documents:

* Proposed investigational plan (use of the device in the study)
* Description of the device/ Product information including handling and storage requirements.
* Copies of all labeling for investigational use
* Reports of prior investigations conducted with the device
* FDA Approval, IDE number
* Risk assessment determination for new investigational device (Significant Risk or Non-Significant Risk) and the rationale
* Choice of comparator and justification (if applicable)
* Summary of the necessary training and the experience needed to use the investigational device.
* Device control, access and accountability.
* List of additional procedures (example: surgery), medical device or medication to be used as part of the investigational study.
* Risk-benefit assessment
* Safety and effectiveness/ performance assessments
* Prohibition against promotion or commercialization of, and certain other practices relative to, investigational devices.
* References.

**h.** Primary reviewers make a decision in expedited review or make a recommendation for discussion during the next full board meeting.

**i.** For full board review, a decision is made after discussion.

**j.** If the MMMC-RERC determines that an investigation involves an SR device that the sponsor thought was an NSR device, it must notify the investigator and, if appropriate, the sponsor. If this occurs, the sponsor may not begin the investigation until an FDA approval is obtained.

**k.** If the protocols are for revision, they are sent back to the principal investigator for modification **(MMMC-RERC F-5-D and MMMC-RERC F-5-B)**

**l.** Documents are resubmitted ***(MMMC-RERC F-2-I Review of Resubmitted Study Protocol Form)*** and reviewed by primary reviewers through expedited channel for minor revision or sent to full board for review of major revisions.

**m.** Approval decision is reached; the approval letter ***(MMMC-RERC F-5-B Approval Letter to the Study Protocol)*** is prepared, signed by the Chair and communicated to the principal investigator. The frequency of continuing review is indicated in the approval letter. The relevant documents are kept in the protocol file.

**n.** The Administrative Staff files the study protocol package in a properly coded Study protocol file folder, places it in the Active Study File cabinet and updated the Protocol Database.

**2.3. INITIAL REVIEW PROCEDURES**

**2.3.1 Initial Review Work Flow**

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| --- | --- | --- |
| **ACTIVITY** | | **RESPONSIBILITY** |
| Receives and checks for completeness of the study protocol submission | | Administrative Staff |
| Receives the proof of payment of RERC Review Fee (deposited) with the submitted protocol | | Administrative Staff |
| Classifies submission as expedited or full board review or exempt from review | | Chair/Member-Secretary |
| Assigns primary reviewers | | Chair/ Member-Secretary |
| |  | | --- | | Sends study protocol package to primary reviewers with ***MMMC-RERC F-2-C1: STUDY PROTOCOL ASSESSMENT FORM*** *and* ***MMMC-RERC F-2-D: INFORMED CONSENT ASSESSMENT FORM*** | | | Administrative Staff |
| |  | | --- | | Review the protocol and return accomplished ***MMMC-RERC F-2-C1: STUDY PROTOCOL ASSESSMENT FORM*** and ***MMMC-RERC F-2-D: INFORMED CONSENT ASSESSMENT FORM*** to the Administrative Staff | | | Primary Reviewers |
| **FULL BOARD REVIEW** | **EXPEDITED REVIEW** |  |
| Checks the completeness, accuracy, and adequacy of review documents and finalizes agenda  Includes the protocol in the agenda of the next full board meeting  Present review findings during full board meeting  Deliberate on full board action on the protocol |  | Administrative Staff  Administrative Staff  Primary Reviewers  Members |
| |  | | --- | | **If Approved:** Sends approval letter and notification of decision to the PI  **If major modification**: Sends notification with recommendations to the PI; processes resubmission by full board review  **If minor modification**: sends notification with recommendations to the PI; processes resubmission by expedited review  **If disapproved:** Sends notification of decision to the PI with justification | | **If approved:** Sends approval letter and notification of decision to the PI  **If major or minor modification:** Sends notification with recommendations to the PI then processes resubmission by expedited review  **If disapproved**, sends to Chair for decision whether to undergo full board. | Administrative Staff |

**2.3.2 Detailed Instructions**

**2.3.2.1 Receipt and management of study protocol submission**

**a.** The administrative staff receives the protocol package for initial review together with duly signed and accomplished forms and documents (as applicable) as enumerated in ***MMMC-RERC F-2-A: REVIEW CHECKLIST.*** Proof of payment of the Reviewers’ fee is also submitted.

b. The Administrative Staff ensures completeness of submitted forms and documents using the above checklist.

c. The Administrative Staff receiving the study protocol assigns the MMMC-RERC code to the package and writes it onto all the forms and documents submitted.

d. The administrative staff signs ***MMMC-RERC F-2-A: REVIEW CHECKLIST FORM*** to document the receipt of study protocol package and gives one copy of duly signed form to the PI or designated representative of the package, and attaches another duly signed form to the study protocol package.

e. The administrative Staff logs the submission using ***MMMC-RERC F-5-H****:* ***SUBMISSION LOG.***

**f.** Payment of the reviewers’ fee must be made before the protocol package is submitted. Review of protocol will be done only on presentation (by the principal investigator or a representative of the clinical trial) to the Administrative Staff of an official receipt from the MMMC.

g. The payment will be made in the name of MMMC. The payment includes MMMC-RERC fee (P50, 000).

h. The MMMC accounting division will then make a check in the amount of P50, 000 to MMMC-RERC. The money received will be used as honorarium for the reviewers (only for reviewers participating the full board review during the monthly meeting). The rest of the fund will be used to support the activities and the maintenance of the daily operation of the RERC and training activities of the members.

i. The administrative staff prepares ***MMMC-RERC F-2-H: ACKNOWLEDGEMENT LETTER*** that will be sent to the Principal Investigator at least fifteen (15) calendar days prior to the scheduled full board meeting. ***MMMC-RERCF-2-H: ACKNOWLEDGEMENT LETTER*** will indicate review date and the study protocol code <**MMMC – RERC code**> which will be used for all communications to the MMMC- RERC related to the study.

**2.3.2.2 Basic Documents (must submit)**

* 1. Review Checklist **[MMMC-RERC F-2-A]**
  2. Registration and Application Form **[MMMC-RERC F-2-B]**
  3. Study Protocol Assessment Form **[MMMC-RERC F-2-C1]**
  4. Informed Consent Assessment Form (for studies with human participants) **[MMMC-RERC F-2-D]**
  5. Study protocol
  6. Informed consent form in English (for studies with human participants)
  7. Informed consent form in local language (for studies with human participants)
  8. Assent form in English (for studies involving minors and relevant populations deemed incompetent to sign an informed consent)
  9. Assent form in local language (for studies involving minors and relevant populations deemed incompetent to sign an informed consent)
  10. Data collection forms (including CRFs)
  11. Diagrammatic workflow
  12. CV of PI/Co - I and study team members
  13. Proof of payment of ethics review fee (as applicable)

**2.3.2.3 Study-specific Documents (submit as needed)**

1. Investigator’s Brochure (for phase I, II, III clinical trials) or Basic Product Information Document (for phase IV clinical trials)
2. Good Clinical Practice (GCP) Training Certificate of PI, Co-I and the rest of the study team (for clinical trials)
3. Recruitment advertisements (as needed by the study protocol)
4. Other information or documents for participants (such as diaries, etc.)
5. Material Transfer Agreement (for any research involving transfer of biological specimens)
6. Memorandum of Agreement (for collaborative studies
7. Clearance or permit from respective regulatory authorities (such as FDA approval for clinical trials and DENR local transport permit, as applicable)
8. Site Resources Checklist for Clinical Trial Outside MMMC By MMMC Personnel **[MMMC-RERC F-2-F]**
9. Site Resources Checklist for Clinical Trial Outside MMMC By non-MMMC Personnel **[MMMC-RERC F-2-G]**
10. Previous ethical review approvals/clearances (for students/personnel of foreign universities researching in the Philippines or those with prior ethical review)
11. National Commission for Indigenous People (NCIP) Clearance (for studies with indigenous populations; can be processed while MMMC-RERC review is ongoing)

**2.3.2.4 Assignment of Primary Reviewers**

**a.** The Chair or the Member-Secretary assigns one (1) scientific reviewer and one (1) non-scientific or lay member as primary reviewers of the study protocol. Reviewers are selected on the basis of their expertise.

b. The scientific/medical reviewer is tasked to focus more on technical soundness and related ethical issues while the non-scientific reviewer is tasked to focus on the informed consent process and forms.

c. The Administrative Staff prepares a letter using ***MMMC-RERC F-2-E: NOTICE OF REVIEW*** and sends the study protocol package to the assigned primary reviewers**.**

**d.** The Administrative Staff files the study protocol package in a properly coded Study protocol file folder and places it in the Active Study File cabinet.

**2.3.2.5 Study Protocol Review**

a. Studies that do not qualify for expedited review and received by the Secretariat Staff **fifteen (15)** calendar days before the scheduled full board meeting are included in the agenda.

b. Primary reviewers accomplish ***MMMC-RERC F-2-C: STUDY PROTOCOL ASSESSMENT FORM*** and ***MMMC-RERC F-2-D: INFORMED CONSENT ASSESSMENT FORM*** completely and comprehensively. They also check for completeness of the documentation and information about the PI/s, study sites, and other documents as required by the study protocol under review such as those listed in **SOP 2.3.2.3 RECEIPT AND MANAGEMENT OF STUDY PROTOCOL SUBMISSION** applicable to the study.

c. The primary reviewers review the study protocol and informed consent documents in accordance with the assessment points and elements detailed in **MMMC-RERC F-2-C: STUDY PROTOCOL ASSESSMENT FORM** and **MMMC-RERC F-2-D: INFORMED CONSENT ASSESSMENT FORM.**

d. In addition to the review elements described above, the primary reviewers should ensure study protocol compliance with the ***National Ethical Guidelines for Health Research 2017*** on:

* Use of biological materials
* Appropriate contracts or memoranda of understanding especially in collaborative studies

e. If applicable, community involvement and impact/benefit of the study to community and/or the institution are examined and if relevant, noting the following if applicable: community consultation, involvement of local researchers and institutions in the study protocol design, analysis and publication of the results, contribution to development of local capacity for research and treatment, benefit to local communities, availability of study results, and benefit sharing.

f. RERC have to acknowledge that some populations require special protection because of characteristics or situations that render them vulnerable. Vulnerable groups should not be included in research unless:

* The research is necessary to promote the health of the population represented.
* The research cannot be performed on legally competent persons.

g. Special Consideration in the review process

* The board will ensure that the protocol to be reviewed has explicit statement/s regarding compensation for research participant- the compensation given to participants is for loss of earnings, transportation and other expenses incurred in taking part in the study, and compensation for the inconvenience and time spent by those who do not have direct benefit from the research. The compensation should not be so large as to induce the prospective subject to consent to participate in the research against his better judgment.
* Compensation in whatever form should also be available to research participants should injury in the person occurs in the course of the study.
* There must be a statement in the protocol stating that the population which the research is carried out will likely benefit from the research result. Likewise, the standard of care and other medical interventions must be offered to subjects after their participation.

h. For full board review study protocols, the primary reviewer as well as the members of RERC, accomplish the aforementioned forms and return them to the Administrative Staff within **seven (7)** calendar days prior to the meeting.

i. For expedited review study protocols, the primary reviewer accomplishes the aforementioned forms, completely signed and dated, and returns them to the Administrative Staff within **Seven (7)** calendar days from receipt of package.

j. The primary reviewers signify their decision by marking the appropriate section of the aforementioned forms and affixing their signature in the space provided. Decision points are: **APPROVE, MAJOR MODIFICATION, MINOR MODIFICATION, DISAPPROVE and TERMINATION.**

* APPROVE is given when there are no proposed changes recommended by the board during the initial presentation in a full board meeting.
* MAJOR MODIFICATION is given when the proposed changes in the research related activities will significantly affect the assessment of the risks and benefits of the study or substantially change the specific aims or design of the study.
* MINOR MODIFICATION is given when a proposed change in research related activities does not significantly affect an assessment of the risk and benefits of the study and does not substantially change the specific aims or design of the study.
* DISAPPROVE is given when a study protocol outweighs the risks

over the benefits.

* + - TERMINATION is ending or discontinuing a research study before its scheduled completion when the safety or benefit of the study participants is doubtful or at risk.

k. Expedited study protocols that are disapproved by any primary reviewer are referred for full board review. The full board review will be done on the next scheduled meeting and will take into consideration the assessment of the rest of the RERC members who have been provided with the same submission package as that of the primary reviewers.

l. The primary reviewers for full board reviewer study protocols present their findings in the meeting where action is deliberated.

m. The documents are presented to RERC Members when amendments are deliberated on.

**2.3.2.6 Communication of results**

1. The PI is notified of the MMMC-RERC decision through an action letter.
2. The MMMC-RERC decision will be sent to the Principal Investigator within **fifteen (15)** calendar days after the MMMC-RERC board meeting.
3. The PI may be required to modify, provide additional information, or submit additional documents.
4. If the decision is to approve the Study Protocol, the PI will receive an approval letter through ***MMMC-RERC F-4-B: APPROVAL LETTER.***

**2.3.2.7 Files management**

The Administrative Staff files the decision together with the study protocol in the Active File Cabinet.

**2.3.3 Management of Resubmitted study protocol**

**2.3.3.1 Resubmitted Study Protocol Workflow**

|  |  |
| --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** |
| Receives the submitted documents and checks for completeness of the study protocol package | Administrative staff |
| Logs the submission in the Submission log/logbook | Administrative staff |
| Sends protocol package to MMMC-RERC Chair and Primary reviewers | Administrative staff |
| Determine whether the recommended changes were carried out. | Primary Reviewers |
| Communicates the decisions of the chair according to the primary reviewers’ assessments. | Administrative staff |
| Communicates the decisions of MMMC-RERC to the Principal Investigator | Administrative staff |
| Includes the protocol/documents in the agenda of the next Full Board Meeting | Administrative staff |
| Files the properly coded submission in the Active Study File Cabinet and updates Protocol Database. | Administrative staff |

**2.3.3.2 Detailed Instructions**

**2.3.3.2.1 Receipt and management of the Resubmitted Study Protocol**

a. The review of a resubmitted study protocol is facilitated through the submission of ***MMMC-RERC F-2-I: RESUBMITTED STUDY PROTOCOL FORM*** by the principal investigator to the MMMC-RERC.

b. The Administrative Staff checks the submission for completeness and gives a receiving copy of ***MMMC-RERC F-2-I: RESUBMITTED STUDY PROTOCOL FORM*** to the PI or his/her representative.

c. Upon receipt of the study protocol amendment package, the Administrative Staff logs the date of submission on *the* ***MMMC-RERC F-5-H: SUBMISSIONS LOG and GENERAL SUBMISSION LOGBOOK.***

d. The Administrative Staff ensures that five (5) copies have been submitted by the PI for full board submissions.

**2.3.3.2.2 Review by the Primary Reviewers**

a. The resubmitted protocol will be sent to the Primary Reviewers for them to determine whether the recommended changes were carried out.

b. For submissions under expedited review, the action is finalized at the level of the Chair within **fifteen (15)** calendar days.

c. The resubmitted protocol subject to full board review must be received within the cut-off period of **fifteen (15)** days before the meeting.

d. The Administrative Staff includes the resubmitted study protocol on the agenda for the next RERC meeting.

e. The Primary Reviewers accomplish the review and return the signed ***MMMC-RERC F-2-I: RESUBMITTED STUDY PROTOCOL FORM*** on the day of the RERC meeting.

f. The documents are presented to RERC Members for deliberation***.***

g. The primary reviewers signify their decision by marking the appropriate section of the aforementioned forms and affixing their signature in the space provided. Decision points are: **APPROVE, MAJOR MODIFICATION, MINOR MODIFICATION, DISAPPROVE and TERMINATION.**

* Approve is given when there are no proposed changes recommended by the board during the initial presentation in a full board meeting.
* Major modification is given when the proposed changes in the research related activities will significantly affect the assessment of the risks and benefits of the study or substantially change the specific aims or design of the study.
* Minor modification is given when a proposed change in research related activities does not significantly affect an assessment of the risk and benefits of the study and does not substantially change the specific aims or design of the study.
* Disapproved is given when a study protocol outweighs the risks over the benefits.
* TERMINATION is ending or discontinuing a research study before its scheduled completion when the safety or benefit of the study participants is doubtful or at risk.

h. Expedited study protocols that are disapproved by any primary reviewer will be decided upon at the level of the chair whether it will be elevated to a full board review. The full board review will be done on the next scheduled meeting and will take into consideration the assessment of the rest of the RERC members who have been provided with the same submission package as that of the primary reviewers.

i. The primary reviewers of full board study protocols present their findings in the meeting where action is deliberated.

j. The documents are presented to RERC Members when amendments are deliberated on.

**2.3.3.2.3 Communication of results**

**a.** The PI is notified of the MMMC-RERC decision through an action letter.

**b.** The MMMC-RERC decision will be sent to the Principal Investigator within **fifteen (15)** calendar days after the MMMC-RERC board meeting.

**c.** The PI may be required to modify, provide additional information, or submit additional documents.

**d.** If the decision is to approve the Study Protocol, the PI will receive an approval letter through ***MMMC-RERC F-5-B: APPROVAL LETTER.***

**2.3.3.2.4 Files management**

**a.** The Administrative Staff files the decision together with the resubmitted study protocol in the Active File Cabinet.

**RELEVANT FORMS**

**MMMC-RERC F-2-A: REVIEW CHECKLIST**

**MMMC-RERC F-2-B: REGISTRATION AND APPLICATION FOR INITIAL REVIEW AND RESUBMISSION FORM**

**MMMC-RERC F-2-C1: STUDY PROTOCOL ASSESSMENT FORM**

**MMMC-RERC F-2C2: MEDICAL DEVICE ASSESSMENT FORM**

**MMMC-RERC F-2-D: INFORMED CONSENT ASSESSMENT FORM**

**MMMC-RERC F-2-E: NOTICE OF REVIEW**

**MMMC RERC F-2-F: SITE RESOURCES CHECKLIST FOR CLINIC**

**TRIALS OUTSIDE MMMC BY MMMC PERSONEL**

**MMMC-RERC F-2-G: SITE RESOURCES CHECKLIST FOR CLINICAL**

**TRIALS OUTSIDE MMMC BY NON-MMMC PERSONEL**

**MMMC-RERC F-2-H: ACKNOWLEDGEMENT LETTER**

**MMMC-RERC F-2-I: RESUBMITTED STUDY PROTOCOL FORM**