

**Request for Revision of an SOP or Guideline**  
**Form 5.36.1**

Please complete this form whenever a problem or a deficiency in an SOP is identified and submit to the BATMC RERC Coordinator for processing.

<b>SOP or Guideline Code</b> Version 4	<b>SOP or Guideline TITLE</b> BatMC RERC SOP Manual & Standard Forms Manual
<b>Reason for request (citing details of problems or deficiency in current document):</b> Harmonizing SOP with New Phreb standards and internal BatMC RERC policies	
<b>Description of requested changes:</b>  <p style="color: red; margin: 0;"><i><b>SOP Manual for Version 5</b></i></p> Table of Organization of BatMC RERC – for updating of new members History of BatMC RERC – for updating on Level 3 Accreditation SOP 1 Membership : Revision in composition of membership and term of office SOP 2 Officers : Add qualification standard and term limit for RERC Chairperson position SOP3 Independent Consultants : Add provision for former RERC members to be appointed as Independent Consultant if needed SOP 5 Incentives : Insert DOH approved honorarium rates SOP 6 Initial Submission : Introduction of Expedited Review Meeting; Revised Timeline for Expedited and Full Review; Requirement for submission of a Research and Technical Review Clearance to include the Turnitin Plagiarism Check and Proof of Payment of Initial Review Fee; Initial Review Fee Table . Also include in the procedures 2 separate meetings - one for EXPEDITED and one for FULLBOARD review. SOP 8 Expedited Review: Streamlined criteria for classifying protocols for Expedited Review; Added Timeline for Expedited Review SOP 9 Full Review: Streamlined criteria for classifying protocols for Full Board Review; Added Timeline for Full Board Review SOP 10 Exempt: Presentation of Exempted Protocols to Full Board Meeting; Submission of Final Report to RERC of all exempted protocols SOP 12 Review of Medical Device : Changes to policy statement, objective, scope, workflow and format of SOP on review of medical devices SOP 13 Rapid Review : Addition of timelines for initial submission and amendments; edit “Covid 19” term to “acute disease or disaster”; edit title to “Rapid Review of Research Protocols Related to Acute Disease & Other Natural or Man-Made Disasters” SOP 14 Assessment Forms : Revised deadline for submission of forms to Secretariat; Presentation and discussion of Expedited Protocols at Expedited PR Review Meeting SOP 15 Resubmission : Revision in review classification of minor and major modifications; Revision in deadline for resubmission; Add the channel of review for all resub SOP 16 Amendments : Add in Policy Statement review classification for minor & major amendments; Revise definition of minor & major amendments; Add channel of review for all types of amendments SOP 17 Progress : Included sending of Reminder Letters ; Modify Activity on Determination of Type of Review; Indicate channel of review for all Progress reports SOP 18 Deviations/Violations : Revision in workflow with the insertion of the Expedited PR Review	



Republic of the Philippines  
Department of Health, Center for Health Development (CHD) IV-CALABARZON  
**BATANGAS MEDICAL CENTER**  
Batangas City  
**ISO 9001:2015 CERTIFIED**



#### Meeting

SOP 19A SAE/SUSAR : Type of Reviews for On-Site and Off-Site SAE/SUSARs; Deadline for submission of reports

SOP 19B RNE : Expanded definition of RNE; Define Special Meeting as Special Full Board Meeting

SOP 21 Continuing Review : Inclusion of Reminder Letters for Continuing Review

SOP 22 Final Report : Definition of "End of Study"; Clarification of Expedited Review under Step 4

SOP 23 Appeals : Change submission of appeal from 1 month to 30 calendar days

SOP 25 Preparing for a Meeting : Revision to include Expedited PR Review Meeting and Preparation for Two regular meetings in a month

SOP 26 Preparing for Notice of Meeting : Separation of Provisional Agenda for Expedited PR Review Meeting and Full Board Review Meeting

SOP 27 Conduct of Meeting : Separation of regular meetings into Expedited Review and Full board review

SOP 28 Conduct of Special Meeting : Addition of clarificatory meeting in the special meeting

SOP 29 Minutes of Meeting : Add digital copy of minutes

SOP 30 Communication Decisions: Specify Expedited and Full Board Meetings in Policy Statement

SOP 33 Archiving : Revision in retention rules ; Addition of rule in disposal of administrative records

SOP 35 Queries and Complaints : Add in Policy Statement presentation of resolved queries in Full Board Meeting

SOP 36 Writing and Revising SOPs : Correction in SOP Numbering and header of SOP Manual

#### ***Standard Forms Workbook for Version 5***

Form 2.6.1 Protocol Package Checklist - Addition of Result of Turnitin Similarity Check and Proof of Payment if applicable

Form 2.6.5 Non Disclosure Agreement – total revision by Atty Jenn Krystel Zaraspe

Form 2.14.1 Study Protocol Assessment – add "Request for Information" on recommendation portion

Form 2.14.2 ICF Assessment – add "Request for Information" on recommendation portion

Form 3.19.0 SAE/SUSAR/RNE Summary Checklist – add new form for documentary checklists to be submitted

Form 3.17.1 Progress Report – Add information on Stage of Research Study in the checklist

Form 3.22.1 Final Report – Add "Dissemination Plans"

Form 4.26.1 Notice of Meeting – separate discussion points for Expedited PR Review Meeting and Full Board Review Meeting

Form 4.26.2a Agenda of the Expedited PR Review Meeting – revised, separated agenda for Expedited and Full Review Meetings





Form 4.26.2b Agenda of the Full Board Review Meeting – revised, separated agenda for Expedited and Full Review Meetings

Form 4.29.1a Minutes of the Expedited PR Review Meeting – revised, separated minutes of Expedited and Full Review Meetings


Form 4.29.1b Minutes of the Full Board Review Meeting – revised, separated minutes of the Expedited and Full Review Meetings



Form 4.30.0 Notice of Receipt of Study Protocol and Assessment for Review Fees (For Non-Institutional PI-Initiated Protocols)

Form 4.30.2B Letter for Modification – separate points for revision for study protocol and for ICF

	<p style="text-align: center;">             Republic of the Philippines              Department of Health, Center for Health Development (CHD) IV-CALABARZON  <b>BATANGAS MEDICAL CENTER</b>              Batangas City  <b>ISO 9001:2015 CERTIFIED</b> </p> <div style="display: flex; justify-content: flex-end; align-items: center;">   </div>	
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Form 4.33.1 Archiving Notification – Changes made : Inactive and Completed (3years), Clinical Trial (5years or as provided in CTA whichever is longer)  
 Form 4.33.3 Register of Disposed Protocols -Edit “guide”: Inactive and Completed (3years), Clinical Trial (5years or as provided in CTA whichever is longer)

<p style="text-align: center;"><b>Revision Requested by:</b></p> <div style="text-align: center;">               Dinna Perez Remo, CPA           </div>	<p style="text-align: center;"><b>Date: (dd/mm/yyyy)</b></p> <p style="text-align: center;">May 14, 2021</p>
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<p>BATMC RERC Coordinator Comments:</p> <p style="text-align: center;">SOP Manual and Standard Forms Handbook for updating.</p>	
<p>Recommendations by BatMC RERC Coordinator</p> <ul style="list-style-type: none"> <li>✓ Revision requirement confirmed, forward to SOP Team</li> <li>• Request further information (state)</li> <li>• Forward to content expert for opinion</li> </ul>	
<p>Signature</p> <div style="text-align: center;">  </div>	<div style="text-align: center;">  </div>
<p>Name of BatMC RERC Coordinator</p>	<p>Dr. Anne Marie Pineda</p>
<p>Date January 24, 2022</p>	<p>May 14, 2021</p>