**VII. MANAGEMENT OF QUERIES/COMPLAINTS**

**7.1 Objectives/Scope/Responsibilities**

**7.2 Managing Queries/ Complaints Workflow**

**7.3 Detailed Instruction**

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| Supersedes | Standard Operating Procedure Version 4 |
| Version  | 5 |
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| Approved By | **Dr. Robert Magsino** President |
| Approval Date | 8 February 2019 |

**7.1. OBJECTIVES/SCOPE/RESPONSIBILITIES**

**7.1.1 Objective**

This SOP describes how the MMMC-RERC manages queries and complaints. This chapter describes the documentation, committee action, communication of committee action, and filing of queries and complaints

**7.1.2. Scope**

This SOP applies to all study protocol-related queries and complaint that arise from the conduct of the study.

**7.1.3. Responsibilities**

It is the responsibility of the Administrative Staff to process study related queries and complaints. It is likewise the responsibility of the Administrative Staff to inform the PI, Chair, and member regarding the queries/complaint and to include it in the agenda of the next RERC meeting.

It is the responsibility of the Chair and members to respond and/or make a decision regarding the queries and complaints.

**7.2 MANAGING QUERIES/COMPLAINTS WORKFLOW**

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| **ACTIVITY** | **RESPONSIBILITY** |
| Receives and manages documents submission | Administrative Staff |
| Submits documents to the MMMC-RERC Chair to determine classification of review as expedited or full board | Administrative Staff |
| Reviews submissions classified as expedited or full board review | Chair/ Primary Reviewers/Members |
| Review queries/complaints | Members |
| Communicates results to PI/Participant | Administrative Staff |
| Files the properly coded submission in the Active Study File Cabinet and updates Protocol Database. | Administrative Staff |

**7.3 Detailed Instruction**

**7.3.1 Management of submitted queries or complaints**

1. Communication of queries and complaints, especially from research participants, are major considerations because they provide mechanisms that contribute both to maintaining transparency of MMMC-RERC decision-making processes, as well as empowerment of study participants.
2. MMMC-RERC can also accept communications of queries, notifications, and complaints from other parties provided these communications are relevant to MMMC-RERC oversight.
3. Information reported in this form ***[MMMC-RERC F-7-A: QUERIES, NOTIFICATION AND COMPLAINTS]*** is processed either as a study-protocol-related or non-study-protocol-related communication, as the case may be.
4. If necessary, a letter may be attached to this form by the sending party, but a summary of the nature of communication should still be encoded in this form to allow proper filing of communication.
5. The Administrative Staff logs the communication into the ***MMMC-RERC F- 5-H SUBMISSIONS LOG*** for proper filing and action by relevant MMMC-RERC personnel.
6. Any MMMC-RERC personnel can receive a query or complaint. Action on queries and complaints is managed through the use of ***MMMC-RERC F-7-A: QUERIES, NOTIFICATIONS AND COMPLAINTS.*** This form should be accomplished by any party communicating queries, notifications, and complaints or grievances or information or action by the MMMC-RERC.
7. In case of communication from research subjects or participants, MMMC-RERC personnel can encode the information on their behalf if needed.

**7.3.2 Classification of Review by MMMC-RERC**

1. The sending party must indicate in ***MMMC-RERC F-7-A: QUERIES, NOTIFICATIONS AND COMPLAINTS*** whether or not the communication is study protocol-related or non-study protocol-related.
2. The MMMC-RERC Chair classifies communication for either full board or expedited review depending on the nature of the communication and response needed from MMMC-RERC.
3. Complaints are classified under full board review.
4. For non-study protocol-related queries, reviews and recommendations can be finalized at the level of the MMMC-RERC Chair.

**7.3.3 Review by RERC Chair and Primary Reviewers of Study Protocol-Related Communications**

1. For communications under expedited review, action is finalized at the level of the RERC Chair within **fifteen (15)** calendar days.
2. Communications subject to full board review received within the cut off period of **fifteen (15)** days before the scheduled RERC full board meetings are sent to the Primary Reviewers.
3. The Administrative Staff places the query/notification/complaint in the agenda of the next RERC meeting.
4. The RERC Chair or Primary Reviewers review the information entered in ***MMMC-REC F-7-A: QUERIES, NOTIFICATIONS AND COMPLAINTS***.
5. If necessary, the PI will be contacted to provide clarificatory information.

**7.3.4 Full board review of study-protocol-related participant query or complaint**

1. The Administrative Staff distributes the completed ***MMMC RERC F-7-A: QUERIES, NOTIFICATIONS AND COMPLAINTS*** to Members along with the meeting agenda.
2. The MMMC-RERC deliberates on how best to address the concerns relevant to the query or complaint, and recommends a course of action.
3. The RERC may request information from the PI, invite the PI for clarificatory interview, or require corrective action.

 **7.3.5 Communication of results**

1. The MMMC-RERC responds to queries, notification, and complaints in writing after a course of action of appropriate response is identified whether through expedited or full board review.
2. The PI may be requested to provide additional information or submit additional documents.

 **7.3.6 Files Management**

The Administrative Staff stores the signed documents in the study protocol file folder.

 **RELEVANT FORMS**

 **MMMC RERC F-7-A: QUERIES, NOTIFICATIONS AND COMPLAINTS**