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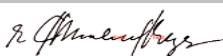

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	<b>OVERVIEW/INTRODUCTION</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

## OVERVIEW / INTRODUCTION

- A. Mission – Vision of Batangas Medical Center
- B. Institutional Organizational Chart
- C. RERC Organization Chart
- D. Establishment and mandate of the Batangas Medical Center – RERC
- E. Principles and Guidelines guiding the Batangas Medical Center – RERC
- F. Brief History of the Batangas Medical Center – RERC

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Authored by:	Batangas Medical Center RERC
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Approved by:	Rhodora Madrid-Reyes MD, FPNA,FPSCOT Chairman 
Approved by:	Dr. Ramoncito C. MagnayeMD,FPCS,FPSGS,MHA  Medical Center Chief II
Approval Date:	June 04, 2021

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>MISSION AND VISION OF BATANGAS MEDICAL CENTER</b>	<b>Version No: 5</b>
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### **VISION**

**The Leading multi-specialty institution working towards a healthy CALABARZON.**

### **MISSION**

As a well-respected, socially accountable, and financially sustainable institution, we provide quality, advanced, and equitable healthcare by strengthening our training and research programs responsive to the needs of a healthy and productive community.

### **QUALITY POLICY**

The Batangas Medical Center is committed to provide quality, advanced and equitable healthcare and related services to all.

We adhere to the legal requirements intended for hospital and improve our training programs to enhance our knowledge, skills, and attitude.

We shall improve our quality and risk based management system for the satisfaction of our clients, personnel and other stakeholders.

### **CORE VALUES**

**I**-integrity

**C**- commitment

**A**- accountability

**R**-respect

**E**-excellence



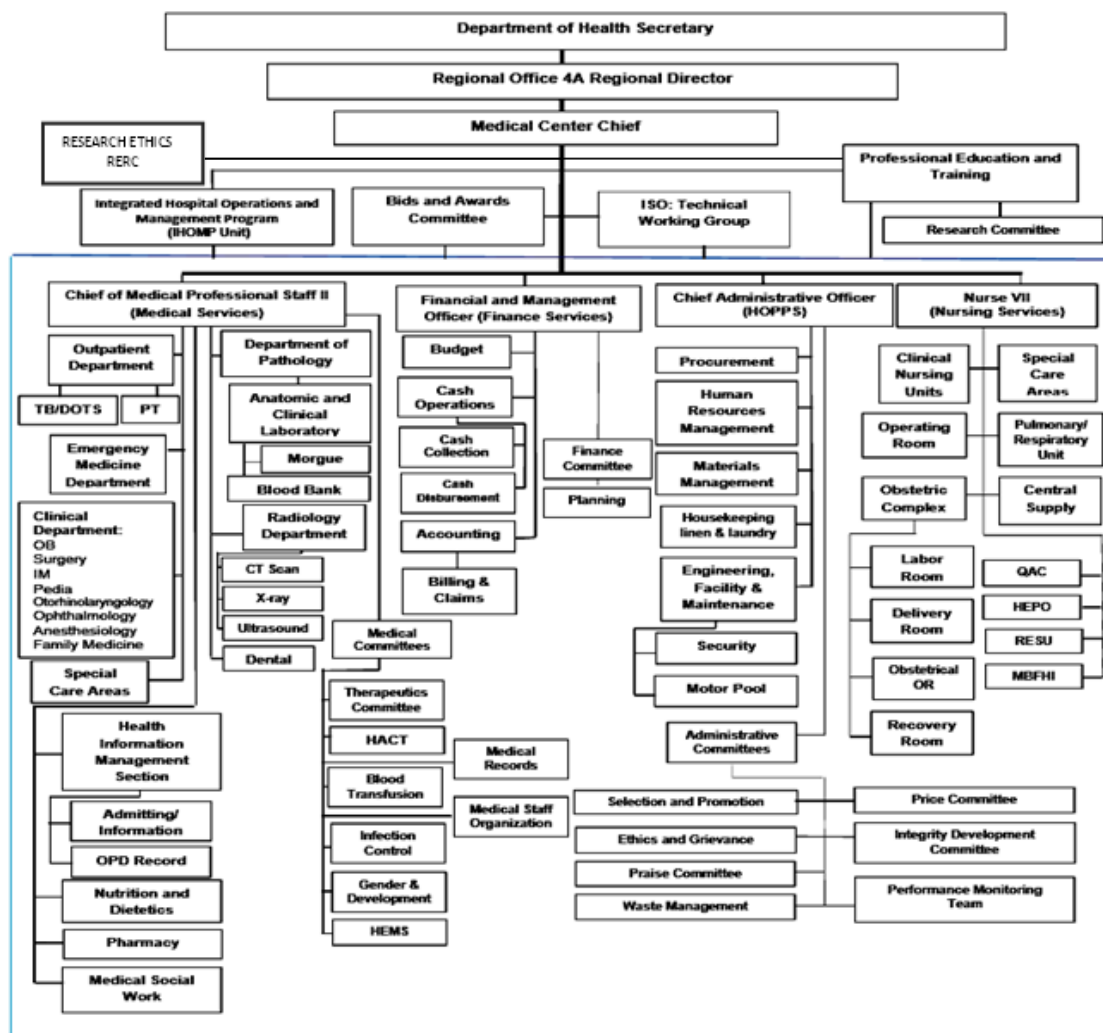
## BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE


### BATANGAS MEDICAL CENTER ORGANIZATIONAL CHART

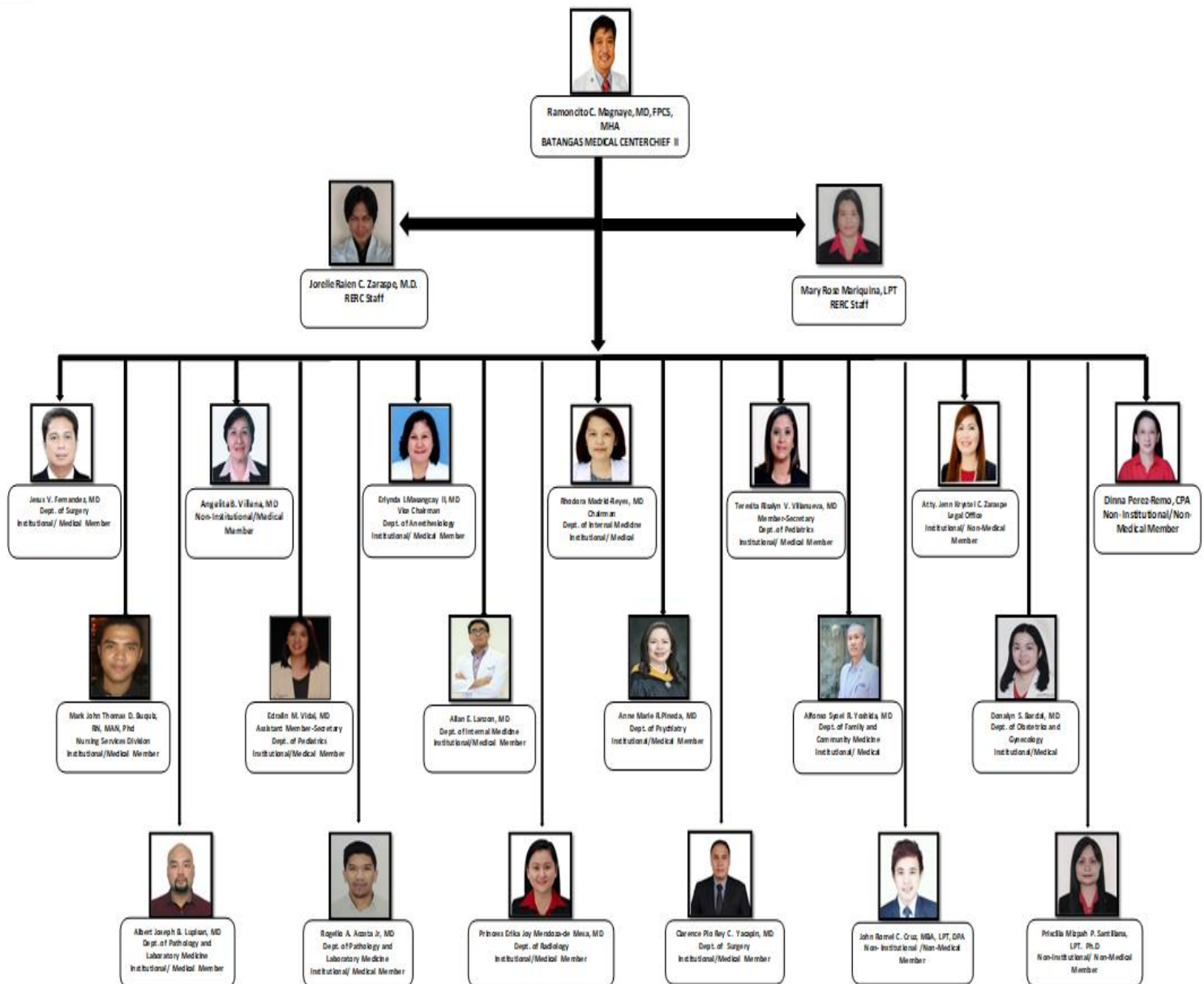
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	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
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	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
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The Batangas Medical Center – RERC is an independent body created by the BATMC under the **Medical Center Chief of the Hospital**, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in health- related research and to provide public assurance of that protection. In accordance with applicable national / international regulations, the BATMC-RERC has the authority to approve, require modifications to, or disapprove research protocols and related documents as well as to ensure compliance with its relevant procedures after approval.

The BATMC-RERC review and monitor health researches that involve:

- BATMC patients, done within the BATMC, or using BATMC facilities, including those initiated by BATMC active, associate active, and visiting staff, residents/fellow in training and other hospital staff
- Pharmaceutical industry sponsored research using BATMC facilities, BATMC patients in cooperation with BATMC active/associate active/visiting staff.
- BATMC-RERC may review health related research protocols from other academic institutions
- BATMC-RERC may review researches referred from the PNHRS, PHREB, DOH, SJREB, industry organizations, other academic institutions on the conditions that the host hospital/institution where the proposal will be done accepts the review of Batangas Medical Center RERC and agrees to abide the rules and regulations that the Batangas Medical Center RERC follows (based on PHREB and FERCAP rules). The other research sites also agree to provide the necessary environment to ensure the safe and ethical conduct of the research, including oversight and stewardship functions as necessary as they agree to monitor procedures that the Committee may deem necessary. These conditions should be written in a document and signed by other hospitals/institutions that accept Batangas Medical Center RERC review.

This SOP provides the Terms of Reference (TOR) that describe the framework for the constitution of the BATMC RERC, the responsibilities and activities of its officers, members, and staff.

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## RESPONSIBILITIES


It is the responsibility of BATMC Medical Center Chief to constitute and establish the BATMC-RERC. The Medical Center Chief is responsible for appointing the BATMC-RERC Chair, Co-Chair, Member-Secretary, Secretariat Staff, and Members. He is also responsible for providing the terms of reference for these appointments in accordance with prevailing hospital policies, guidelines, and regulations.

It is the responsibility of the BATMC-RERC Chair, Co-Chairs, Member-Secretary, Secretariat Staff and Members to study, comprehend, comply and respect the procedures and guidelines set forth by the BATMC – RERC.

It is responsibility of the newly appointed BATMC-RERC Chair and member to read, understand, respect, and sign the required appointment forms at the start of their appointment or reappointment to the RERC. Refusal of any members to sign such agreement may be ground for his/her disqualification from the Committee.

It is the responsibility of newly appointed BATMC-RERC member and the staff to undergo training during the course of his appointment. The existing BATMC-RERC member and staff should continuously update themselves and train on relevant knowledge and skills. The BATMC-RERC Chair shall enjoin BATMC-RERC members and staff to attend trainings/seminars/workshops as needed, and ensure that adequate resources are provided for continuing professional development. Therefore BATMC is responsible for allocating an annual budget for specific trainings and other educational activities for BATMC-RERC member and staff.



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In line with Department of health (DOH) initiative in organizing the DOH research Ethics Committee (DREC) provided for under D.O. 255-1s 2002 dated October 2, 2002, a functional institutional ethics review committee was established for the first time at Batangas Regional Hospital. This was first presented in a meeting held at the office of the Chief of Hospital on April 29, 2004. The meeting was presided by Dr. Belinda Kalaw who acted as the chair in the presence of Dr. Eleanor Gamo, the Chief of Hospital together with other non-hospital personnel including Sr. Ma. Catalina Santos, RGS, Rev. Fr. Ramon M. Manalo, Bro. Camilo C. Cabreros. The agenda during this meeting was the committee's policies, functions and duties and remunerations for non-BRH (Batangas Regional Hospital) members. No subsequent follow up meeting was held.

The Institution Ethics Review committee was again revived in November 19, 2010 by virtue of Hospital Order no. 244 s. 2010 issued by Dr. Renato Dimayuga who was the new Chief of Hospital then. The members of the committee were: Dr. Belinda Kalaw as chairperson, Dr. Angelita Babao-Villena as co-chair, Dr. Teresita Risalyn Villanueva as Secretary, Dr. Ramoncito Magnaye and Ms Mary Eileen Carandang. The members who were not personnel of BRH were Atty. Gregorio Moraleja, Miss Rona Tadeja, Mr. Camil Cabreros and Marilou Cua.

The Institutional Research Committee was recognized in December 2011. And due to the illness of the Chair, Dr. Belinda Kalaw, the leadership was turned over to Dr. Angelita Babao Villena as Chair and a new membership lineup was appointed. There were physicians added to the committee as representatives of their Departments namely – Dr. Onofre Concepcion for Anesthesia, Dr. Rhodora Madrid Reyes for Internal Medicine. The layperson included was Ms. Anita Aguirre. The previous non-BRH members did express interest in renewing their membership. During a meeting it was discussed the following agenda that the (1) tenure of office should be 2 years (2) two meetings were to be scheduled to review researches of resident physicians during the months of March and November (3) it was also mentioned that only non-BRH members will receive a 2000 pesos per meeting per year as remuneration (4) the training office and Office Secretary will act as secretariat.

The committee followed the guidelines set by the National Ethical Guidelines for Health Research 2006 as stated:

1. To evaluate the conduct of research in accordance with provisions of the Helsinki Declaration and the NEC Guidelines on the conduct of Biomedical research in the Institution.
2. To determine the acceptability of specific research proposals based on the organizational commitments and regulations, local laws, standards of professional conduct and practice, community mores, values and needs.

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3. To promote research integrity by identification and resolution of conflicts of interest.
4. To establish appropriate mechanism in all stages of the research.

This reorganization was affirmed by virtue of Hospital Order no.16 – As. 2012 issued by Dr. Arceli Hernandez who was then acting as Officer in Charge and Chief of Hospital on January 20, 2012. On the same day, a meeting was presided by Dr. Angelita Babao-Villena who reviewed the background, membership, policies and guidelines. It was agreed upon that training residents should pass their research protocol to the hospital's research committee which will recommend the review to the Hospital

Research Ethics committee specifically those researches involving human subjects. Only research proposals of residents will be entertained for review.

In February 7, 2013, another meeting was held. The membership was reviewed. Dr. Jesus Fernandez replaced Dr. Ramoncito Magnaye as representative for the Dept. of Surgery. The honorarium for the laypersons was raised to 2000 pesos per person for a total of 16k annually for the two laypersons. The budget for the year was laid out including expenses for communication and secretary. Mrs. Anita Aguirre (layperson) tendered her resignation as member.


On April 18-19, 2013 Dr. Jess Fernandez attended a seminar on Research Ethics hosted by the Health Research and Development Consortium Region IVA and held at the De La Salle Health Research Institute.

On April 14, 2014, another meeting was held to recognize the committee due to the retirement of Dr. Babao-Villena, the chairperson and Dr. Onofre Concepcion. A member of the IERC– Atty Moraleja had an untimely demise, hence a replacement for the position of lawyer for the committee was discussed.

Also it was the unanimous decision of the group that Dr. Rhodora Madrid-Reyes, be the new chairperson who was subsequently appointed by the Medical Center Chief II Dr. Ramoncito Magnaye. It was proposed that the committee should apply for accreditation as it has already reviewed several researches.

Over the years, members attended various trainings on research ethics to improve its expertise and to standardize its operating policies.

The Philippine Health Research Ethics Board (PHREB) granted the BatMC RERC a provisional Level 2 accreditation in year 2016, after which a three (3) year accreditation was granted for the period 2017 to 2019. In March 2021, BatMC RERC was granted a one (1) year Level 3 accreditation paving the way

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for the acceptance of clinical trials in the hospital. On the same year, the BatMC RERC received recognition from the Forum for Ethical Review Committees in Asia and the Pacific (FERCAP).

Further, in 2019, by virtue of the Department of Health Administrative Order 2019-0049, the BatMC RERC started participating in the Single Joint Review Ethics Board.

#### **BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE MEMBERS (through the years).**

##### **2004**

1. Dr. Belinda Kalaw – chair
2. Sr. Mary Catalina Santos, RGS –member
3. Rev. Fr. Ramon M. Manalo – member
4. Bro. Camilo C. Cabrerros – member

##### **2010 – reactivation**


1. Dr. Belinda Kalaw – chair
2. Dr. Angelita Babao – Villena as co-chair
3. Dr. Teresita Risalyn Villanueva as secretary
4. Dr. Ramoncito Magnaye
5. Mary Eileen Carandang
6. Atty. Gregorio Moraleja
7. Rona Tade
8. Bro. Camil Cabrerros
9. Marilou Cua

##### **2011-2013**

1. Dr. Angelita Villena – chair
2. Dr. Risalyn Villanueva
3. Dr. Onofre Concepcion
4. Dr. Rhodora Madrid Reyes
5. Anita Aguirre
6. Atty. Gregorio Moraleja

##### **2014**

1. Dr. Rhodora M. Reyes – chair
2. Dr. Risalyn Villanueva - secretary
3. Dr. Angelita Villena
4. Dr. Jesus Fernandez
5. Dr. Erlynda Masangcay II
6. Eileen Carandang
7. Dinna P. Remo, CPA

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## 2015 – 2016


1. Dr. Rhodora M. Reyes – Chair
2. Dr. Risalyn Villanueva – Member Secretary
3. Dr. Angelita Villena
4. Dr. Jesus Fernandez
5. Dr. Erlynda Masangcay II – Vice Chair
6. Mr. Gueven Asuncion, RN
7. Dinna P. Remo, CPA
8. Atty. Jenn Krystel Zaraspe

## 2017 – 2018

1. Dr. Rhodora M. Reyes – Chair
2. Dr. Erlynda Masangcay 11 – Vice Chair
3. Dr. Risalyn Villanueva – Member Secretary
4. Dr. Jesus Fernandez
5. Dr. Angelita Villena – Medical, Non Affiliated
6. Mark John Thomas Buquiz, RN, RM, MAN, LPT, Phd
7. Atty Jenn Krystel Zaraspe – Non Medical, Affiliated
8. Dinna P. Remo, CPA – Non Medical, Non Affiliated

## 2019 – 2020

1. Dr. Rhodora M. Reyes – Chair
2. Dr. Erlynda Masangcay 11 – Vice Chair
3. Dr. Risalyn Villanueva – Member Secretary
4. Dr. Edralin M. Vidal – Asst. Member Secretary
5. Dr. Rogelio A. Acosta
6. Dr. Jesus Fernandez
7. Dr. Alan E. Lanzon
8. Dr. Albert Joseph B. Lupisan
9. Dr. Anne Marie Pineda
10. Dr. Annie Valdez
11. Dr. Donalyn S. Vidal
12. Dr. Alfonso Syoei R. Yoshida
13. Dr. Angelita Villena – Medical, Non Affiliated
14. Mark John Thomas Buquiz, RN, RM, MAN, LPT, Phd
15. Atty Jenn Krystel Zaraspe – Non Medical, Affiliated
16. Dinna P. Remo, CPA – Non Medical, Non Affiliated

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## 2021

### *Chairperson :*

1. Dr. Rhodora M. Reyes – Dept. of Internal Medicine (Neurology)

### *Vice Chairperson:*

2. Dr. Erlynda Masangcay 11 – Dept. of Anesthesia

### *Member- Secretary*

3. Dr. Risalyn Villanueva – Dept. of Pediatrics

### *Assistant Member-Secretary*

4. Dr. Edralin M. Vidal – Dept. of Pediatrics

### *Member – Medical, Affiliated*

5. Dr. Rogelio A. Acosta – Dept. of Pathology & Laboratory Medicine
6. Dr. Princess Erika Joy M. De Mesa – Dept. of Radiology
7. Dr. Jesus Fernandez – Dept. of Surgery
8. Dr. Allan E. Lanzon – Dept. of Internal Medicine (Rheumatology)
9. Dr. Albert Joseph B. Lupisan – Dept. of Pathology & Laboratory Medicine
10. Dr. Anne Marie Pineda – Dept. of Psychiatry
11. Dr. Donalyn S. Vidal – Dept. of Obstetrics & Gynecology
12. Dr. Clarence C. Yacapin – Dept. of Surgery
13. Dr. Alfonso Syoei R. Yoshida – Dept. of Family and Community Medicine
14. Mark John Thomas Buquiz, RN, RM, MAN, LPT, Phd – Nursing Services Division

### *Member - Non-Medical, Affiliated*


15. Atty. Jenn Krystel Zaraspe – Legal Office

### *Member - Medical , Non-Affiliated*

16. Dr. Angelita Villena – Obstetrics & Gynecology

### *Member - Non-Medical, Non-Affiliated*

17. John Rommel Cruz, MBA, LPT, DPA
18. Dinna P. Remo, CPA
19. Priscilla Mizpah Santillana , LPT, Phd

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>HISTORY OF THE STANDARD OPERATING PROCEDURES OF BATANGAS MEDICAL CENTER RERC</b>	<b>VERSION: 5</b>
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#### HISTORY OF STANDARD OPERATING PROCEDURES (SOP)

The BATMC RERC started to function in 2015 using the DOH TEMPLATE for Standard Operating Procedures in 2016. Members underwent basic research ethics training and Good Clinical Practice Training. Research protocols were now submitted to the Committee and the RERC applied to PHREB for accreditation to Level 2. The Members then, worked on the SOP and the RERC got a provisional accreditation for one year from 2016-2017. RERC added the position of a Vice Chairman as one of the officers of the Committee. In 2017, the BatMC RERC submitted the requirements as stipulated in the PHREB Recommendations for Corrective Actions. Submitted revisions were as follows: (1) Elaboration of the role of the Independent Consultants, (2) Improvement in the review process by adherence to the Guidelines of PHREB and other international guidelines, (3) Minor revisions in the Form Templates that being used (4) addition of forms like the Continuing Review Form and (5) BatMC RERC participation in Single Joint Review Ethics Board (SJREB).

In September 2017 accredited as PHREB granted Level 2 accreditation to BatMC RERC for the period 2017 to 2019.

In August 2019, before the accreditation expired, members then decided to apply for a Level 3 accreditation because of the increase in the number of research protocols and the quality and varied type of research proposals being submitted. A number of drug companies had started to inquire in the capability of the BatMC RERC to review clinical trial protocols. Since the hospital has increased the number of medical specialists, the need for clinical trials and more complicated research became more evident. All the members need more training to be able to handle these ethics work.

On March 3, 2021, the Philippine Health Research Ethics Board granted the BatMC RERC a one (1) year Level 3 Accreditation paving the way for acceptance of clinical trials. On the same year, the BatMC RERC received recognition from the Forum for Ethical Review Committees in Asia and the Pacific (FERCAP).

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## 1. Policy Statement

The selection of RERC members shall be through a nomination process that ensures representation of different disciplines (medical and non-medical members), sectors (male and female, older and younger age groups) and member/s who are not affiliated with the institution. The Medical Center Chief has the final authority to appoint RERC members.

The members shall be appointed and serve for a period of one (1) year, renewable yearly but not exceeding six (6) consecutive years. Members may be re-appointed as regular members after a break of one (1) year. Members may likewise be appointed as Independent Consultants after their term as regular members.

To ensure continuity, development and maintenance of expertise of the RERC, there will be a transition year for regular members who would have served five consecutive years.

At the start of the 6th year of any regular member, nominee for replacement must be submitted and if appointed will be considered as junior member with two (2) months mentoring period. This will ensure sufficient time is given for the incumbent to turnover responsibilities, if any, and provide guidance on the work and functions that go with the position. Junior members would have the same responsibilities, functions and privileges as incumbent members of the RERC.


The role of the medical member is to focus on the review of the study protocol, while the role of the non medical member is to focus on the review of the informed consent process. The non-medical members serves as the voice of the research participant in a Research Ethics meeting. They along with the medical members have to ensure scientific soundness as well as ethical validity.

The roles of the affiliated and non-affiliated members in terms of the review are similar, however, the non-affiliated member is expected to provide an external perspective to ensure the independence of the position of BatMC RERC, even from possible bias posed by its own institution that may impact rights, safety, and well being of human subjects in research.

## 2. Objective/s of the Activity

Selection and Appointment of RERC Members aims to ensure that the composition of the RERC complies with the international, national and institutional guidelines and that appropriate expertise is taken into consideration.



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### 3. Scope

This SOP applies specifically to the selection of members of the RERC. This SOP begins with the call for nominations and ends with the filing of appointment documents and Curriculum Vitae of RERC members in the membership file.

### 4. Workflow

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1 :</b> <i>Nomination of potential new members.</i>	<i>RERC Chair and Members</i>
<b>Step 2 :</b> <i>Submission of names of potential members to the Chair for final deliberation and shortlisting.</i>	<i>Member Secretary</i>
<b>Step 3 :</b> <i>Endorsement of potential members to the Medical Center Chief</i>	<i>RERC Chair</i>
<b>Step 4 :</b> <i>Receipt of Appointment Letters for new members.</i>	<i>Member Secretary</i>
<b>Step 5 :</b> <i>Forwarding Appointment Letters to new Members with Confidentiality and Conflict of Interest Disclosure Agreement.</i>	<i>RERC Staff</i>
<b>Step 6 :</b> <i>Submission of signed Appointment Letters, Confidentiality and Conflict of Interest Disclosure Agreement and Curriculum Vitae (CV)</i>	<i>New member/s</i>
<b>Step 7 :</b> <i>Filing of appointment documents and CVs in the membership file (SOP on Managing Active Files (SOP#32)</i>	<i>RERC Staff</i>


### 5. Description of Procedures

#### Step 1 – Nomination of potential new members:

The Chair informs the RERC members regarding the need for new member/s. The call for nominations should be based on qualifications and requirements stated in the international, national and institutional policies. Members submit names, preferably with Curriculum Vitae of possible new members to Member Secretary for consolidation.

#### Step 2 – Submission of names of potential member/s to Chair:



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The Member Secretary submits the final list of nominees with summary of credentials for reference. The RERC Chair deliberates nominees based on scientific and research ethics knowledge and expertise, as well as willingness to volunteer time and effort to perform the responsibilities and attend trainings as member of the RERC.

### **Step 3 – Endorsement of potential members to the Medical Center Chief:**

The REC Chair recommends a list of potential members based on requirements and qualifications and the RERC Staff submits the list to the Medical Center Chief. The Medical Center Chief has the final authority to appoint regular members.

### **Step 4 – Receipt of Appointment Letters for New Members:**

The RERC Member Secretary receives the appointment papers from the Medical Center Chief and informs the Chair accordingly. The *Appointment Letters (Form 1.1.1)* specify the conditions of the appointment including the roles and responsibilities.

### **Step 5 – Forwarding of Appointment Letters to New Members:**

The Chair signs the appointment papers as noted and dated and then instructs the RERC staff to forward the *Appointment Letter (Form 1.1.1)* together with the *Confidentiality and Conflict of Interest Disclosure Agreement (Form 1.1.2)* to the concerned new member.

### **Step 6 – Submission of signed Appointment Letters, Confidentiality and Conflict of Interest Disclosure Agreement and Curriculum Vitae :**


The new REC member/s submits the signed *Appointment Letter (Form 1.1.1)*, and *Confidentiality and Conflict of Interest Disclosure Agreement (Form 1.1.2)* and *Curriculum Vitae (Form 1.1.3)*.

### **Step 7 - Filing of appointment documents and CVs and signed Agreements in the membership file:**

The RERC Staff files the appointment documents in the membership file. *See SOP Management of Active files (4SOP 32)*.

#### **5.1 Requirement for Membership**

1. The BatMC RERC shall be composed of thirteen (13) regular members at all times. Junior Members will be added when there are regular members serving on their 6th

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consecutive year. Junior members will have the same responsibilities, function and privileges as that of the incumbent members of RERC.


There should be at least one (1) but not to exceed two (2) representative member for each of the Training Departments with accreditation from their respective medical societies. At all times, the following major departments must be represented : Internal Medicine, Obstetrics & Gynecology, Pediatrics and Surgery.

There should be one (1) representative member from the Nursing Services. There should be at least one (1) Lawyer either affiliated or non-affiliated. There should be two (2) non-medical non-affiliated regular members at all times.


- Membership shall be multi-disciplinary and multi-sectoral to ensure diverse background and experience.
- Membership shall include persons whose primary concerns are in medical science, with at least one pediatrician member, at least one non-medical or non-scientific member and at least one non affiliated member.
- Relevant expertise may include medicine and research, social or behavioral science, law, philosophy, environmental science and public health. It is recommended that the RERC should include a person who will represent the interest and concerns of the community.
- The RERC shall aim for gender balance in its membership with equal representation of men and women members in order to promote gender sensitivity in its review procedures.
- The RERC shall have representatives from both the older and younger generations.
- The RERC shall adhere to quorum requirements as defined in international and national guidelines for RERCs that review health research (50% plus one) . When reviewing clinical trials involving children or pediatric patients, a pediatrician or child development specialist shall be present during its board meeting.

## 5.2 Responsibility of Members

- Members are selected based on their good moral character and personal capacities, their ethical and/or scientific knowledge and expertise, as well as their willingness to dedicate their time and effort to perform their functions in the RERC.

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2. Members shall have prior training in Good Clinical Practice, research methodology and research Ethics, or should be willing to undergo such training during their membership.
3. Members shall disclose in writing and verbally state during meetings any financial, professional or personal interest or involvement in a project or proposal under consideration, which is in conflict with their function as a reviewer.
4. Members shall submit their curriculum vitae, properly signed and dated and update them at least once every two years.
5. Members will be required to sign a confidentiality/conflict of interest agreement at the start of their term. The agreement should cover all applications, meeting deliberations, information on research participants and related matters. The Secretariat/ Administrative staff is likewise expected to sign a similar document. The RERC shall decide on how to manage specific conflicts of interest of members related to their participation in committee deliberations/actions regarding a particular protocol covered by the provisions of the Confidentiality/Conflict of Interest Agreements.
6. Participation in the conduct of study protocol review and discussion during RERC meetings.
  - Review, discuss and consider research proposals submitted for evaluation; act as Primary Reviewer
  - Assess serious adverse event reports and recommend appropriate action
  - Review progress reports and monitor ongoing studies as appropriate
  - Evaluate final reports
  - Maintain confidentiality of the documents and deliberations during RERC meetings
  - Declare any conflict of interest
  - Participate in continuing education activities in health research and ethics
  - Non Medical Members reviews the ethical considerations in the conduct of the research which includes: social value, vulnerability issues, risk vs benefit, measures to mitigate risks, privacy and confidentiality and the informed consent process and forms. Non-medical members may review the ICF for clinical trials; however, they cannot review SAE's and SUSARs."

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7. Junior Members will be shadowing the assigned mentors and observing the RERC meetings for a period of 2 months after which the junior member will be tasked to review study protocols, submit assessment forms and participate in the discussion and deliberations and cast votes during RERC meetings.

**5.3 Conditions of Appointment of Members :** All RERC members must be willing to -


1. To make public his/her full name, profession, and affiliation as an RERC member
2. Disclose all financial accountability, reimbursement for work and expenses, related to their work in the Batangas Medical Center RERC that shall record and publicly disclose its financial records upon request.
3. All RERC members shall sign the Confidentiality/Conflict of Interest Agreements regarding meeting deliberations, applications, information on research participants, and related matters.

**5.4 Resignation, Disqualification, and Replacement of Members :**

1. Members may resign their positions by submitting a letter of resignation to the Chair and endorsed to the Medical Center Chief.
2. Members may be removed from the committee by disqualification for valid reasons as determined by majority vote of the committee members.
3. Members who have resigned or have been disqualified may be replaced by following the nomination and appointment procedures previously stated.
4. The terms of replacement shall be limited to the remaining term of the member that he/she has replaced.

**5.5 Terms of Office**

1. The appointing authority shall indicate in the appointment letter the RERC's functions, terms of office, scope of work, conditions of appointment, system of replacement or recall, and compensation, if any.
2. The members shall be appointed and serve for a period of one (1) year, renewable yearly but not exceeding six (6) consecutive years. Members may be re-appointed as regular members after a break of one (1) year. Members may likewise be appointed as Independent Consultants after their term as regular members.

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3. The RERC shall adopt some mechanism for rotation of its membership roster, to enable participation of new members with fresh outlook and approaches, but it shall also strive to ensure continuity, the development and maintenance of expertise.

#### 6. Forms:

- Form 1.1.1 Appointment Letter Template
- Form 1.1.2 Confidentiality and Conflict of Interest Disclosure Agreement <members>
- Form 1.1.3 Curriculum Vitae Template

#### 7. History of SOP

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
1	2015 October	Rhodora M Reyes, MD	First draft
2	2016	Rhodora M Reyes, MD	No change
3	2017 February	Rhodora M Reyes, MD	No change
4	2020 October	Erlynda I. Masangcay II, MD Dinna P. Remo, CPA	Adopted new Phreb SOP format  Amended member's term of office from 2 to 1 year, renewal from 3 to 6 years  Change composition from 9 to 17 members  Change Form Number of Appointment Letter, Confidentiality & COI Disclosure Agreement, Curriculum Vitae Template
5	2021 June	Dinna P. Remo, CPA	Revision in composition of membership Introduction of concept of Junior Member Clarification in Term of Office

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## 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*


*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

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## 1. Policy Statement

The ethics review committee shall have a Chair, Vice-Chair, Member-Secretary and Assistant Member-Secretary who shall be selected among the members who have been with the committee for, at least, one year. However, for Chair position, candidate must have been a regular member of the RERC for at least three (3) years. Chairmanship must not exceed three (3) consecutive years. The Chair is appointed by the Medical Center Chief. The other officer posts are selected by the appointed Chair.

## 2. Objective/s of the Activity

This activity aims to ensure that the RERC officers are qualified and are selected in a transparent manner in conformity with institutional policy and practice.

## 3. Scope


The scope of this SOP includes the selection of Chair, Vice-Chair and Member-Secretary and Assistant Member-Secretary. It starts with the call for a special meeting to select the concerned officers and ends with the filing of appointment documents of the officers

## 4. Workflow

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1 :</b> <i>Appointment of new RERC Chair</i>	<i>Medical Center Chief</i>
<b>Step 2 :</b> <i>Appointment of RERC officer positions</i>	<i>RERC Chair</i>
<b>Step 3 :</b> <i>Signing of conformity on appointment documents</i>	<i>RERC Chair, Vice Chair, Member Secretary, Assistant Member Secretary</i>
<b>Step 4 :</b> <i>Filing of appointment documents</i>	<i>RERC Staff</i>

## 5. Description of Procedures

**Step 1 – Appointment of new RERC Chair :**

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The BatMC Medical Center Chief appoints the RERC Chair among the roster of the medical consultants and officers of the institution. An *Appointment Notice of RERC Officer (Form 1.2.1)* is issued to the selected Chair.

#### **Step 2 – Appointment of RERC officer positions:**

The RERC Chair deliberates and select members who will hold officer post, issuing *Appointment Notice of RERC Officer (Form 1.2.1)* that contains the role and responsibilities of the specific officer position and the corresponding term of office.

#### **Step 3 – Signing of conformity on appointment documents:**

The RERC staff notifies the officers of their appointments and the need to sign the conforme. The concerned officers forthwith report to the RERC office to sign the conforme documents.

#### **Step 4 – Filing of appointing documents:**

The RERC Staff files the appointment papers accordingly (*see SOP for Management of Active Files (4SOP 32)*).

#### **5.1 Responsibilities of the RERC Chair**


- Presides over the RERC meetings and is directly reporting to the Medical Center Chief
- Prepares an annual report summarizing RERC activities and decision outcomes
- Ensures sufficient financial and administrative support for RERC operations
- Monitors available training/s related to research ethics for the continuing education of RERC members
- Represents the RERC interests within the hospital administration
- Represents the RERC to the external organizations and entities
- Principally responsible for the classification of study protocols received and assignment of Primary Reviewers

#### **5.2 Responsibilities of the RERC Vice Chair**

- Presides over meetings in the absence of the Chair
- Classifies study protocols and assign Primary Reviewers in the absence of the Chair
- Performs other duties as designated by the Chair

#### **5.3 Responsibilities of the Member – Secretary**



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- Supervises the RERC Staff
- Calendars meetings, takes the minutes and releases notice of meetings to all members
- Ensures good RERC documentation
- Ensures overall RERC compliance with good clinical practice
- Classifies study protocols and assign Primary Reviewers in the absence of the Chair and Vice Chair

#### 5.4 Responsibilities of the Assistant Member – Secretary


- Performs all duties of the committee secretary in the absence of the Member-Secretary
- Classifies study protocols and assign Primary Reviewers in the absence of the Chair, Vice Chair and Member-Secretary
- Assists in the designated duties of the Member-Secretary

## 6. Forms:

Form 1.2.1 Appointment Notice of RERC Officer Template

## 7. History of SOP

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
1	2015 October	Rhodora M Reyes, MD	First draft
2	2016	Rhodora M Reyes, MD	No change
3	2017 February	Rhodora M Reyes, MD	No change
4	2020 October	Erlynda I. Masangcay II, MD Dinna P. Remo, CPA	Adopted new Phreb SOP format Addition of position for Assistant Member Secretary Change Form Number of Appointment Notice of RERC Office Template
5	2021 June	Dinna P. Remo, CPA	Added qualification standard and limit to tenure of RERC Chair

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## 8. References

*World Medical Association Declaration of Helsinki, 2013*

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### 1. Policy Statement

The RERC shall maintain a Roster of Independent Consultants who may be called upon when their expertise is needed for study protocols under review. He/she need not be affiliated with the institution.

The RERC Chair determines the external expertise requirements and sends invitations, upon prior approval of the Medical Center Chief, to various professionals with specific scientific expertise to be part of the BatmC RERC Roster of Independent Consultants representing expertise not present in the current RERC composition.

The Medical Center Chief, for special purpose and on his discretion, may invite as Independent Consultants, former members of the RERC to guide and provide advice to the current RERC composition regarding past practices, ensure smooth transition within the team, participation in special projects and other matters on an as-needed basis.

### 2. Objective/s of the Activity


This activity aims to ensure that the appointment of independent consultants conforms with institutional practice and complements the pool of expertise in the RERC.

### 3. Scope

This SOP specifically pertains to the selection and designation of independent consultants in the review of research protocols of the RERC. This SOP begins with the identification of the study that requires an independent consultant and ends with the inclusion of the name of the Independent Consultant in the pool of consultants.

### 4. Workflow

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1:</b> Identification of the study that requires an independent consultant	Primary Reviewer, Member-Secretary, or Chair
<b>Step 2:</b> Identification of the independent consultant	Primary Reviewer, Member-Secretary, or Chair

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	<b>CHAPTER 1 STRUCTURE and COMPOSITION SOP 03 Appointment of Independent Consultants</b>	<b>Version No: 5</b>
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<b>Step 3: Invitation of the independent consultant</b>		
<b>Step 4: Receipt of the Appointment of independent consultant</b>		<b>Chair</b>
<b>Step 5: Receipt of the Signed conflict of interest disclosure and confidentiality agreement</b>		<b>RERC Staff</b>
<b>Step 6: Inclusion in the pool of independent consultants</b>		<b>RERC Staff</b>
<b>Step 7: Filing of appointment documents and CVs in the Roster of Independent Consultants file (SOP on Managing Active Files (4SOP32))</b>		<b>RERC Staff</b>

## 5. Description of Procedures

### Step 1 - Identification of the study that requires an independent consultant:

Either the Primary Reviewer, Member-Secretary, or Chair identifies the study that requires an expertise necessary in the review of a research proposal and that may not be provided by the current members of the RERC.

### Step 2 - Identification of the independent consultant:


The Chair refers to the roster of specialists in the institution or in other institutions for the necessary expertise and selects the appropriate expert. S/he instructs the RERC staff to prepare the letter of invitation.

### Step 3 - Invitation of the independent consultant:

The RERC Staff prepares a *Letter of Invitation (Form 1.3.1)* containing the Terms of Reference for signature of the Chair and sends this to the identified expert. The letter of invitation contains a section for acceptance of the invitation.

### Step 4 - Appointment of independent consultant:

Upon receipt of the acceptance of the invitation, the RERC Staff prepares a *Letter of Appointment (Form 1.3.2)* for signature of the Chair and sends the appointment to the independent consultant together with the Confidentiality and Conflict of Interest Disclosure Agreement (1.3.3).

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**Step 5 - Receipt of the signed conflict of disclosure and confidentiality agreement:**

The staff receives the signed Confidentiality and Conflict of Interest Disclosure agreement and files this in the appropriate folder.

**Step 6 - Inclusion in the pool of independent consultants:**


The RERC Staff enters the name of the new independent consultants in the appropriate database containing name, expertise, institution and date of appointment.

**Step 7 - Filing of appointment documents and CVs and signed Agreements in the file of Roste of Independent Consultants :**

The RERC Staff files the appointment documents in the file of the Roster of Independent Consultants. *See SOP Management of Active Files (4SOP 32).*

**5.1 Responsibilities of Independent Consultant**

1. The RERC Secretariat provides study protocol documents to the concerned consultant for review. Review must focus on :
  - Scientific procedures and methodology
  - Any new information about the disease/research topic and the proposed interventions
  - Benefits and Risks of the intervention and how to mitigate the risks
2. The consultant must complete the assessment form to be reviewed by the RERC at the time the study is reviewed.
3. The consultant may attend the RERC meeting, present his/her assessment, and participate in the discussion but without the right to vote. The report becomes a permanent part of the study file.
4. The Non Medical Consultant reviews the ethical considerations in the conduct of the research which includes: social value, vulnerability issues, risk vs benefit, measures to mitigate risks, privacy and confidentiality and the informed consent process and forms. Non-medical consultants may review ICF of clinical trials, however, they cannot review SAE's and SUSARs.
5. The consultant will be given an honorarium.

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## 5.2 Termination of Services


1. Consultant's services may be terminated by either the consultant or by the Batangas Medical Center RERC.
2. Upon termination of the consultant's services, the RERC Staff shall ensure that all the necessary documentation related to the Independent Consultant is filed with the other administrative documents.

## 6. Forms:

- Form 1.3.1 Letter of Invitation <independent consultant>  
Form 1.3.2 Appointment Letter <independent consultant>  
Form 1.3.3 Confidentiality and Conflict of Interest Disclosure Agreement <independent consultant>

## 7. History of SOP

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
1	2015 October	Rhodora M Reyes, MD	First draft
2	2016	Rhodora M Reyes, MD	No change
3	2017 February	Rhodora M Reyes, MD	No change
354	2020 October	Erlynda I. Masangcay II, MD Dinna P. Remo, CPA	Adopted new Phreb SOP format  Addition of Appointment Letter (Form 1.3.2)  Change Form Number of Letter of Invitation and Confidentiality and COI Disclosure Agreement
5	2021 June	Dinna P. Remo, CPA	Revise policy statement to include appointment of former RERC members

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		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

## 8. References

*World Medical Association Declaration of Helsinki, 2013*

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## 1. Policy Statement

The continuing education and training of RERC members and staff will ensure that members and staff are knowledgeable and in harmony with the updated international, national and institutional guidelines.

It is the responsibility of all BatMC RERC members and staff to undergo training during the course of their appointment and to continuously update themselves and train on relevant knowledge and skills. The RERC Chair shall enjoin all members and staff to attend trainings / seminars / workshops as needed, and ensure that adequate resources are provided for continuing professional development. Therefore, Batangas Medical Center is responsible for allocating an annual budget for the specific trainings and other educational activities for BatMC RERC members and staff.

## 2. Objective/s of the Activity

This SOP describes and provides the guidelines and procedures, templates and forms that are related to the training of RERC members and staff to ensure training needs and requirements of accrediting bodies are met.


## 3. Scope

This SOP applies specifically to the process of providing training to RERC members and staff. This SOP begins with the provision for training and ends with the filling of training records of RERC members in the membership file.

## 4. Workflow

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1:</b> Set training requirements	RERC Chair
<b>Step 2 :</b> Find available trainings, seminars, lectures or workshops	RERC Chair Member Secretary
<b>Step 3 :</b> Signify intention to attend training or Chair instructs member/s to attend	RERC Chair Members and Staff
<b>Step 4 :</b> Attend training and keep the Training Record	Members and Staff
<b>Step 5 :</b> Store and update Training Record in BatMC membership file. (SOP on Managing Active Files (4SOP32)	RERC Staff



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		<b>Date of Effectivity:</b> June 04, 2021

## 5. Description of Procedures

### Step 1 – Set training requirements:

The Chair periodically reviews compliance with training requirements for RERC members and staff. The following are required courses:

- BatMC RERC Standard Operating Procedures (*initial mandatory in-house training*)
- Basic Research Ethics and Good Clinical Practice (GCP) (*initial mandatory training*)
- Continuing Ethics Education
- Declaration of Helsinki
- CIOMS
- Ethical Guidelines
- Relevant laws and regulations
- Relevant developments in science, health and safety, etc
- Other educational activities on international trends including international specialists' meetings organized for the exchange of experiences and information

### Step 2 – Find available trainings, seminars, lectures or workshops:

The Chair gets information about training courses, workshops, conferences, etc which are periodically announced on websites, and various media channels and selects the ones most appropriate.


### Step 3 – Signify intention to attend training or Chair instructs member/s to attend:

Once an offered training has been identified, the Chair or member or staff files request for possible participation and request for funds to cover registration fees and travel allowances. *Training Referral Request Form (Form 1.4.2)* is accomplished and submitted with supporting documents, including but not limited to Registration Form and Program at least one (1) month before the training date. Chair recommends and endorses the participation to the Medical Center Chief for his final action.

### Step 4 – Attend training and keep the Training Record:

The member or staff attends the training and submits proof of attendance to the Chair, such as Certificate of Participation and official receipt for paid training courses. Attendees are encouraged to echo their experiences and learnings during regular monthly meeting

### Step 5 – Store and update Training Record in BatMC membership file:

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The RERC Staff updates the *Training Record (Form 1.4.1)* of the attending member to document the attendance in trainings in chronological order. A copy of the Certificate of Attendance is filed in the BatMC membership file. The Secretariat Staff updates the training record annually. (4SOP 32 on Managing Active Files)

#### 6. Forms:

Form 1.4.1	Training Record of RERC Member
Form 1.4.2	Training Referral Request Form

#### 7. History of SOP


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1	2015 October	Rhodora M Reyes, MD	First draft
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3	2017 February	Rhodora M Reyes, MD	No change
4	2020 October	Erlynda I. Masangcay II, MD Dinna P. Remo, CPA	Adopt new Phreb format  Revise workflow  Change Form Number of Training Record and Training Referral Request
5	2021 June	Dinna P. Remo, CPA	None

#### 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*

*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*


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*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 1 STRUCTURE and COMPOSITION SOP 05 Incentives for RERC Members and Consultants</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

## 1. Policy Statement

BatMC RERC recognizes the contribution of members and consultants in ensuring the protection of the rights, safety and well-being of human subjects involved in health related research and to provide public assurance of that protection. The incentives for RERC members and consultants aim not to compensate but rather to provide incentive for the works completed. The honorarium is given for all meetings attended to include : Expedited Review PR Meeting, Full Review Board Meeting, SJREB, Site Visits other Special an/or Emergency and/or Clarificatory and other Administrative Meetings that the RERC Chair may call for.

The Department of Health is cognizant of the importance of ethics review process and has included in the *DOH Department Order 2017-0265* dated July 1, 2017 (*Appendix : Reference 1*) provision allowing the grant of honoraria for review committee members.

Honorarium Rates per Meeting (DOH DO No. 2017-0265; subject to change based on DOH advise):

Chairperson	Php3,000.00
Institutional or Affiliated Members	Php1,500.00
Non-Institutional or Non-Affiliated Members	Php2,000.00
Independent Consultant (Affiliated)	Php1,500.00
Independent Consultant (Non-Affiliated)	Php2,000.00
Attendance in SJREB	Php1,500.00

## 2. Objective/s of the Activity

This SOP will describe procedures to facilitate granting of honorarium to RERC members and consultants.

## 3. Scope

This SOP describes how RERC members and consultants may be given incentives for their work in the Batangas Medical Center RERC and will end with the dispensation of the incentive.

## 4. Workflow

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1</b> : Explore administrative mechanisms and precedents to provide incentives for RERC	RERC Chair

<b>Step 2 :</b> Prepares recommendation and endorse request to Medical Center Chief	RERC Chair
<b>Step 3 :</b> Approval or disapproval of request.	Medical Center Chief
<b>Step 4 :</b> Communication of honorarium / incentive information to members and consultants	RERC Chair RERC Staff
<b>Step 5 :</b> Dispensation of Incentive for approved request.	RERC Staff Batmc Cashier

## 5. Description of Procedures

### Step 1 – Explore administrative mechanisms and precedents to provide incentives for RERC:

The Chair explores possible financial and administrative mechanisms and precedents to be able to provide honorarium for RERC work using as fundamental basis DOH Department Order 2017-0265 dated July 1, 2017 "Guidelines for the Streamlined Research Ethics Review Process in the Department of Health" (Appendix: Reference 1).

### Step 2 – Prepares recommendation and endorses request to the Medical Center Chief:

The Chair makes a recommendation for honorarium or its adjustment to the Medical Center Chief and includes the recommendation in the Annual Operational Plan of the RERC.

### Step 3 – Approval or Disapproval of request:

The Medical Center Chief may either approve or disapprove the recommended amount of honorarium.

### Step 4 – Communication of honorarium / incentive information to members and consultants:

Members and consultants will be informed during the regular meeting if request for honoraria has been approved.


The RERC Staff then prepares and submits the voucher for the incentive / honoraria based on attendance together with supporting documents (Minutes of Meetings) and monitors the timely processing of the said request.

### Step 5 – Dispensation of incentive for approved request:

The RERC Staff notifies the members and consultants of the availability of the honorarium check for pick up at the BatMC Cashier.

## 6. Forms:

## 7. History of SOP

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VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2015 October	Rhodora M Reyes, MD	First draft
2	2016	Rhodora M Reyes, MD	No change
3	2017 February	Rhodora M Reyes, MD	No change
4	2020 October	Erlynda I. Masangcay 11, MD Dinna P. Remo, CPA	Adopt new Phreb format Revise workflow
5	2021 June	Dinna P. Remo, CPA	Insert latest DOH approved honorarium rates

## 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*


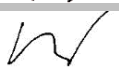
*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*


*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

Supersedes:	<b>Version 4</b>
Authored by:	Batangas Medical Center RERC
Effective Date:	June 04, 2021
Approved by:	Rhodora Madrid-Reyes MD, FPNA,FPSCOT Chairman 
Approved by:	Dr. Ramoncito C. Magnaye MD,FPCS,FPSGS,MHA Medical Center Chief II 
Approval Date:	June 04, 2021

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 2 INITIAL REVIEW PROCEDURES SOP 06 Management of Initial Submissions</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021  <b>Date of Effectivity:</b> June 04, 2021

## 1. Policy Statement

The RERC shall require the submission of a set of pertinent documents for an application for ethical review to be accepted. A preliminary evaluation shall determine whether a research proposal is exempted from or needs to undergo ethical review based on the NEGHR 2017 The Research Ethics Review Process Guideline 3.1. Subsequent amendments to a protocol that was exempted from review shall be submitted for a preliminary evaluation to determine whether the revised protocol can still be “exempted from review.


## 2. Objective/s of the Activity

Management of Initial Submissions ensures that study documents are complete, properly recorded, and properly evaluated to determine appropriate action or type of review.

## 3. Scope

BatMC RERC accepts study protocols on health-related research dealing with human participants. Study protocols that may be accepted are as follows:

- A. Batangas Medical Center initiated researches done by its members
- B. Researches done in Batangas Medical Center by other institutions
- C. Researches referred from the PNHRs, PHREB, DOH, industry organizations, other academic institutions, provided with an agreement of the host hospital/institution where the actual research will be done and on the condition that the host hospital/institution where the proposal will be done accepts the review of BatMC RERC and agrees to abide by the rules and regulations that the BatMC RERC follows (based on PHREB and FERCAP rules). The other research sites also agree to provide the necessary environment to ensure the safe and ethical conduct of the research, including oversight and stewardship functions as necessary as they agree to monitor procedures that the Committee may deem necessary. These conditions should be written in a document and signed by other hospitals/ institutions that accept Batangas Medical Center RERC review.
- D. Protocols referred by the Single Joint Review Ethics Board (SJREB) to be submitted by Sponsor / PI or its representative where the BatMC RERC is one of the sites of a multicenter research (*Refer to Appendix: Reference 2 - DOH Administrative Order No.2017-021*).

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The BatMC RERC's EXPEDITED PR REVIEW MEETING is every 1st Friday of the month while the FULL BOARD REVIEW MEETING is every 2nd Friday of the month. However, the Chair may schedule extra meeting days on the same month depending on the basis of: (1) bulk of protocols to be reviewed; and (2) in cases of emergency protocol(s) needing emergency review process; (3) in cases where clarificatory interview/dialogue is deemed necessary principally attended by the Primary Reviewers, but with other members volunteering to attend as well. Deadline for submission of complete protocol package is 12 noon of the last Friday of the month or at least fourteen (14) days prior to the nearest regular BatMC RERC FULL BOARD REVIEW Meeting. Assigning of type of protocol review, as well as Primary Reviewer should be completed within one (1) calendar day from receipt of complete protocol package. Only complete protocol package based on the Protocol Package Checklist (*Form 2.6.1*) will be accepted for initial submission.

This SOP begins with the receipt of study documents for initial review and ends with entry of protocol information in the database and filing of the original study protocol package in the Active Study File cabinet.

#### 4. Workflow

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1:</b> Receipt of study documents for initial review and determination of completeness of submission .	RERC Staff
<b>Step 2:</b> Assignment of permanent code to the package	RERC Staff
<b>Step 3:</b> Log the received protocol in the RERC database	RERC Staff
<b>Step 4:</b> Determination of type of Action/ Type of Review a. Exemption from Review (2SOP 10) b. Expedited Review (2SOP 8) c. Full Review (2SOP 9)	RERC Staff
<b>Step 5:</b> Preparation of a protocol folder	RERC Staff
<b>Step 6 :</b> File the original package in a properly coded Protocol File folder and place it in the active study file cabinet (4SOP 32 Management of Active Files)	RERC Staff



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## 5. Description of Procedures


### Step 1 - Receipt of study documents for initial review and determination of completeness of submission:

The RERC office is open from 8:00 AM to 5:00 PM during which time the Staff accepts study documents. Deadline for submission of complete protocol package is 12 noon of the LAST Friday of the month. The Staff checks completeness of the documents based on the Protocol Package Checklist (Form 2.6.1). If incomplete, the Staff informs the proponent of the missing documents.


#### Important Reminder:

- All study protocols need technical approval prior to ethical review. For Batangas Medical Center-initiated protocols, the Technical Review Committee should have addressed the technical issues apparent to the study protocol. A letter of endorsement signed by the Department Technical Review Committee Chair, or Co-chair in the absence of the chair, to signify that the protocol has been approved should be included in the protocol package for submission to RERC. For non-BatMC initiated protocols, a document stating that the research protocol has undergone and passed technical review should be attached to the study protocol submitted for ethical review.
- Result of TURNITIN SIMILARITY CHECKER and proof of payment of Initial Review Fee for non BatMC initiated protocols must be submitted along with the protocol package.
- At present, acceptable Turnitin rate, as agreed with the Research Technical Team, has been set at 15%. Turnitin rate is subject to annual review by the RERC for approval by the Medical Center Chief and the PETRO Chief in behalf of the Research Technical Committee, any change in Turnitin acceptable rate to take effect January 1 of the year following Board approved revision.
- "The Initial Review Fee Rates for non BatMC initiated protocols are as follows : (based on DOH Department Order No. 2017-0265, Annex C)

Type of Protocol	Review Fee (Initial, Renewal)
<i>Clinical Trial</i>	Based on Clinical Trial Agreement

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<b>Sponsor - Initiated Protocol</b>	For Investigational New Drugs (IND) : a. Full Board Review Fee not exceeding Php50,000.00 b. Expedited Review Fee not exceeding Php30,000.00	
<b>Principal Investigator - Initiated Protocol</b>		
Protocols from professional researchers (e.g. researchers from the academe, consultants affiliated to recognized local and international organizations, etc	a. Full Board Review Fee not exceeding Php10,000.00 b. Expedited Review Fee not exceeding Php5,000.00 C. Exempt from Review Fee not exceeding Pph3,000.00	
Protocols from trainees such as : hospital fellows, residents, graduate and undergraduate students	For trainees of the <b>home institution</b> , no fees shall be charged. For trainees of <b>other institutions</b> , the following shall apply : a. Undergraduate students - not to exceed Php1,000.00 b. Fellows, Residents and Graduate students - not to exceed Php5,000.00	


- Likewise, Initial Review Fee rate for non-BatMC initiated protocols is subject to annual review by the RERC for approval by the Medical Center Chief, any change to take effect January 1 of the year following Board approved revision.
- Upon submission of the initial protocol for RERC review, the principal investigator or his/her representative should ensure that the protocol follows the standard protocol format and contains the following RERC forms :
  - Form 2.6.1 – Protocol Package Checklist
  - Form 2.6.2 – Application Form for Protocol Review
  - Form 2.6.3 – Protocol Evaluation Form
  - Form 2.6.4 – Protocol Summary Sheet
  - Form 2.6.5 – Non-Disclosure Agreement <Principal Investigator>
  - Form 2.14.1 - Study Protocol Assessment Form
  - Form 2.14.2 - Informed Consent Assessment Form
  - Informed Consent Templates- Appendix (WHO ICF Templates 1 to 5)

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- For Investigator-initiated protocols, the Principal Investigator must submit complete protocol package in three (3) copies and an electronic copy of the complete package sent to BatMC RERC email address.
- For sponsored studies, the Principal Investigator will submit an electronic copy of the protocol while other documents will be stored in USB likewise submitted to the RERC office.
- The RERC Staff accepts complete protocol submissions only and returns incomplete or incorrect submissions. Principal Investigators are encouraged to use as guide the WHO Templates for Informed Consent and Assent Forms (*WHO Form ICF-1 to ICF-6*).
- Study protocols qualified for SJREB review are given instructions to submit to SJREB and endorsed to the SJREB Secretariat through e-mail.
- A protocol package has to include the following:

**Basic Documents (ALL must be submitted)**

- ☐ Protocol package checklist (*Form 2.6.1*)
  - ☐ Application form for Protocol Review (*Form 2.6.2*)
  - ☐ Protocol Evaluation Review (*Form 2.6.3*)
  - ☐ Protocol Summary Sheet (*Form 2.6.4*)
  - ☐ Study Protocol
  - ☐ Diagrammatic work flow
  - ☐ Gantt Chart for Schedule of activities
  - ☐ Supplementary Documents (if applicable)
    - ☐ Questionnaire
    - ☐ Data Collection Forms
    - ☐ Product Brochure
    - ☐ Investigator's Brochure (for clinical trials phase I, II, III) or Basic Product Information Document (for Phase IV clinical trials)
    - ☐ Philippine FDA Marketing Authorization or Import License
    - ☐ Permit/s for Special Population (please specify)
- 
- ☐ Informed Consent Form
    - ☐ English      ☐ Tagalog      ☐ Others
  - ☐ Assent Form (if applicable)
    - ☐ English      ☐ Tagalog      ☐ Others
  - ☐ Technical Review Certificate

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- ☐ Statistical and Turnitin Similarity Clearances (valid for 6 months from date of initial issuance)
- ☐ Good Clinical Practice (GCP) Training Certificate of PI, Co-I and the rest of the study team: updated at least within THREE (3) years (for clinical trials)
- ☐ Curriculum Vitae for all members of the Study Team
- ☐ Non-Disclosure Agreement <Principal Investigator> (Form 2.6.5)
- ☐ Proof of Payment of Initial Review Fee, if applicable
- ☐ Study Protocol Assessment Form (Form 2.14.1)
- ☐ Informed Consent Assessment Form (Form 2.14.2)
- ☐ WHO TEMPLATES FOR ICF (Appendices)

**Study Specific Documents (submit as needed particularly for externally originated studies and sponsored studies)**


- ☐ Recruitment advertisements (as needed by the study protocol)
- ☐ Other information or documents for participants (such as diaries, etc.)
- ☐ Material Transfer Agreement (for any research involving transfer of biological specimens)
- ☐ Memorandum of Agreement (for collaborative studies)
- ☐ Site Resources Checklist for Clinical Trial Outside BATMC By BATMC Personnel
- ☐ Site Resources Checklist for Clinical Trial Outside BATMC By non-BATMC Personnel
- ☐ Previous ethical review approvals/clearances (for students/personnel of foreign universities researching in the Philippines or those with prior ethical review)
- ☐ National Commission for Indigenous People (NCIP) Clearance (for studies with indigenous populations; can be processed while BATMC-RERC review is ongoing)
- ☐ Clearance or permit from respective regulatory authorities (such as FDA approval for clinical trials and DENR local transport permit, as applicable)
- ☐ Contracts and/or Approval of relevant offices / regulatory authorities (Written review agreement / Authorization and Acknowledgement of review)

**Step 2 – Assignment of permanent code to the protocol package :**

If the documents are determined to be complete, the staff with the supervision of the member secretary assigns a protocol code . This code is the ID number of the protocol and cannot be assigned to

any other protocol. When referring to the protocol in communications or presentations, the code will always be indicated for easier referencing. All codes will follow the format BATMC-RERC-YYYY-NNN, example, all protocol submissions in Year 2020 will start with the protocol code *BATMC-RERC-2020-001*.

**Step 3 - Entry into logbook and electronic database:**

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The REC logbook is an official document of having received particular documents on a specific date and time. It includes information on (1) title of the study, (2) name of proponent, (3) date of submission, (4) name of receiver and (5) Action. It is also good to include the name and signature of the individual who actually submitted the documents in case s/he is not the proponent. The electronic database for all BatMC RERC study protocols received is updated.

#### **Step 4 - Determination of type of Review/Action:**


The RERC Staff submits all received complete protocol package to the Chair / Vice Chair or Member Secretary / Assistant Member Secretary. The Chair conducts a preliminary review of the protocol to determine level of review i.e Exempted, Expedited, or Full, and assignment of Primary Reviewers.

If the Chair decides that the protocol is exempted from review, s/he directs the RERC staff to follow the procedure to communicate the decision to the researcher (*4SOP 30 Communicating REC Decisions*).

If the Chair determines that the protocol should undergo either Full or Expedited review, then the REC staff proceeds to follow either *2SOP 8 Expedited Review* or *2SOP 9 Full Review*.

The BatMC RERC adheres to the following guidelines in classifying protocols as to the level of review required :

1. Exempted – (*Refer to 2SOP 10 Exempt From Review*) Study protocols may be exempted from ethical review based on the criteria listed in the 2017 National Ethical Guidelines for Health and Health-related Research (NEGHHR 2017) The Research Ethics Review Process Guideline 3.1. The decision to exempt from review rests on the RERC Chair for efficiency and in the interest of time. Study protocols that may be exempted are :
  - (1) Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols)
  - (2) Protocols that do not involve more than minimal risks or harms, such as :
    - Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests;
    - 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: (a) There will be no disclosure of the human participants' responses outside the research; and (b) The information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant; and (c) Protocols that involve the use of publicly available data or information.

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2. Expedited –(Refer to 2SOP 8 Expedited Review) An expedited review shall be conducted for study protocols that :
  - (1) do not entail more than minimal risk to the study participants,
  - (2) do not have study participants belonging to a vulnerable group, and
  - (3) the study procedures do not generate vulnerability.
  - (4) the study does not involve the collection of stigmatizing information
  - (5) the study uses anonymized or archived samples
  
3. Full – (Refer to 2SOP 9 Full Review) A full review shall be conducted when :
  - (1) a proposed study entails more than minimal risk to study participants,
  - (2) when study participants belong to vulnerable groups, or
  - (3) when a study generates vulnerability to participants

**Step 5 - Preparation of a Protocol Folder:**


The RERC staff files the protocol documents in a protocol folder and labels it accordingly. (4SOP 32 *Management of Active Files*). The RERC Staff also prepares sufficient copies of the complete set of protocol documents for distribution to the Primary Reviewers and Member Reviewers in case of Full Board Review. In case of online meetings, the RERC Staff sends through email the soft copy of the study protocol to the Primary Reviewers and Member Reviewers for Full Board Review.

**Step 6 – Filing in Active Study File cabinet:**

The complete protocol folder is filed for safekeeping in the Active Study File cabinet. Electronic database is likewise updated as to type of review and assigned primary reviewers. (4SOP 32 *Management of Active Files*)

**TIMELINE FOR EXPEDITED PR REVIEW**

TIMELINE	FROM	ACTIVITY
Last Friday of the month prior to Regular Protocol Review Meeting	Principal Investigator	Last day for submission of research protocol to RERC office for inclusion in Regular Protocol Review Meeting
1 calendar day after submission	RERC Chair	Classification of research protocol, assignment of Primary Reviewers and online transmission of complete protocol package to PR

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		<b>Date of Effectivity:</b> November 02, 2020
5 calendar days	Primary Reviewers	Review of research protocol and completion of assessment forms
1st Thursday of the Month	Primary Reviewers	Submit online filled up and signed assessment forms
1st Friday of the Month	EXPEDITED REVIEW PRIMARY REVIEWERS MEETING	
7 calendar days after RERC meeting	Member Secretary	Send out Notice of RERC Decision to Principal Investigator


#### **TIMELINE FOR FULL BOARD REVIEW**

TIMELINE	FROM	ACTIVITY
Last Friday of the month prior to Regular Protocol Review Meeting	Principal Investigator	Last day for submission of research protocol to RERC office for inclusion in Regular Protocol Review Meeting
1 calendar day after submission	RERC Chair	Classification of research protocol, assignment of Primary Reviewers and online transmission of complete protocol package to PR / Member Reviewers
12 calendar days	Primary Reviewers &/or Member Reviewers	Review of research protocols by the Primary Reviewers, and/or the member reviewers in case of Full Review
2nd Thursday of the Month	Primary Reviewers &/or Member Reviewers	Submit online filled up and signed assessment forms
2nd Friday of the Month	FULL REVIEW BOARD MEETING	
7 calendar days after RERC meeting	Member Secretary	Send out Notice of RERC Decision to Principal Investigator

#### **6. Forms**

- Form 2.6.1 – Protocol Package Checklist
- Form 2.6.2 – Application Form for Protocol Review
- Form 2.6.3 – Protocol Evaluation Form
- Form 2.6.4 – Protocol Summary Sheet



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Form 2.6.5 – Non Disclosure Agreement <Principal Investigator>

Form 2.14.1 - Study Protocol Assessment Form ( Adapted from UPMREB Form 2(C)2012 )

Form 2.14.2 – Informed Consent Assessment Form ( Adapted from UPMREB Form 2(D)2012 )

**Guide WHO ICF Templates – Informed Consent and Assent Forms (Appendices Reference No. 3)**

**WHO ICF-1** - Informed Consent form in English and Local language (for studies involving adult human participants)

**WHO ICF-2** - Informed Consent form for Co-signature in English and Local language (for studies involving minors ages more than or equal to 15 years up to less than 18 years of age and relevant populations deemed incompetent to execute decision and signing of informed consent form)

**WHO ICF-3** - Assent form in English and Local language (for studies involving minors less than or equal to 12-15 years of age and relevant populations deemed incompetent to sign an informed consent form)

**WHO ICF-4** - Informed Parental Consent for Research Involving Children (Qualitative Studies)


**WHO ICF-5** - informed Consent for Storage and Future Use of Unused Sample

**WHO ICF-6** - Informed Consent for Qualitative Studies -research interventions that use questionnaires, in-depth interviews or focus group discussion

## 7. History of SOP

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
<b>1</b>	<i>2015 October</i>	<i>Dr. Rhodora Madrid-Reyes</i>	<i>First draft</i>
<b>2</b>	<i>2016</i>	<i>Dr. Rhodora Madrid-Reyes</i>	<i>None</i>
<b>3</b>	<i>2017 February</i>	<i>Dr. Rhodora Madrid-Reyes</i>	<i>None</i>
<b>4</b>	<i>2020 October</i>	<i>Dr. Jesus V. Fernandez Dr. Alfonso Syoei R. Yoshida Dinna P. Remo, CPA</i>	<i>Updated schedule of deadline of protocol package submission Added clause for Protocol Review Meeting schedule in Policy section Revised Protocol Review Timeline</i>



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			<b>Date of Approval:</b> October 19, 2020
			<b>Date of Effectivity:</b> November 02, 2020
			Updated document submission requirements aligned with Protocol Package Check list (Form 2.6.1) Added glossary of terminologies related to activity Additional clause for referencing source of current RERC forms 2.14.1 and 2.14.2
5	2021 June	Dr. Alfonso Syoei R. Yoshida Dinna P. Remo, CPA	Introduction of Expedited Review Meeting  Revised Timeline for Expedited and Full Review  Requirement for submission of Result of Turnitin Similarity Checker and Proof of Payment of Initial Review Fee  Initial Review Fee Table

## 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*


*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

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	<b>CHAPTER 2</b> <b>INITIAL REVIEW PROCEDURES</b> <b>SOP 07</b> <b>Selection of Primary Reviewers</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021  <b>Date of Effectivity:</b> June 04, 2021

## 1. Policy Statement

BatMC RERC protocol review are conducted through the Primary Review system. Primary reviewers are selected on the basis of expertise related to the protocol. Research proposals are given to both medical and non-medical, institutional and non-institutional members for review. The medical members evaluate the scientific and ethical procedures in the protocol while the non-medical and non-institutional members focus their assessment on the informed consent form as well as the ethical procedures in the conduct of the study.

## 2. Objective/s of the Activity

This SOP describes the process on the assignment of Primary Reviewers for study protocols received for ethical review.


## 3. Scope

This SOP begins with receipt of the RERC Chair, or Vice Chair or Member secretary or Assistant Member secretary of the complete initial protocol package that underwent checking for its completion by the Secretariat, and ends with submission of the protocol package to the assigned Primary reviewers, and Independent Consultant if any.

## 4. Workflow

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<i>Step 1: Submission of protocol package to RERC Chair / Vice Chair / Member secretary / Assistant Member secretary</i>	<i>RERC Staff</i>
<i>Step 2: Conduct of Preliminary Review of the Study Protocol for classification and assignment of Primary Reviewers</i>	<i>Chair or Vice Chair or Member Secretary or Assistant Member Secretary</i>
<i>Step 3: Preparation of copies of protocol package for distribution.</i>	<i>RERC Staff</i>

## 5. Description of Procedures

	<b>BATANGAS MEDICAL CENTER</b> <b>RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 2</b> <b>INITIAL REVIEW PROCEDURES</b> <b>SOP 07</b> <b>Selection of Primary Reviewers</b>	<b>Version No: 4</b>
		<b>Date of Approval:</b> October 19, 2020  <b>Date of Effectivity:</b> November 02, 2020

**Step 1 – Submission of protocol package to RERC Chair / Vice Chair / Member secretary / Assistant Member secretary :**

The RERC Staff, after checking the completeness of the protocol package submitted, submits the whole package to the RERC Chair, or in the absence, the Vice Chair or Member Secretary or Assistant Member Secretary for preliminary review.

**Step 2 – Conduct of Preliminary Review of Study Protocol :**

Upon receipt of protocol package, the RERC Chair, or in the absence, the Vice Chair or Member Secretary or Assistant Member Secretary will conduct preliminary review to classify the type of review to be required. Primary Reviewer for the protocol will also be assigned as well as determination if there is a need for an Independent Consultant (*refer to 1SOP 3 Appointment of Independent Consultants*).

For every protocol, there will be at least two (2) Primary reviewers, composed of one (1) medical (affiliated or non-affiliated) member to review scientific soundness and ethical issues of the protocol and one (1) non-Medical (affiliated or non-affiliated) member to review the informed consent process and forms. Primary reviewers are selected by the Chair on the basis of expertise and experience related to the protocol with consideration of distribution of workload among members.

The Application Form for Protocol Review (*Form 2.6.2*) and Protocol Evaluation Form (*Form 2.6.3*) will be filled up and complete protocol package will be returned to the RERC Staff.

**Step 3 – Preparation of copies of protocol package for distribution :**

The Secretariat receives the complete protocol package with the signed and filled up forms on classification and assignment of primary reviewers. Classification and assignment will be logged in the RERC protocol database. The RERC Staff then prepares copies of the protocol package for distribution to the Primary Reviewers for expedited review, and to other member reviewers for full review. In case an independent consultant is required, the RERC Staff prepares and sends the invitation letter with confidentiality form to the identified independent consultant.


**6. Forms**

Form 2.6.2 – Application form for Protocol Review

Form 2.6.3 – Protocol Evaluation Form

Form 1.3.1 - Letter of Invitation to Independent Consultant

Form 1.3.3 - Confidentiality and Conflict of Interest Disclosure Agreement <Independent Consultant>

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	<b>CHAPTER 2 INITIAL REVIEW PROCEDURES SOP 07 Selection of Primary Reviewers</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

## 7. History of SOP

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
1	2015 October	Dr. Rhodora Madrid-Reyes	First draft
2	2016	Dr. Rhodora Madrid-Reyes	None
3	2017 February	Dr. Rhodora Madrid-Reyes	None
4	2020 October	Dr. Jesus V. Fernandez Dr. Alfonso Syoei R. Yoshida Dinna P. Remo, CPA	First draft as independent SOP
5	2021 June	Dr. Alfonso Syoei R. Yoshida Dinna P. Remo, CPA	None

## 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*


*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 2 INITIAL REVIEW PROCEDURES SOP 08 Expedited Review</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021  <b>Date of Effectivity:</b> June 04, 2021

## 1. Policy Statement

An expedited review shall be conducted for study protocols that (1) do not entail more than minimal risk to the study participants, and (2) do not have study participants belonging to a vulnerable group, and (3) the study procedures do not generate vulnerability. The result of initial review shall be presented and discussed during the Expedited PR Review Meeting. Approved protocol that underwent expedited review shall be reported in the subsequent Full Board Review Meeting.

Criteria for protocols to be initially classified as subject to Expedited Review are as follows:

### 1. The study do not entail *more than minimal risk* to the study participants:


- Protocol that will not likely harm the status or interests of the study participants and not likely to offend the sensibilities nor cause psychological stress of the people involved.
- Protocol that involves collection of anonymized personal data, 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).
- Protocol that deals with data or documents involving anonymized human data, biological specimens that have been already collected or will be collected for ongoing medical treatments or diagnosis

### 2. The study do not have participants belonging to a *vulnerable group* :

- Protocol that will not deal with : 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

### 3. The study procedures do not generate vulnerability:

- Protocols that are non-confidential in nature defined as;
- Not dealing with private character such as sexual preference etc
- Not dealing with sensitive issues that may cause social stigma

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4. Protocols referred by the Single Joint Research Ethics Board (SJREB) classified for Expedited Review by the RERC Chair. *(2SOP 11 SJREB Protocol Review)*

Criteria for study protocols to be subject to Expedited Review, after initial approval :

1. Protocols initially classified for Expedited review, even if with major modifications recommended, will still undergo expedited review upon resubmission as long as minimal risk is not elevated.

2. All post-approval amendments, deviations, violations, off-site SAEs/SUSARs shall be subject to Expedited Review, regardless of initial review classification if the study protocols satisfy any of the following criteria: *(See 2SOP15-Management of Resubmission )* :


- Administrative revisions, such as correction of typing error
- Addition or deletion of non-procedural items, such as the addition of study personnel names, laboratories, etc.
- Minor protocol amendments, deviations, violations on the study and related documents that do not impact on the potential risk/benefits to the participant and no substantial change in the study population, methodology and consent that will impact on the integrity of the research

3. Progress Reports and Continuing Review Applications will be subject to Expedited Review if initial classification of study protocol was likewise expedited.

4. All Final Reports, regardless of type of initial classification of review, will be subject to Expedited Review. However, In the event that a PI decides not to continue the application for ethics review, the PI must write a letter requesting for withdrawal of study protocol from the RERC. All requests for withdrawal will be discussed during the Full Board Review Meetings regardless of initial review classification.

It is the responsibility of assigned Primary Reviewers to assess any protocol that qualifies for the expedited process. The same assessment forms used for full board review should be used to evaluate the scientific and ethical merits of the protocol.

Only complete protocols submitted on or before 12noon of the LAST FRIDAY OF THE MONTH shall be included in the agenda for the EXPEDITED PR REVIEW MEETING. Initial review of protocols classified for expedited review shall commence no later than FIVE (5) calendar days prior to the next scheduled RERC Expedited PR Review Meeting.

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The conduct of meeting is governed by 4SOP 27 whether online or virtual meetings or face to face meetings will be conducted. The Chair/Member Secretary or the Asst. Member Secretary will decide on the type of platform to be used.

## 2. Objective/s of the Activity

Expedited Review aims to demonstrate due diligence and high standards in the system of protection of human participants.


## 3. Scope

This SOP applies to initial review of protocols and resubmissions which do not entail more than minimal risk to study participants, whose participants do not belong to vulnerable groups, and where vulnerability issues do not arise. This SOP begins with the assignment of reviewers or independent consultant/s and ends with the inclusion of the review in the agenda of the next meeting.

## 4. Workflow

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1:</b> <i>Assignment of Reviewers or Independent Consultant/s (2SOP 7 Selection of Primary Reviewers and 1SOP 3 Appointment of Independent Consultants)</i>	<i>Chair/ Vice Chair / Member secretary/ Assistant member secretary</i>
<b>Step 2:</b> <i>Notification of Primary Reviewers and Independent Consultant and provision of study documents and assessment forms</i>	<i>RERC Staff</i>
<b>Step 3:</b> <i>Conduct of review and accomplishment of assessment forms</i>	<i>Primary Reviewer  Independent Consultant</i>
<b>Step 4:</b> <i>Presentation of review findings and recommendations during the Expedited PR Review meeting (SOP on Conduct of Meeting (4SOP 27))</i>	<i>Primary Reviewers  Independent Consultant</i>



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<b>Step 5:</b> <i>Communication of review results to the researcher (4SOP 30 Communicating of RERC Decisions)</i>	<i>RERC Chair</i>  <i>RERC Staff</i>	
<b>Step 6:</b> <i>Filing of documents in the protocol file (4SOP 32 Management of Active Files)</i>	<i>RERC Staff</i>	

## 5. Description of Procedures

### Step 1 – Assignment of Primary Reviewers and/or Independent Consultants :

The Chair/ Vice Chair / Member Secretary/ Assistant Member Secretary shall conduct Preliminary review to go over the submitted protocol to decide on the type of review to be applied.

Once decided that the study satisfied any of the criteria to be classified for Expedited Review, the Chair nominates at least two (2) BatMC RERC members to be the Primary Reviewer for expedited review. Nominees, at a minimum, should preferably be composed of a Medical member (affiliated or non-affiliated) with related expertise to review the protocol and a Non-Medical member (affiliated or non-affiliated) to review the informed consent.


If there are no RERC member with field of expertise to adequately review the scientific aspect of the study protocol, an Independent Consultant may be invited to join the protocol review. The protocol of request for the Independent Consultant is governed by 1SOP 3.

The Chair/ Vice Chair / Member Secretary/ Assistant Member Secretary then shall return the protocol with decision to Secretariat to facilitate distribution for primary review

### Step 2 – Notification of Primary Reviewers and Independent Consultant and provision of study documents and protocol assessment forms :

The REC Staff gathers the pertinent documents; for initial submissions: the complete protocol package; for post approval submissions: the pertinent information from the retrieved protocol and the report itself. The RERC staff prepares copies of the protocol and/or protocol-related documents and assessment forms for delivery, either through manual delivery or through electronic mail, to the primary reviewers and/or independent consultants, if any, at least six (6) calendar days prior to the next scheduled RERC Expedited PR Review meeting.



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### **Step 3 – Conduct of review and accomplishment of assessment forms :**

Assigned Primary Reviewer shall carry out the expedited review on the protocol and related documents (patient information sheet, consent form, advertisements, etc.). This process must be completed with accomplished Study Protocol Assessment Form (*Form 2.14.1*) and Informed Consent Assessment Form (*Form 2.14.2*) at least one (1) day before the scheduled RERC Expedited PR Review meeting.

Assessment forms may be submitted in hard copies, duly signed and dated by the Primary Reviewers and Independent Consultant.

Electronic copy of the assessment forms may likewise be submitted provided bearing the e-signature of the Primary Reviewers and Independent Consultant. Electronic copy will be printed by the RERC Staff.

RERC Staff shall check for completeness in entries in the form before filing.


### **Step 4 - Presentation of review findings and recommendations during a Committee meeting (SOP on Conduct of Meeting (4SOP 27)):**

The primary reviewers submit their findings and recommendations (Form 2.14.1 Study Protocol Assessment Form and Form 2.14.2 and Informed Consent Assessment Form) to the RERC Chair one (1) day before the meeting and present these during the actual meeting (4SOP 27 Conduct of Meetings). If a primary reviewer cannot attend the meeting, the RERC Chair exercises his/her prerogative to take over the role of the primary reviewer so that the meeting can proceed.

The RERC Chair will consolidate and finalize the review results. In case of differing opinions, RERC Chair may mediate to reach an agreement, and may have the final say. In case of considerable difference and consensus cannot be reached, the Chair may refer the protocol to the RERC board for full review. (*Refer to 2SOP 9 Full Review*)

If deemed necessary, the Primary Reviewers may call for a clarificatory meeting or dialogue with the Principal Investigator to request for additional information or to explain recommendations or decisions. The PR has to echo the result of the dialogue and anything that transpired in the interim during the Expedited PR Meeting, and even during Full Board Review Meeting, if deemed necessary.

All study protocols approved under Expedited Review will be presented by one of the Primary Reviewers during the scheduled Full Review Board Meeting.

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**Step 5 : Communication of review results to the researcher (*4SOP 30 Communicating of RERC Decisions*) :**


As soon as the decision of Primary Reviewers is reached, the decision is communicated to the principal investigators within one (1) week from scheduled RERC Expedited PR Review meeting. (*Refer to 4SOP 30- Communicating RERC Decisions*)

The reviewers recommend approval if there are no issues. Notification of RERC Decision (*Form 4.30.2A*) and Letter of Approval (*Form 4.30.1*) are issued to the Principal Investigator.

If there are findings, reviewers shall recommend revisions. Notification of RERC Decision (*Form 4.30.2A*) and Letter for Modification (*Form 4.30.2B*) are issued to the Principal Investigator. (*Refer to 2SOP 15 Management of Resubmissions*)

Recommended revisions may be classified as follows :

- *Minor modification* – a recommended revision applying to protocols found to have particular aspect/s on its study or related document that do not impact on potential risks/harms to participants and on the integrity of the research (e.g. incomplete documentation, informed consent elements, unsatisfactory informed consent format). To wit :
  1. Administrative corrections like typographical errors or grammar
  2. Minor changes on items not directly related on procedure to be done
  3. Revisions will not impact risk-benefit example: additional related literature requested
- *Major modification* – a recommended revision applying to protocols found to have significant aspect/s of the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data, statistical analysis, mitigation of risk, protection of vulnerability, etc.) that impact on potential risks/harms to participants and on the integrity of the research . To wit :
  1. If there will be major revisions on either the protocol or informed consent form; such as inclusion/exclusion criteria, safety issues, methodology, that may impact on the scientific validity of the protocol
  2. Revision will have impact on the risk-benefit ratio

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No protocol may be disapproved during an expedited review; only full board has the prower to disapprove. If the PR recommends disapproval, protocol must be elevated to full board for final decision. In the absence of a consensus or if a member expresses a concern, protocol is referred for full review. Reviewers forward decision to secretariat and full board is notified.

#### Step 6 – Filing of documents in the protocol files.

*See 4SOP 32 Management of Active Files.*

#### TIMELINE FOR EXPEDITED PR REVIEW

TIMELINE	FROM	ACTIVITY
Last Friday of the month prior to Regular Protocol Review Meeting	Principal Investigator	Last day for submission of research protocol to RERC office for inclusion in Regular Protocol Review Meeting
1 calendar day after submission	RERC Chair	Classification of research protocol, assignment of Primary Reviewers and online transmission of complete protocol package to PR
5 calendar days	Primary Reviewers	Review of research protocol and completion of assessment forms
1st Thursday of the Month	Primary Reviewers	Submit online filled up and signed assessment forms
1st Friday of the Month	EXPEDITED REVIEW PRIMARY REVIEWERS MEETING	
7 calendar days after RERC meeting	Member Secretary	Send out Notice of RERC Decision to Principal Investigator

#### 6. Forms


Form 4.30.2A – Notification of RERC Decision

Form 4.30.2B- Letter for Modification

Form 4.30.1– Letter of Approval


Form 2.14.1 – Study Protocol Assessment form (Adopted from UP-PGH MREB form)

Form 2.14.2 – Inform Consent Assessment form (Adopted form UP-PGH MREB form)

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		<b>Date of Effectivity:</b> June 04, 2021

## 7. History of SOP

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
1	2015 October	Dr. Rhodora Madrid-Reyes	First draft
2	2016	Dr. Rhodora Madrid-Reyes	Revision included addition of the position of the Vice Chairman in the RERC organizational chart
3	2017 February	Dr. Rhodora Madrid-Reyes	Revisions included addition of information in the Forms of the SOP, addition of forms like the Continuing Review Form; BatMC RERC participation in Single Joint Review Ethics Board (SJREB) reviews, more elaborate description of the role of the independent consultants; clarification of timeline for initial review to approval of protocols; addition of the guidelines on ethics review fees and other board honorarium;
4	2020 October	Dr. Jesus V. Fernandez Dr. Alfonso Syoei R. Yoshida Dinna P. Remo, CPA	Added criteria for protocol to classify as expedited review  Added "Assistant member secretary" in person responsible for step 1 and Independent Consultants in the Primary Review Process in case RERC is deficient of medical member to adequately review the study protocol  Added clause to clarify completion of Forms 2.14.1 and 2.14.2 by the primary reviewer and submission deadline

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			<b>Date of Approval:</b> June 04, 2021
			<b>Date of Effectivity:</b> June 04, 2021
			<p><i>Added section for protocols from SJREB classified to be Expedited review</i></p> <p><i>Added provision for appeal on RERC decision by the PI (As referral to specific 3SOP No.23)</i></p> <p><i>Added provision for review of resubmitted protocol with revisions, with additional guide to refer to 2SOP No. 15 (Management of Resubmissions) for further discussions</i></p> <p><i>Additional clause for referencing source of current RERC forms 2.14.1 and 2.14.2 included</i></p>
5	2021 June	Dr. Alfonso Syoei R. Yoshida  Dinna P. Remo, CPA	<p><i>Streamlined criteria for classifying protocols for Expedited Review</i></p> <p><i>Added Timeline for Expedited Review</i></p>

## 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*


*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

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	<b>CHAPTER 2 INITIAL REVIEW PROCEDURES SOP 09 Full Review</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021  <b>Date of Effectivity:</b> June 04, 2021


## 1. Policy Statement

A full review shall be conducted when a proposed study entails more than minimal risk to study participants or when study participants belong to vulnerable groups or when a study generates vulnerability to participants.

Only complete protocols submitted on or before 12 noon of the LAST FRIDAY OF THE MONTH shall be included in the agenda for FULL REVIEW BOARD MEETING. Full review shall be conducted through a primary reviewer system. If necessary, independent consultants and or the proponents shall be invited during the meeting to clarify certain issues. The decision shall be communicated to the proponent within one (1) week after the adjournment of the most recent protocol review meeting.

Criteria for protocols to be classified as subject to Full Review are as follows:

1. Clinical trials about investigational new drugs, biologics or device in various phase (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 (individual 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, in prisons 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 protection from the RERC during review
5. Protocols that involve collection of identifiable biological specimens for research
6. Protocols referred by the Single Joint Research Ethics Board (SJREB) classified as for Full Review by the RERC Chair. *(2SOP 11 SJREB Protocol Review)*
7. Any protocol initially classified for full review shall again be subject to full review if with major modification of the protocol and informed consent upon resubmission. *(See 2SOP15- Management of Resubmission).*

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8. . All post-approval major amendments, deviations, violations, on-site SAEs/SUSARs shall be subject to Full Board Review, regardless of initial review classification (See 2SOP15- Management of Resubmission ).

9. . Progress Reports and Continuing Review Applications will be subject to Full Board Review if initial classification of study protocol was likewise full review.

10. RNEs and Early Termination Application are all subject to Full Board Review regardless of initial review classification.

Initial Review shall commence no later than thirteen (13) calendar days prior to the next scheduled RERC protocol review meeting.

The conduct of meeting is governed by 4SOP 27 whether online or virtual meetings or face to face meetings will be conducted. The Chair/Member Secretary or the Asst. Member Secretary will decide on the type of platform to be used.

## 2. Objective/s of the activity

A full review aims to ensure compliance with technical and ethical standards in the conduct of researches involving human participants and identifiable human data and materials.


## 3. Scope

This SOP applies to initial review and resubmissions which are classified as entailing more than minimal risk to study participants or whose participants belong to vulnerable groups. This SOP begins with the assignment of primary reviewers or independent consultant/s and ends with the filing of protocol-related documents.

## 4. Workflow

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1:</b> <i>Assignment of Reviewers or Independent Consultant/s (2SOP 7 Selection of Primary Reviewers and 1SOP 3 Appointment of Independent Consultants)</i>	<i>Chair/ Vice Chair / Member secretary/ Assistant member secretary</i>



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<b>Step 2:</b> Notification of Primary Reviewers and Independent Consultant and provision of study documents and assessment forms to the Primary Reviewers, Independent Consultant and the rest of the committee members.		
<b>Step 3:</b> Presentation of review findings and recommendations during a Committee meeting (SOP on Conduct of Meeting (4SOP 27))		
<b>Step 4:</b> Discussion of technical and ethical issues		
<b>Step 5:</b> Summary of issues of all Member Reviewers		
<b>Step 6:</b> Summary of Major points for Decision and Action or Recommendation		
<b>Step 7:</b> Documentation of Committee deliberation and action (SOP on Preparing the Meeting Minutes (4SOP 29))		
<b>Step 8:</b> Communication of Committee Action to the researcher (SOP Communicating REC Decisions (4SOP 30))		
<b>Step 9:</b> Filing of protocol-related documents and Updating of the Protocol Database		


## 5. Description of Procedures

### Step 1 - Assignment of Reviewers or Independent Consultant/s :

The RERC Chair / Vice Chair / Member Secretary / Assistant Member Secretary assigns members who have the necessary expertise as primary reviewers (designates an independent consultant in case such expertise is not present among the members) including a non-scientist member to review the Informed Consent Process and Form.

Once decided that the study satisfied any of the criteria to be classified for Full Review, the Chair nominates at least two (2) BatMC RERC members to be the Primary Reviewer for expedited review. Nominees, at a minimum, should preferably be composed of a Medical member (affiliated or non-



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affiliated) with related expertise to review the protocol and a Non-Medical member (affiliated or non-affiliated) to review the informed consent.

If there are no RERC member with field of expertise to adequately review the scientific aspect of the study protocol, an Independent Consultant may be invited to join the protocol review. The protocol of request for the Independent Consultant is governed by *1SOP 3*.

The Chair/ Vice Chair / Member Secretary/ Assistant Member Secretary then shall return the protocol with decision to Secretariat to facilitate distribution for primary review

**Step 2 - Notification of Primary Reviewers and Independent Consultant and provision of study documents and assessment forms to the Primary Reviewers, Independent Consultant and the rest of the committee members:**

The REC Staff gathers the pertinent documents; for initial submissions: the complete protocol package; for post approval submissions: the pertinent information from the retrieved protocol and the report itself. The RERC staff prepares copies of the protocol and/or protocol-related documents and assessment forms for delivery, either manually or through electronic mail, to the primary reviewers and/or independent consultants, if any, as well as the rest of the committee members, at least thirteen (13) calendar days prior to the next scheduled RERC Full Board Review meeting.


**Step 3 - Presentation of review findings and recommendations during a Committee meeting :**

The primary reviewers submit their findings and recommendations (*Form 2.14.1 Study Protocol Assessment Form and Form 2.14.2 and Informed Consent Assessment Form* to the RERC Chair one (1) day before the meeting and present these during the actual meeting (*4SOP 27 Conduct of Meetings*). If a primary reviewer cannot attend the meeting, the RERC Chair exercises his/her prerogative to take over the role of the primary reviewer so that the meeting can proceed.

Assessment forms may be submitted in hard copies, duly signed and dated by the Primary Reviewers and Independent Consultant and the rest of the committee members.

Electronic copy of the assessment forms may likewise be submitted provided bearing the e-signature of the Primary Reviewers and Independent Consultant and committee members. Electronic copy will be printed by the RERC Staff.

If deemed necessary, the Primary Reviewers may call for a clarificatory meeting or dialogue with the Principal Investigator to request for additional information or to explain recommendations or decisions. The PR may echo the result of dialogue during the Full Review Board Meeting, upon request.


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#### **Step 4 : Discussion of technical and ethical issues :**

The RERC Primary Reviewers lead the discussion of the technical and ethical issues using the Study Protocol Assessment Form (*Form 2.14.1*) and the Informed Consent Assessment Form (*Form 2.14.2*) for an orderly exchange of ideas.

Some major points to be considered during the discussion are the following :

- The protocol manifests scientific validity and contains all the standard sections to ensure scientific soundness. This would include statistical design, sample size, methodology etc.
- In assessing the degree of risk against the benefit, determine whether the risks are reasonable in relation to anticipated benefits; and/or if the risk can be minimized.
- Study participants are selected equitably especially if randomization is not to be used - Study participant's information sheet should be clear, complete and written in understandable language.
- There is voluntary, non-coercive recruitment of study participants.
- The informed consent is adequate, easy to understand and properly documented.
- There should be a translation of the Informed Consent document into the local dialect which should be comprehensible by the general public.
- The procedure for getting the informed consent is clear and unbiased.
- The persons who are responsible for getting the informed consent are named and they introduce themselves to the study participants.
- The research plan makes adequate provision for monitoring data collection to ensure the safety of study participants, where appropriate.
- There are adequate provisions to protect the privacy of study participants and to maintain the confidentiality of data, where appropriate.


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- There is provision for compensation to study participants. There should be reasonable provision for medical/psychosocial support; treatment for study related injuries, as well as compensation for participation to cover expenses like transport and lost wages because of participation.
- There are appropriate safeguards included to protect vulnerable study participants.
- Contact persons with address and phone numbers are included in the informed consent.
- There is clear justification for the use of biological materials and a separate consent form for future use of biological specimens.
- There are appropriate contract or memoranda of understanding especially in collaborative studies.
- Examine community involvement and impact/benefit of the study to the community and/or the institution. If relevant, the reviewer looks for the following in the protocol.
- Community consultation should be described and planned with community leaders.
- Involvement of local researchers and institutions in the protocol design, analysis and publication of the results.
- Contribution to development of local capacity for research and treatment in benefit to local communities.
- Sharing of study results with the participants/community should be described and discussed.

#### **Step 5 - Summary of issues of all Member Reviewers :**

The RERC Primary Reviewers summarize the technical and ethical issues that were identified, the issues that were resolved /not resolved, including the recommendations for the issues that were not resolved.

#### **Step 6 – Summary of the RERC Chair and Discussion on Committee Action and Recommendation :**

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The RERC Chair emphasizes the points discussed by all members in a summary and recommends action for compliance and proposes the action. Committee decides on action which may be either of the following:

- Approved
- For Modification
- Disapproved

Decision of the board is arrived at by voting and the majority decision is arrived at and is adopted. If there is a strong objection, the deliberation continues until the strong objector is convinced. A clarificatory interview with the Principal Investigator may be requested.

**Step 7: Documentation of Committee deliberation and action :**

See 4SOP 29 *Preparing the Meeting Minutes*

**Step 8 - Communication of Committee Action to the researcher (SOP Communicating REC Decisions (4SOP 30)**

As soon as a committee decision is reached, the decision is communicated to the principal investigators within one (1) week from scheduled RERC protocol review meeting. (*Refer to 4SOP 30- Communicating RERC Decisions*)


The reviewers recommend approval if there are no issues. Notification of RERC Decision (*Form 2.8.1*) and Letter of Approval (*Form 2.8.3*) are issued to the Principal Investigator.

If there are findings, reviewers shall recommend revisions. Notification of RERC Decision (*Form 2.8.1*) and Letter for Modification (*Form 2.8.2*) are issued to the Principal Investigator. (*Refer to 2SOP 15 Management of Resubmissions*)

In the case of disapproval the principal investigator may appeal the decision if deemed necessary. Principal Investigator will receive the Notice of RERC Decision (*Form 2.8.1*). (*Refer to 3SOP 23 Management of Appeals*)

Recommended revisions may be classified as follows :

- **Minor modification** – a recommended revision applying to protocols found to have particular aspect/s on its study or related document that do not impact on potential risks/harms to participants and on the integrity of the research (e.g. incomplete

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documentation, informed consent elements, unsatisfactory informed consent format). To wit :

1. Administrative corrections like typographical errors or grammar
2. Minor changes on items not directly related on procedure to be done
3. Revisions will not impact risk-benefit example: additional related literature requested

- **Major modification** – a recommended revision applying to protocols found to have significant aspect/s of the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data, statistical analysis, mitigation of risk, protection of vulnerability, etc.) that impact on potential risks/harms to participants and on the integrity of the research . To wit :


1. If there will be major revisions on either the protocol or informed consent form; such as inclusion/exclusion criteria, safety issues, methodology, that may impact on the scientific validity of the protocol
2. Revision will have impact on the risk-benefit ratio

#### Step 9 - Filing of protocol-related documents and Updating of the Protocol Database :

See 4SOP 32 Management of Active Files.

#### TIMELINE FOR FULL BOARD REVIEW

TIMELINE	FROM	ACTIVITY
Last Friday of the month prior to Regular Protocol Review Meeting	Principal Investigator	Last day for submission of research protocol to RERC office for inclusion in Regular Protocol Review Meeting
1 calendar day after submission	RERC Chair	Classification of research protocol, assignment of Primary Reviewers and online transmission of complete protocol package to PR / Member Reviewers
12 calendar days	Primary Reviewers &/or Member Reviewers	Review of research protocols by the Primary Reviewers, and/or the member reviewers in case of Full Review

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2nd Thursday of the Month	Primary Reviewers &/or Member Reviewers	Submit online filled up and signed assessment forms
2nd Friday of the Month	FULL REVIEW BOARD MEETING	
7 calendar days after RERC meeting	Member Secretary	Send out Notice of RERC Decision to Principal Investigator

## 6. Forms

Form 4.30.2A – Notification of RERC Decision

Form 4.30.2B - Letter for Modification

Form 4.30.1– Letter of Approval

Form 2.14.1 – Study Protocol Assessment form (Adopted from UP-PGH MREB form)

Form 2.14.2 – Inform Consent Assessment form (Adopted form UP-PGH MREB form)


## 7. History of SOP

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
<b>1</b>	<i>2015 October</i>	<i>Dr. Rhodora Madrid-Reyes</i>	<i>First draft</i>
<b>2</b>	<i>2016</i>	<i>Dr. Rhodora Madrid-Reyes</i>	<i>Revision included addition of the position of the Vice Chairman in the RERC organizational chart</i>
<b>3</b>	<i>2017 February</i>	<i>Dr. Rhodora Madrid-Reyes</i>	<i>Revisions included addition of information in the Forms of the SOP, addition of forms like the Continuing Review Form; BatMC RERC participation in Single Joint Review Ethics Board (SJREB) reviews, more elaborate description of the role of the independent consultants; clarification of timeline for initial review to approval of protocols; addition of the guidelines on ethics review fees and other board honorarium</i>

<b>4</b>	<i>2020 October</i>	<i>Dr. Jesus V. Fernandez</i> <i>Dr. Alfonso Syoei R. Yoshida</i> <i>Dinna P. Remo, CPA</i>	<i>Added criteria for protocol to classify as full review</i>  <i>Added "Assistant member secretary" in person responsible for step 1</i>  <i>Added provision for inclusion of Independent Consultants in the Primary Review Process in case RERC is deficient of medical member to adequately review the study protocol</i>  <i>Added clause to clarify completion of Forms 2.14.1 and 2.14.2 by the primary reviewer and submission deadline</i>  <i>Added section for protocols from SJREB classified for Full Review</i>  <i>Added provision for appeal on RERC decision by the PI (As referral to specific 3SOP No.23)</i>  <i>Added provision for review of resubmitted protocol with revisions, with additional guide to refer to 2SOP No. 15 (Management of Resubmissions) for further discussions</i>  <i>Additional clause for referencing source of current RERC forms 2.14.1 and 2.14.2 included</i>
<b>5</b>	<i>2021 June</i>	<i>Dr. Alfonso Syoei R. Yoshida</i> <i>Dinna P. Remo, CPA</i>	<i>Streamlined criteria for classifying protocols for Full Board Review</i>  <i>Added Timeline for Full Board Review</i>

## 8. References

*World Medical Association Declaration of Helsinki, 2013*

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*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*

*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*


*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*



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## 1. Policy Statement

Study protocols may be exempted from ethical review based on the criteria listed in the 2017 National Ethical Guidelines for Health and Health-related Research (NEGHHR 2017) The Research Ethics Review Process Guideline 3.1. The decision to exempt from review rests on the RERC Chair for efficiency and in the interest of time. Exempt from Review protocols do not involve more than minimal risks or harms.


Study protocols that may be exempted are :

1. Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols)
2. Protocols 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 be 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;
  - The information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers I. linked to the participant.
  - Protocols that involve the use of publicly available data or information.

Decision to exempt must be documented and reported to full board.

Protocols that qualify for EXEMPTION are automatically archived and reclassified as INACTIVE, and protocol records will be made available for three (3) years from date.

Study protocols granted exemption are likewise exempt from further review including progress and continuing review. The RERC must be notified for modifications that will significantly affect the previous risk-benefit assessment or qualification for exemption, in which case it may be submitted as new protocol for initial review.

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The RERC must be provided with a copy of the FINAL report not later than one (1) month from end of study.

**"End of Study"** is defined as follows :

- For Batmc-initiated protocols - End of Study refers to date of dissemination of the Final Report by the Department
- For Clinical Trials - End of Study as defined on the terms in the Clinical Trial Agreement when applicable

## 2. Objective/s of the Activity


The activity aims to classify research protocols that would not need ethical review.

## 3. Scope

This SOP applies to the initial evaluation of a study protocol for initial submission which satisfy the criteria for exemption from ethics review. This SOP begins with submission of complete protocol package to the RERC Chair, or in her absence, the Vice Chair / Member Secretary / Assistant Member Secretary for classifying the level of ethics review required and ends with the filing of protocol-related documents and ends with the filing of protocols exempted from ethical review.

## 4. Workflow

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1 :</b> Submission of complete protocol package for classification and assignment of Primary Reviewer	RERC Staff
<b>Step 2:</b> Determination of type of Action/ Type of Review d. Exemption from Review (2SOP 10) e. Expedited Review (2SOP 8) f. Full Review (2SOP 9)	RERC Chair Vice Chair Member Secretary Assistant Member Secretary
<b>Step 3 :</b> Presentation of protocols exempted from review during Full Board Review Meeting	RERC Chair
<b>Step 4 :</b> Communication of decision to exempt study protocol from ethics review	RERC Staff

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<b>Step 5 : Filing of documents in the protocol file (4SOP 33 Archiving of Terminated, Inactive and Completed Studies)</b>		<i>RERC Staff</i>

## 5. Description of Procedures

### Step 1 – Submission of the complete protocol package for classification and assignment of Primary Reviewer :

The RERC Staff submits all received complete protocol package to the Chair / Vice Chair or Member Secretary / Assistant Member Secretary for classification and assignment of Primary Reviewer.

Only protocols submitted on or before the deadline set by the RERC or fourteen (14) calendar days prior to the next scheduled protocol review meeting shall be accepted for preliminary evaluation.

### Step 2 – Determination of Type of Review :

The RERC Chair, or alternate, conducts a preliminary review of the protocol to determine level of review i.e Exempted, Expedited, or Full, and assignment of Primary Reviewers.

If the RERC Chair decides that the protocol is exempted from review, the reviewer's Checklist for Exemption from Ethical Review (*Form 2.10.1*) shall be accomplished and signed by the evaluator.


If the Chair determines that the protocol should undergo either Full or Expedited review, then the REC staff proceeds to follow either *2SOP 8* Expedited Review or *2SOP 9* Full Review.

### Step 3 – Presentation of protocols exempted from review during Full Board Review Meeting :

Protocols exempted from review will be presented during Full Board Review Meeting.

### Step 4 – Communication of decision to exempt study protocol from ethics review:

If the RERC Chair decides that the protocol is exempted from review, s/he directs the RERC staff to follow the procedure to communicate the decision to the researcher (4SOP 30 Communicating REC Decisions).

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The RERC Staff prepares the Notification of RERC Decision (*Form 4.30.2A*) and the Certificate of Exemption from Ethical Review (*Form 2.10.2*). Once signed by the RERC Chair, these are released to the Principal Investigator.

#### Step 5 - Filing of documents in the protocol file :

The complete protocol folder, including all protocol-related documents, is filed for safekeeping in the Archived Study File cabinet. Electronic database is likewise updated as to type of review and assigned primary reviewers.


See 4SOP 33 *Archiving of Terminated, Inactive and Completed Studies*.

#### 6. Forms

Form 4.30.2C	Letter of Exemption from Ethical Review
Form 2.10.1	Checklist for Exemption from Ethical Review
Form 2.10.2	Certificate of Exemption from Ethical Review

#### 7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2015 October	Rhodora M Reyes, MD	No SOP
2	2016	Rhodora M Reyes, MD	No SOP
3	2017 February	Rhodora M Reyes, MD	No SOP
4	2020 October	Jesus V. Fernandez, MD, Alfonso Shoei R. Yoshida, MD Dinna P. Remo, CPA	First Draft
5	2021 June	Alfonso Shoei R. Yoshida, MD Dinna P. Remo, CPA	Presentation of Exempted Protocols to Full Board Meeting  Submission of Final Report to RERC of all exempted protocols

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## 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*


*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

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## 1. Policy Statement


Single Joint Ethics Review Board (SJREB) is a joint review mechanism among PHREB duly accredited Research Ethics Committees (RECs) of DOH hospitals. It is a cooperative mechanism, rather than a stand-alone REC, that draws its review authority from RECs duly accredited by the Philippine Health Research Ethics Board. SJREB (*Appendix Reference No. 4*) conducts joint review of study protocols to be implemented in at least three (3) sites in the Philippines. Sponsors and researchers who choose to do their studies in 3 or more sites may submit their protocols to SJREB. It accepts multi-site protocols that are funded by DOH, PCHRD, DOST, PHIC, PHREB, CHED and other local organizations, including industry organizations and other foreign entities. Sponsors or PI or its representative may submit their protocol to BATMC RERC in parallel to their submission to the SJREB. BATMC RERC upon signing the Letter of Intent (*Appendix-Reference No.5*) agrees to participate in the review and oversight of multisite or multicenter protocols involving human participants.

## 2. Objective/s of the Activity

The objective of activities described is to ensure that study documents are complete, properly recorded, and properly evaluated to determine appropriate action or type of review to be applied for protocols on initial submission on protocol for SJREB of which Batangas Medical Center is one of the sites of the research proposal.


## 3. Scope

The process begins with the submission of a protocol package for initial review by the Sponsor/ PI or its representative to BatMC RERC and ends with reporting of the result and committee decision on the protocol reviewed to the SJREB protocol review meeting by the assigned Primary Reviewers.

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#### 4. Workflow

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1:</b> Receive THREE (3) set (HARD COPY) and ONE (1) set (ELECTRONIC COPY) of protocol package from the Sponsor/ PI or its representative for review; Secretariat will check for the completeness of the documents according to the Protocol Package Check list (Form 2.6.1)	RERC Staff
<b>Step 2:</b> Check on the Application Form for Protocol Review (Form 2.6.2 )	RERC Staff
<b>Step 3:</b> Assign a permanent SJREB protocol code to the package	RERC Staff
<b>Step 4:</b> Distribute protocol package to RERC Chair / Member secretary / Assistant Member secretary for facilitation of Preliminary review.	RERC Staff
<b>Step 5:</b> Determination of type of Review as well as Assignment of Primary Reviewer ( See Chap 2SOP7, 2SOP8, 2SOP9)  <input type="checkbox"/> Expedited Review <input type="checkbox"/> Full Review	Chair/ Member secretary/ Assistant Member secretary
<b>Step 6:</b> Log the received protocol and result of the preliminary review in the RERC database  Send out the protocol package to Primary Reviewer/ Independent consultant (for Expedited review) as well as to all RERC member reviewers (if for Full review).	RERC Staff

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<p><b>Step 7;</b> Primary reviewer/ Independent consultant/ RERC member reviewer shall facilitate initial review process in accordance to the level or review applied on the protocol assigned</p> <p><input type="checkbox"/> Expedited Review (Refer to SOP No.8) <input type="checkbox"/> Full Review (Refer to SOP No.9)</p>	Primary reviewer/ Independent consultant/ RERC member reviewer	
<p><b>Step 8:</b> Filing of Original Package</p>	RERC Staff	
<p><b>Step 9:</b>Primary reviewer shall represent the BatMC RERC by attending the SJREB’s protocol review meeting to where the result / committee decision shall be reported</p>	Primary reviewer	

## 5. Description of procedures:

**STEP 1** Only protocols submitted on or before the deadline set by the RERC (set as 2 WEEKS or 14 DAYS PRIOR TO THE NEXT PROTOCOL REVIEW MEETING) shall qualify to be included in the initial protocol review process;

Make sure that the PI has signed the Batangas Medical Center RERC Application Form for Protocol Review (Form 2.6.2), make a copy of the filled-in application form, keep the original copy for the RERC files and give the duplicate to the PI or his/her representative


Check the documents being submitted based on the RERC checklist.

A protocol package has to include the following:

Basic Documents [Must submit ALL for both institutionally originated and sponsored studies]

- ☐ Technical review certification
- ☐ Protocol package checklist (Form 2.6.1)
- ☐ Application form for Protocol Review (Form 2.6.2)
- ☐ Protocol Evaluation Review (Form 2.6.3)
- ☐ Protocol Summary Sheet (Form 2.6.4)
- ☐ Protocol Assessment Form (Form 2.6.5)
- ☐ Informed Consent Assessment (Form 2.6.6)
- ☐ CV of PI and study team members
- ☐ Informed Consent form in English and Local language (for studies involving adult




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human participants)

- ☐ Informed Consent form for Co-signature in English and Local language (for studies involving minors ages more than or equal to 15 years up to less than 19 years of age and
- ☐ relevant populations deemed incompetent to execute decision and signing of informed consent form)
- ☐ Assent form in English and Local language (for studies involving minors less than or equal to 14 years of age and relevant populations deemed incompetent to sign an informed consent form)

Study Specific Documents [Submitted as needed particularly for externally originated studies and sponsored studies]

- ☐ Document receipt form (for externally originated protocol)
- ☐ Informed consent form for Genetic Studies in English and Local language
- ☐ Data Collection forms (including CRFs)
- ☐ Diagrammatic work flow
- ☐ Good clinical Practice (GCP) Training Certificate of PI, Co-I and the rest of the study team : updated at least within THREE (3) years (for clinical trials)
- ☐ Investigator's Brochure (for clinical trials phase I, II, III) or Basic Product Information Document (for Phase IV clinical trials)
- ☐ Recruitment advertisements (as needed by the study protocol)
- ☐ Other information or documents for participants (such as diaries, etc.)
- ☐ Material Transfer Agreement (for any research involving transfer of biological specimens)
- ☐ Memorandum of Agreement (for collaborative studies)
- ☐ Site Resources Checklist for Clinical Trial outside BATMC By BATMC Personnel
- ☐ Site Resources Checklist for Clinical Trial outside BATMC By non-BATMC Personnel
- ☐ Site Resources Checklist for Clinical Trial outside BATMC By BATMC Personnel
- ☐ Site Resources Checklist for Clinical Trial outside BATMC By non-BATMC Personnel
- ☐ Previous ethical review approvals/clearances (for students/personnel of foreign universities researching in the Philippines or those with prior ethical review)
- ☐ National Commission for Indigenous People (NCIP) Clearance (for studies with indigenous populations; can be processed while BATMC-RERC review is ongoing)
- ☐ Clearance or permit from respective regulatory authorities (such as FDA approval for clinical trials and DENR local transport permit, as applicable)
- ☐ Contracts and/or Approval of relevant offices / regulatory authorities (Written review

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agreement / Authorization and Acknowledgement of review)

**STEP 2** The secretariat must ensure that the PI has signed the BatMC RERC Application Form for protocol review (*Form 2.6.2*). Upon confirmation, make a copy of the filled application form. Secretariat must keep the original copy for the RERC files, and give the duplicate to the PI or his/her representative.

**STEP 3** This code shall serve as reference on the submitted protocol. The code will be communicated to the PI in subsequent communications regarding the protocol.

Make a copy of the protocol package and deliver to RERC Chair, Member secretary, Assistant Member secretary for Preliminary review to decide on the level of review, as well as assignment of Primary Reviewer.

**STEP 4** The Secretariat will distribute the complete protocol package and research protocol to The Chair, Member secretary, or Assistant Member secretary

**STEP 5** The Chair, Member secretary, or Assistant Member secretary conducts Preliminary review of the protocol to determine the type of review whether it is for Expedited or Full review. and assigns the Primary Reviewers.

Preliminary Review shall commence NO LATER THAN TWELVE (12) CALENDAR DAYS PRIOR TO THE NEXT SCHEDULED RERC PROTOCOL REVIEW MEETING, and shall not take more than MAXIMUM OF TWO (2) CALENDAR DAYS to complete.


The Chair, Member secretary, or Assistant Member secretary shall appoint at least TWO (2) BatMC RERC members to be the Primary Reviewers which should preferably be composed of a Medical member (affiliated or non-affiliated) with related expertise to review the protocol and a Non-Medical member (affiliated or non-affiliated) to review the informed consent form.

If there are no RERC member with field of expertise to adequately review the scientific aspect of the study protocol, an Independent Consultant may be invited to join the protocol review.

The Chair/ Member Secretary/ Assistant Member Secretary returns the protocol and duly accomplished Protocol Assessment form (*Form 2.6.2*) to the secretariat to which the result / decision of preliminary review will be noted.

Decision on the level of review to be applied may either be of the following:

**EXPEDITED REVIEW** - Shall be conducted for study protocols that :

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	<b>CHAPTER 2</b> <b>INITIAL REVIEW PROCEDURES</b> <b>SOP 11</b> <b>SJREB Protocol Review</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

1. Do not entail more than minimal risk to the study participants;
2. Do not have study participants belonging to vulnerable group;
3. The study procedures do not generate vulnerability.

**FULL REVIEW** - A full review shall be conducted when a proposed study entails more than minimal risk to study participants or when study participants belong to vulnerable groups or when a study generates vulnerability to participants.

**STEP 6** The primary reviewers discuss the SJREB protocol in a scheduled monthly meeting. Considerations of the scientific design, ethical issues, and informed consent process are main points of discussion. Final decision can be approval, minor or major modifications or disapproval (*See 4SOP27 Conduct of Meetings and 4SOP30 Communicating of RERC Decisions*)

**Step 7** File the folder in the Active Study File cabinet

Prepare a transmittal letter with the name of the reviewer, the date of actual delivery, prior to the actual delivery of the protocol package. This transmittal letter shall be signed by the reviewer or representative upon receipt.

Update the RERC database with the following details:


- ☐ Name of PR
- ☐ Date of delivery
- ☐ Expected date of accomplishment of review
- ☐ Date of RERC meeting to which protocol is included in the agenda

These details shall serve as reference in case of queries from the PI, Department Technical Review Committee, other Hospital/Institution on the status of the protocol.

**STEP 8** File the original package in a properly coded protocol file folder and place in the active study file cabinet

**STEP 9** The Primary reviewers, upon invitation by SJREB, shall represent the BatMC RERC through its attendance to SJREB's protocol review meeting, to where the result and committee recommendation for the assigned protocol for review shall be reported.

## 6. Forms (see description of procedures)

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 2 INITIAL REVIEW PROCEDURES SOP 11 SJREB Protocol Review</b>	<b>Version No: 4</b>
		<b>Date of Approval:</b> October 19, 2020
		<b>Date of Effectivity:</b> November 02, 2020

## 7. History of SOP

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
1	2015 October		No SOP
2	2016		No SOP
3	2017 February		No SOP
4	2020 October	Dr. Rhodora Madrid-Reyes	First Draft
5	2021 June	Dr. Rhodora Madrid-Reyes	Revised Number of Days for Review

## 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*


*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

	<b>BATANGAS MEDICAL CENTER</b> <b>RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 2</b> <b>INITIAL REVIEW PROCEDURES</b> <b>SOP 12</b> <b>Review of Medical Device</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

### 1. Policy Statement:

Experimental researches sometimes involve the use of medical devices, which, like drugs and other kinds of intervention, can be investigated for their potential medical purposes. Like with ethical reviews of other research types, the benefits and risks of medical devices to human participants are evaluated in this type of review. However, the review of medical devices differs significantly because of the likely necessity of including independent consultants in the review, who can offer their knowledge and expertise on the technical aspects of the device that the RERC members are usually not familiar with. Depending on the level of risk, reviews of medical devices may undergo full board review or expedited review.


### 2. Objective of the Activity:

The activity aims to review researches involving the use of medical devices on human participants, taking into account all relevant technical and safety data regarding the use of the device, as well as evaluating the level of risk involved for the participants. If necessary, these researches may be reviewed in collaboration with an independent consultant with knowledge and expertise on the medical device.

### 3. Scope:

This policy applies to the review of researches using medical devices. According to the WHO<sup>1</sup>, a medical device is “any instrument, apparatus, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings” for “specific medical purpose(s)”. The effects of a medical device are not achieved by direct changes to physiology like that of drugs. Specific medical purposes include, but are not limited to, examples such as diagnosis, treatment and monitoring of disease or injury; augmentation, modification or replacement of an anatomic function; life support; birth control; disinfection of other devices; and others. The review of investigational medical devices shall evaluate the benefits and risks to human participants in the context of their specific intended medical purpose(s).

This policy also applies to review of medical devices that have already been previously approved by appropriate regulatory bodies, but are being investigated anew due to changes or modifications in their form or components (which may bring new benefits and risks to human participants), changes in their previously intended function and/or application (e.g., novel uses or “off-label” uses, repurposing), and/or changes in their locality of use (e.g., previously approved in other countries but newly tested here in the Philippines).

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Medical Devices for this SOP will cover the following :

- Diagnostic: Accuracy, reduce subjectivity
  - Imaging (e.g. x-ray)
  - Sensors
  - Laboratory tests on body fluids
- Surgical robotics:
- Treatment: Enhanced physiologic function such as Implants
- Rehabilitative

This SOP proceeds similarly as *2SOP 06 (Management of Initial Submissions)*, and then *2SOP 08 (Expedited Review)* or *2SOP 09 (Full Review)*: it begins with the receipt of study documents for initial review and ends with the filing of protocol-related documents and updating of the protocol database.

#### 4. Workflow

Activity	Responsibility
Step 1: Receipt of study documents for initial review and determination of completeness of submission, up to filing of original package in a properly coded protocol file folder and placing in the active study file cabinet ( <i>2SOP 06 Management of Initial Submissions</i> ).	RERC staff
Step 2: Assignment of reviewers and/or independent consultant/s ( <i>2SOP 07 and 1SOP 03</i> ), and notification of primary reviewers, independent consultant/s, and/or committee members, as well as provision of study documents and assessment forms	Chair/Vice Chair/Member Secretary/Assistant Member Secretary  RERC staff
Step 3: Conduct of meeting and discussion of technical and ethical issues of study	Primary Reviewers, Independent Consultant/s (if necessary), RERC Members (if full review)
Step 4: Consolidation and finalization of review results and decision	RERC Chair

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Step 5: Communication of RERC review decision to primary investigator (PI) (4SOP 30)	RERC Chair  RERC staff	
Step 6: Filing of protocol-related documents and updating of protocol database	RERC staff	

## 5. Description of Procedures

**Step 1: Receipt of study documents for initial review and determination of completeness of submission, up to filing of original package in a properly coded protocol file folder and placing in the active study file cabinet**

SOP step details are similar to the steps outlined in *2SOP 06 (Management of Initial Submissions)*. However, for review of medical device with human participants, protocols are only classified into expedited or full review, depending on level of risk (as defined in the aforementioned 2SOP 06).

Similar to clinical trials, investigators should provide, as part of the required supplementary documents, a document/brochure that outlines all device characteristics, technical and safety data, prior clinical data and prior regulatory approval (if applicable).

**Step 2: Assignment of reviewers and/or independent consultant/s, and notification of primary reviewers, independent consultant/s, and/or committee members, as well as provision of study documents and assessment forms**

See *2SOP 07 (Selection of Primary Reviewers)* and *1SOP 03 (Appointment of Independent Consultants)*. In reviewing researches involving medical devices, RERC members may not possess the adequate scientific or technical knowledge and expertise on the device being reviewed. The appointment of independent consultants who have sufficient background in such cases is thus essential in facilitating these reviews.


**Step 3: Conduct of meeting and discussion of technical and ethical issues of study**

Depending on the type of review, SOP step is similar to that outlined in *2SOP 08 (Expedited Review)* or *2SOP 09 (Full Review)*.

**Step 4: Consolidation and finalization of review results and decision**

Depending on the type of review, SOP step is similar to that outlined in *2SOP 08 (Expedited Review)* or *2SOP 09 (Full Review)*.



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**Step 5: Communication of RERC review decision to primary investigator**

*See 4SOP 30 (Communicating of RERC Decisions).*

**Step 6: Filing of protocol-related documents and updating of protocol database**

*See 4SOP 32 (Management of Active Files).*


**6. Forms**

Form 1.3.1	Letter of Invitation <independent consultant>
Form 1.3.2	Appointment Letter <independent consultant>
Form 1.3.3	Confidentiality and Conflict of Interest Disclosure Agreement (Ind Consultant)
Form 2.6.2	Application Form for Protocol Review
Form 2.14.1	Study Protocol Assessment form (adapted from UP-PGH MREB form)
Form 2.14.2	Informed Consent Assessment form (adapted from UP-PGH MREB form)
Form 4.30.2A	Notification of RERC Decision
Form 4.30.2B	Letter for Modification
Form 4.30.1	Letter of Approval

**7. History of SOP**

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
1	2015 October	Dr. Rhodora Madrid-Reyes	First Draft
2	2016	Dr. Rhodora Madrid-Reyes	No Change
3	2017 February	Dr. Rhodora Madrid-Reyes	No Change
4	2020 October	Dr. Albert Joseph B. Lupisan Dr. Rogelio A. Acosta	Separate SOP for Review of Medical Device
5	2021 June	Dr. Albert Joseph B. Lupisan Dr. Rogelio A. Acosta	Changes to policy statement, objective, scope, workflow and format of SOP on review of medical devices



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		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

## 8. References *World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*

*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*


*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

*Medical Device – Full Definition: [https://www.who.int/medical\\_devices/full\\_definition/en/](https://www.who.int/medical_devices/full_definition/en/)*

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 2 INITIAL REVIEW PROCEDURES SOP 13</b>	<b>Version No: 5</b>
	<b>Rapid Review of Research Protocols related to Acute Disease Outbreaks &amp; Other Natural or Man-made Disasters</b>	<b>Date of Approval:</b> June 04, 2021  <b>Date of Effectivity:</b> June 04, 2021

## 1. Policy Statement

This SOP was formulated due to the exigencies of the Pandemic of Severe Acute Respiratory Syndrome Coronavirus 2 which affected the Philippines in year 2020. There was no known cure and WHO supported the numerous clinical trials to determine the most effective treatment for this disease. As a consequence, numerous clinical research protocols involving human participants materialized hence, research ethics committees need to be activated for review and oversight. This SOP hopefully may also be a basic template for review of protocols regarding other acute disease outbreaks or any acute events or disasters natural or manmade (armed conflicts, chemical incidents, or natural disasters) of major social and health impact to our country. Since the pandemic has put restrictions to travel and face to face contact of all members, we have utilized digital platforms for communication, submission of documents and online meetings.

The Protocol adheres to the Guidelines set forth by *National Ethical Guidelines for Health and Health-related Research on "Research involving populations in Disaster Situations" p 146, 2017*. Full review of these protocols is mandatory due to emergency nature of the situation and the involvement of vulnerable population.

## 2. Objective/s of the Activity

This SOP presents the key points that the RERC must incorporate in their SOP to guarantee a rapid and rigorous review of any acute disease outbreak or disaster related research during a health emergency.


This review protocol may be adapted, revised and tailored to other research protocols submitted during disease outbreaks and disaster events of manmade (like chemical incidents, fire) or natural causes.

## 3. Scope

The activity starts from the time a research protocol regarding acute disease outbreak, a health research protocol dealing with human participants involved in an acute emergency incident or disaster whether man made or of natural causes like earthquakes, severe typhoon or chemical incidents is submitted for review either as multicenter or multisite, PI initiated or sponsor initiated up to the time of approval, oversight and completion of research activity.

These topics have been divided into three sections.

- A. Preparation of the RERC
- B. Ethics review process of research protocols related to acute disease outbreaks and man-made or natural disasters

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C. Ethics oversight of research protocols on acute disease outbreaks and man-made or natural disasters, including the follow-up and monitoring during the event.


#### 4. Workflow:

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1:</b> Acceptance of a complete protocol package online	RERC Staff
<b>Step 2:</b> Determination of quorum requirement and selection of members conducting the review.	Chairman
<b>Step 3:</b> Selecting and convening independent consultants if needed	Chairman
<b>Step 4:</b> Distribution and assignment of Acute Disease or Disaster related research to primary reviewers	Chairman
<b>Step 5:</b> Review of the RERC members of Acute Disease or Disaster related research	Chairman/Reviewers
<b>Step 6:</b> Preparation of the meetings for the Acute Disease or Disaster related research	Member Secretary/ Asst Member Secretary
<b>Step 7:</b> Review of protocol and decision making	Chair, reviewers and independent consultants
<b>Step 8:</b> Communicating the decision of the RERC	Member Secretary/ Asst Member Secretary
<b>Step 9:</b> Post approval oversight	Chairman/Reviewers
<b>Step 10:</b> Completion of the study, filing and archiving	Member Secretary/ Asst Member Secretary

#### 5. Description of Procedures

##### A. Preparation of the RERC

##### STEP 1 Acceptance of request for Initial review

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The request for review of Acute Disease or Disaster related research should be considered a high priority for the RERC is received by the Secretary and forwards the letters addressed to the Medical Center Chief thru the Chairman of the RERC. The Chairman reviews the request to determine if this protocol is related to health emergency and accepts the request. The research protocol will be assigned a protocol code which should be used for all communications with RERC.

#### **Receive the documents for Initial review**

The Secretariat shall receive the protocol package (2SOP 6) online and receive via e-mail all the necessary documents for Initial review ( protocol package, CV, GCP certificate, assessment forms) to include as well:

- Summary of the study in two pages or less in non –technical language
- Previously published and up to date evidence, if any
- The risk minimization plan, taking extreme care to avoid spreading the acute disease or straining the health system
- Materials transfer agreement for biologic samples or data or their preliminary version,
- Plans to publish and disseminate the data and results, indicating the process through which the results will be returned to the affected community and the health authorities.

For clinical trials, the following should also be submitted :

- In case of multi-center studies, the decision of other RERCs or the SJREB (See 2SOP11) or medical regulatory authorities (FDA in-country or external)
- List of centers in the country where clinical trial is being carried out if any
- The procedures through which intervention will be made available to participants and to the community if found effective


#### **STEP 2 Determination of quorum and composition of the RERC**

The RERC Chairman identifies the members to participate in the **full review** of the protocols to ensure that they have adequate knowledge of the protocols and ethical aspect of the review of researches in emergency situations.

#### **Selection of members conducting the review**

The RERC Chairman consults members via email or messaging platform about their availability for a rapid review before assigning them research protocols to review.

The selection will be based on their expertise and knowledge related to the acute disease or disaster related research in question.

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### **STEP 3 Selecting and convening independent consultants (1SOP 3)**

The RERC Chairman may seek an independent consultant who may serve as an ad-hoc member with voice and vote during situations in which the RERC needs a member with the expertise and knowledge for the disease or disaster related research. The Chairman issues a call for the independent consultant Via email or messaging platform at the request of the RERC. Before receiving the corresponding documentation, the consultant should sign a declaration of conflict of interest and a confidentiality statement. (See 1SOP3)

### **STEP 4 Distribution and assignment of the Disease or Disaster related research to primary reviewers**

The documents will be sent electronically by the secretariat to the initial reviewers assigned by the Chairman (2SOP7). The primary reviewers should be at least two (2) members of the RERC. One of the reviewers is a medical professional and another is non-medical and may be non-affiliated. The documents are sent within 24 hours after receiving the request for review.

## **B. ETHICS REVIEW PROCESS**

### **STEP 5 Review of the RERC members of Acute Disease or Disaster related research**


The reviewers will maintain a deadline of 72 hours from receipt of the documents electronically to review the protocol. The deadline could be longer depending on the complexity of the study.

### **STEP 6 Preparation of the meetings for the Acute Disease or Disaster related research**

The virtual meeting for the deliberation and decision making of the research protocol is scheduled within 24 hours of receiving the reports from reviewing members. This maybe scheduled as a special or emergency meeting apart from the usual committee meeting. The exact time and date will be communicated to the reviewers and members via messaging platform and email. Preparations and notice of agenda shall be done in accordance with the standard protocols set by the RERC. (2SOP8 for expedited protocols 2SOP9 for full review)

### **STEP 7 Conduct of the Meeting**

#### **a. Virtual Meeting**

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The standard procedure for the emergency meeting starts with the call to order, attendance, approval of the notice of the agenda, declaration of quorum, declaration of conflict of interest if any, presentation of the research protocol by the primary reviewers, clarificatory interview if needed and decision making about the research protocol. Quorum may constitute one third of the total number of members to include one non-medical and one non-affiliated member. In cases in which members cannot participate in the virtual meeting, they may be considered for quorum as long as they send in their reviews electronically in advance. The decision adopted is similar for other protocols – approve, major modification or minor modification and disapproved (*2SOP8 for expedited and 2SOP9 for Full Review*). All reviewers review the protocol assessment and ICF forms (*Form 2.14.1 and 2.14.2*) rigorously and evaluate the risks and benefits related to the study.

#### **b. Staggered decision making and review**

For cases in which the RERC members are not able to organize a prompt virtual meeting, the review, deliberation and decision making may be carried out in a staggered manner. The Chairman in coordination with the secretariat will send the protocol to be reviewed to all members of the RERC through email. Members will send their comments and observations through email. Discussion may be carried out through email or messaging platform. The RERC aims to make decisions by consensus but if this is not possible then a simple majority vote can be done.

#### **STEP 8 Communicating the decision of the RERC**

Communications to the primary investigator are made by the Secretariat with the approval of the RERC Chairman via email within 24 hours from the adoption of decisions by the RERC. Primary investigators should acknowledge within 48 hours.

Communications and decisions of the RERC only require the signature of the RERC Chairman. Once the health emergency is over they will be countersigned by other members as appropriate.


Communications to the institution, other RERCs or health authorities shall be made as soon as possible.

#### **C. ETHICS OVERSIGHT**

##### **STEP 9 Post approval oversight**

a. Review of amendments, progress report, final report and other documents will be conducted by members who have reviewed the original protocol.

b. Documents to be reviewed will be sent to members via email within 24 hours of being received from the principal investigator. If additional information is needed from the principal

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investigator, a clarificatory interview would be requested within 24 hours of the completion of the member's review.

c. Members have a deadline of 48 hours from the receipt of documentation to give a response. The response will be sent via email of the RERC so that the Chairman can communicate to the principal investigator within 24 hours.

d. Monitoring and follow-up of the Acute Disease or Disaster related research will be done through reports of deaths, SAE, Susars, RNE (*Refer 3SOP 18,19A,19B*), protocol violation and noncompliance.

e. The RERC Chairman can designate a group of RERC members to be in charge of following up on an investigation or research in question in a timely manner with established deadlines in order to avoid putting the members at risk and affecting patient care. The reports maybe done remotely by the investigator in a way the privacy and confidentiality of the information is maintained. An Emergency meeting could be called anytime by the Chair.

f. Reports of off site SAE, SUSARS, RNE must be received by the Secretary using the timeline on *3SOP 18,19A,19B*. Secretary must also receive Progress reports submitted to RERC every month or the frequency of which depends on the risks of the study.


g. Early termination of the study, accrual, withdrawal of consent, withdrawal of patients from the study, complaints related to the study must be evaluated and discussed in a special meeting.

h. Regular update on scientific information regarding the disease affecting the research must be available.

i. Site visit may be organized by the Chair to monitor compliance to protocol and ICF process (*see 3SOP 24- Conduct of Site Visits*)

**STEP 10** At the completion of the research study, the final report is received and the documents are archived and filed by the Secretariat (*see 4SOP 33*).



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**TIMELINE FOR RAPID REVIEW (INITIAL SUBMISSION)**


<b>TIMELINE</b>	<b>FROM</b>	<b>ACTIVITY</b>
<b>Day 1</b>	Principal Investigator	Submission of research protocol to RERC office for Rapid Review
<b>Day 2</b>	RERC Chair	(1) Creation of Rapid Review Committee; (2) assignment of Primary Reviewers and (3) invitation for Independent Consultant
	RERC Chair / RERC Staff	Send electronic copy of complete protocol package to Primary Reviewers / Member Reviewers
<b>Day 2 to 4 (72 hours from receipt of electronic documents)</b>	Primary Reviewers & Member Reviewers	Review of research protocols by the Primary Reviewer and Rapid Review Committee members; submit online fill up and signed assessment forms
<b>Day 5 or 24 hours from receipt of assessment forms</b>	<b>EMERGENCY RAPID REVIEW COMMITTEE MEETING</b>	
<b>Day 6 or 24 hours from meeting</b>	Member Secretary	Email Notice of RERC Decision to Principal Investigator
<b>Day 7 or 48 hours from email of decision</b>	Principal Investigator	Acknowledge receipt of Decision

**TIMELINE FOR RAPID REVIEW (AMENDMENTS/OTHER REPORTS)**

<b>TIMELINE</b>	<b>FROM</b>	<b>ACTIVITY</b>
<b>Day 1</b>	Principal Investigator	Submission of Reports such as Amendments, SAE, SUSAR
<b>Day 1</b>	RERC Chair / Secretariat	Send electronic copy of reports to Rapid Review Committee Members and convene for emergency meeting
<b>Day 2 or 24 hours from receipt of documents from PI</b>	<b>EMERGENCY RAPID REVIEW COMMITTEE MEETING</b>	
<b>Day 4 or 48 hours from meeting</b>	Member Secretary	Email Notice of RERC Decision to Principal Investigator

NOTE : The complete review process until issuance of approval should not exceed 14 calendar days.



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## 6. Forms

FORMS: Protocol Package(Forms2.6.1-2.6.6)

WHO Templates for ICF

Form 4.30.2B Letter for Modification

Form 4.30.1 Letter of Approval

Form 2.15.1 Review or Resubmitted Protocol

POST-APPROVAL FORMS:

Form 3.16.1 Amendment Form

Form3.18.1 Deviation / Non-Compliance / Violation Report

Form 3.19B.1 RNE Report

Form 3.19A.1 SAE/SUSAR/ Report Form

Form 3.17.1 Progress Report

Form 3.21.1 Continuing Review

Form 3.24.1 Site Visit Report

Form 3.20.1 Early Termination Report

Form 4.30.3 Letter of Document Receipt and Recommended Action


Form 3.16.2 Letter of Approval of Amendment

## 7. History of SOP

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
1	2015 October	Dr. Rhodora Madrid-Reyes	No SOP
2	2016	Dr. Rhodora Madrid-Reyes	No SOP
3	2017 February	Dr. Rhodora Madrid-Reyes	No SOP
4	2020 October	Dr. Rhodora Madrid-Reyes	First Draft SOP
5	2021 June	Dinna P. Remo, CPA	Addition of timelines for initial submission and amendments

## 8. References:

▪ CIOMS. International ethical guidelines for health-related research involving humans. (Guideline 20: Research in disasters and disease outbreaks). Available at: <https://cioms.ch/publications/product/international-ethical-guidelines-for-health-related-research-involving-humans/>


	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 2 INITIAL REVIEW PROCEDURES SOP 13</b>	<b>Version No: 5</b>
	<b>Rapid Review of Research Protocols related to Acute Disease Outbreaks &amp; Other Natural or Man-made Disasters</b>	<b>Date of Approval:</b> June 04, 2021  <b>Date of Effectivity:</b> June 04, 2021

▪ PAHO. Ethics guidance on issues raised by the novel coronavirus disease (COVID-19) pandemic. Available at: <https://www.paho.org/en/documents/ethics-guidance-issues-raised-novel-coronavirus-disease-covid-19-pandemic>

▪ Nuffield Council on Bioethics, Research in global health emergencies: ethical issues. Available at: <https://www.nuffieldbioethics.org/publications/research-in-global-health-emergencies>

▪ WHO. Guidance for managing ethical issues in infectious disease outbreaks. Available at: <https://apps.who.int/iris/bitstream/handle/10665/250580/9789241549837-eng.pdf?sequence=1>

WHO. Guidance for research ethics committees for rapid review of research during public health emergencies. ISBN 978-92-4-000621-8 (electronic version) ISBN 978-92-4-000622-5 (print version) © World Health Organization 2020

	<b>BATANGAS MEDICAL CENTER</b> <b>RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 2</b> <b>INITIAL REVIEW PROCEDURES</b> <b>SOP 14</b> <b>Use of Study Assessment Forms</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
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## 1. Policy Statement

Assigned Primary Reviewers are required to submit duly filled up assessment forms to ensure an exhaustive evaluation of the study protocol's scientific design, ethical issues and corresponding measures to reduce the risks to human participants, laboratory animals and the environment as well as assessment of informed consent processes and forms.

The name of PR will be indicated on the assessment forms by the RERC Secretariat after submission of PI of complete protocol package.

## 2. Objective/s of the Activity


Comprehensive review of study protocols submitted may be ensured through the use of a guided and detailed assessment forms to cover all aspects such as scientific design and ethical considerations in the conduct of the study and all essential elements in securing informed consent from human participants. In addition to the review elements described above, the primary reviewers should ensure the study protocol's compliance with existing international and national guidelines and policies including, but not limited to, the **2017 National Ethical Guidelines for Health and Health-related Research** and **Data Privacy Act of 2012**. The assessment forms are designed to standardize the review process and to facilitate the reporting of the findings and recommendations pertaining to the study protocol as well as related documents.

## 3. Scope

This SOP covers the use of the Study Protocol Assessment Form and Informed Consent Assessment Form in the review and assessment of protocols and related documents submitted to Batangas Medical Center RERC for initial review and approval. This SOP begins with the review exercise and accomplishment of the assessment forms including findings as well as recommendations and ends with the filing of the accomplished assessment forms in the respective protocol folders. There are two (2) assessment forms to be used for protocol review:

- a. Study Protocol Assessment Form (Form 2.14.1)
- b. Informed Consent Assessment Form (Form 2.14.2)

## 4. Workflow

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<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1:</b> Read and evaluate study protocol and related documents; fill up completely Study Protocol Assessment Form (Form 2.14.1) and Informed Consent Assessment Form (Form 2.14.2). Summary Section at the end of each assessment form must be accomplished.	Primary Reviewers
<b>Step 2:</b> Submits the filled up and signed assessments forms to the Secretariat	Primary Reviewers
<b>Step 3:</b> Includes reviewed study protocol classified under Full Board Review in the Agenda for the succeeding board meeting; Prepares official Notice of RERC Decision and sends to Principal Investigator for study protocols classified under Expedited Review.	RERC Staff
<b>Step 4 :</b> Collection of all Study Protocol Assessment Form and Informed Consent Assessment Forms for final signature of Chairman and consolidation of findings	RERC Staff
<b>Step 5 :</b> Files Study Protocol Assessment Form and Informed Consent Assessment Form in the protocol folder	RERC Staff


## 5. Description of Procedures

### Step 1 – Accomplishment of Study Protocol and Informed Consent Assessment Forms :

The assigned Primary Reviewers and, in case of Full Review all other RERC members, accomplish completely and comprehensively the Study Protocol Assessment Form (Form 2.14.1) and Informed Consent Assessment Form (Form 2.14.2) after reading of the study protocol.

### Step 2 – Submission of assessment forms to RERC secretariat:

The Primary Reviewers and reviewer-members in case of Full Review accomplish assessment forms and submits to the RERC Secretariat at least ONE (1) day before actual meeting. All blocks in the forms including the Summary Sheet portion must be completely filled up, duly signed by the reviewers before submission to the REERC (wet signature if hard copy, e-signature for online submission). Submission

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may be through physical submission at the RERC office or through online platform provided assessment forms contain the e-signature of the Primary Reviewer/RERC members.

### **Step 3 – Inclusion in Meeting Agenda or Preparation of Notice of Decision:**

The Secretariat, after collection of all filled-up assessment forms performs the following functions:

a. For protocols under Expedited Review, PR assessment is presented first during Expedited PR Review Meeting prior to informing the PI. If approved, the protocol is presented in the Full Review Board Meeting. the Secretariat prepares the approval letter (*Form 4.30.1*) that is signed by the Chairman and sent to the Principal Investigator. If there are revisions required, these are communicated to the principal Investigator who has to resubmit the revised protocol and related documents before approval is given.

b. For study protocols under Full Board Review, the Secretariat includes the protocol in the agenda of the next BatMC RERC meeting for discussion and decision. The Primary Reviewer presents the protocol to the members with her/his comments during the monthly board meeting. An independent consultant may be asked to elucidate on the validity and ethics of the study also using the assessment forms. An approval letter is prepared, signed by the Chair and sent to the PI once a protocol is approved. If there are revisions required, they are communicated to the Principal Investigator who has to resubmit the revised protocol and related documents before approval is given. It is the Chair who is tasked to summarize the important ethical issues and revisions required. The Member Secretary/Chair includes all comments of reviewers in the Minutes for checking. Decisions are put to a vote or are collegial before the Secretariat informs the Principal Investigator through a letter (*Form 4.30.2A Notification of RERC Decision*)

### **Step 4 – Collation of all assessment forms for signature of Chairman and consolidation of findings:**


The Secretariat ensures all concerned Primary Reviewers and in case of Full Board Review, all RERC members submit and sign duly accomplished assessment forms and secures the signature of the Chairman on all forms.

### **Step 5 – Filing of Study Protocol Assessment Form and Informed Consent Assessment Form:**

All forms duly signed by both the reviewers and the Chairman are filed in the corresponding protocol folder.

## **6. Forms**


Form 2.14.1 Study Protocol Assessment Form\_(*Adapted from UPMREB Form 2(C)2012*)

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Form 2.14.2 Informed Consent Assessment Form ( *Adapted from UPMREB Form 2(D)2012*)

## 7. History of SOP

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
<b>1</b>	<i>2015 October</i>	<i>Dr. Rhodora Madrid-Reyes</i>	<i>First draft</i>
<b>2</b>	<i>2016</i>	<i>Dr. Rhodora Madrid-Reyes</i>	<i>None</i>
<b>3</b>	<i>2017 February</i>	<i>Dr. Rhodora Madrid-Reyes</i>	<i>None</i>
<b>4</b>	<i>2020 October</i>	<i>Dinna P. Remo, CPA</i>	<i>Use of new Phreb format</i>  <i>Changed form number</i>  <i>Added name of Primary Reviewers on the information section of the assessment forms</i> <i>Revised age range for Assent on study protocol assessment form</i>  <i>Additional clause for referencing source of current RERC forms 2.14.1 and 2.14.2</i>
<b>5</b>	<i>2021 June</i>	<i>Dinna P. Remo, CPA</i>	<i>Revised deadline for submission of forms to Secretariat</i>  <i>Presentation and discussion of Expedited</i>

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			<b>Date of Approval:</b> June 04, 2021
			<b>Date of Effectivity:</b> June 04, 2021
			<i>Protocols at Expedited PR Review Meeting</i>

## 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*


*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

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	<b>CHAPTER 2</b> <b>INITIAL REVIEW PROCEDURES</b> <b>SOP 15</b> <b>Management of Resubmissions</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

## 1. Policy Statement

The REC shall require a resubmission of a protocol that requires either minor or major modification/s within twenty one (21) days and not to exceed sixty (60) days\_ after receipt of the Decision Letter.

Protocols initially classified for expedited review but with minor or major revisions shall still undergo expedited review upon resubmission for as long as minimal risk is not elevate. Protocols initially classified for full review shall be subject to expedited review if with minor revisions and to full review if with major revisions upon resubmission.

Protocol resubmissions approved through expedited review will be reported during the Full Board Review Meeting. Resubmission of protocols initially classified for full review with major revisions will be included in the Agenda of the nearest Full Board Review Meeting for discussion and decision.

## 2. Objective/s of the Activity

The management of resubmission ensures that the protocol and related documents that requires either minor or major modification/s were addressed by the researcher.

## 3. Scope

This SOP applies to the resubmission of study protocols and related documents that requires minor or major modifications as decided by the Batangas Medical Center RERC. The procedure begins with receipt of the revised protocol and filing of these documents to protocol database.

## 4. Work Flow

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1</b> Receipt, record and manage coding of resubmitted protocol into logbook.	RERC Staff
<b>Step 2:</b> Notification of Chair and assigned reviewer/s	RERC Staff
<b>Step 3:</b> Review of the Resubmission and make recommendation a. Expedited Review (2SOP8 Expedited Review) b. Full Review (2SOP9 Full Review)	Reviewers



<b>Step 4</b> : Review recommendations and decide if it should be expedited or full review	Chair
<b>Step 5</b> : Discuss at full board if necessary	Members
<b>Step 6</b> : Communication of committee action (SOP on Communication Decisions (REFER TO 4SOP 30)	REC Chair

## 5. Description of Procedures

### Step 1 - Receipt, record and manage coding of resubmitted protocol into logbook

The RERC Secretariat receives the resubmitted documents by the Investigator, take note of the date , version code, completeness of the documents and ensures entry into the logbook.

### Step 2 Notification of Chair and Primary or assigned reviewer/s

The staff retrieves the Letter for Modification (*Form 4.30.2B*) that pertains to the original protocol and informs the Chair and the assigned reviewers about the resubmission and about the nature of the modifications required from the researcher.

### Step 3 - Review of the Resubmission and make recommendation.

The assigned reviewers conduct review of the resubmitted protocol by referring to the resubmission form noting the different recommendations made by the REC and evaluating whether these were satisfactorily addressed in the resubmitted protocol. The reviewers submit the report to the Chair for inclusion in the next Expedited PR Review Meeting or Full Board Review Meeting, as per guidelines.

### Step 4 - Review recommendations and decide if it should be expedited or full review

The RERC Chair reviews the recommendations of the primary reviewers and decide whether its for expedited or full board. If only minor changes are involved, the reviewers recommendation become the basis for the final decision of the RERC and a letter granting approval (*FORM 4.30.1*) is prepared by the RERC Secretariat. (*Refer to 2SOP 8 for criteria Expedited review*)


### Step 5 - Discuss at full board if necessary

If major modifications are involved for protocols initially classified for full review, it is referred to full board after review by the primary reviewers as agreed with the RERC Chair. The members discuss the issues related to the modifications to arrive at a decision. (*REFER to 2SOP 9 for criteria of Full Review*)

### Step 6 - Communication of committee action

For Resubmissions approved at the level of the Chair: the Chair informs the staff of his/her decision for preparation of the draft letter, finalization and sending to the researcher. For the resubmissions that underwent Full Review, the Chair will inform the Secretariat for preparation of the draft letter informing the PI of the major revisions and recommendations (*see 4SOP 30*)

### Step 7 - Filing of Documents in the Protocol Folder and update of the database

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The staff gathers all the pertinent documents related to the resubmission (revised protocol, assessment forms, excerpts of minutes, approval letter,) and enters the relevant information on resubmission in the appropriate protocol database.

## 6. Forms


Form 4.30.2B Letter For Modification  
Form 4.30.1 Letter of Approval  
Form 2.15.1 Review of Resubmitted Protocol  
Form 3.23.1 Letter of Appeal

## 7. History of SOP

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
1	2015 October	Dr. Rhodora Madrid-Reyes	First draft
2	2016	Dr. Rhodora Madrid-Reyes	None
3	2017 February	Dr. Rhodora Madrid-Reyes	None
4	2020 October	Dr. Angelita B. Villena Dr. Donalyn Barcial	Revision of Management of Resubmission
5	2021 June	Dr. Donalyn Barcial Dinna P. Remo, CPA	Revision in review classification of minor and major modifications & channel of review  Revision in deadline for resubmission

## 8. References

World Medical Association Declaration of Helsinki, 2013

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*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*

*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*


*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

Supersedes:	<b>Version 4</b>
Authored by:	Batangas Medical Center RERC
Effective Date:	June 04, 2021
Approved by:	Rhodora Madrid-Reyes MD, FPNA,FPSCOT Chairman
Approved by:	Dr. Ramoncito C. MagnayeMD,FPCS,FPSGS,MHA
	Medical Center Chief II
Approval Date:	June 04, 2021

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 3 POST APPROVAL PROCEDURES SOP 16 Review of Amendments</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

## 1. Policy Statement

The REC shall require the submission of proposed amendments for review and approval before their implementation. This requirement shall be explicitly stated in the Approval Letter.

As a general rule, regardless of initial protocol review classification, minor amendments are subject to expedited review of the original Primary Reviewers for as long as minimal risks are not elevated; while major amendments require full board review.

## 2. Objective of the Activity


This activity aims to ensure that the conduct of the study is in compliance with the approved protocol such that any change such as amendments does not impact safety and welfare of study participants. It describe the RERC review procedures for amendments of the protocol and related documents

## 3.Scope

This SOP applies to the management and review of protocol amendments submitted by the proponent while the study is on-going. It applies to previously approved study protocols and related documents that are being amended later and submitted for approval by the Batangas Medical Center RERC. Any amendment of the study related documents may not be implemented until reviewed and approved by the RERC. This SOP begins with the receipt and entry of the submission of amendment to logbook of incoming documents and the protocol database and ends with filing of the amendments and committee decision in the protocol file.

## 4. Workflow

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1.</b> Receipt and entry into logbook of the submission of amendments (4SOP32 on Management of Active Files).	RERC Staff
<b>Step 2.</b> Retrieval of pertinent protocol file	RERC Staff
<b>Step 3.</b> Notification of Chair and Primary Reviewer	RERC Staff
<b>Step 4.</b> Determination of type of review: expedited (2SOP8 on Expedited Review) or full review (2SOP9 on Full Review) Determination of type of amendment (Major or Minor Amendment)	Chair and Primary Reviewer

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		<b>Date of Effectivity:</b> June 04, 2021
<b>Step 5.</b> <i>Communication of committee action (4SOP30 on Communication of REC Decisions)</i>		<i>Chair</i>
<b>Step 6.</b> <i>Filing of Amendments and decision letter and update of the protocol database. (4SOP32 on Management of Active Files)</i>		<i>RERC Staff</i>

## 5. Description of Procedures

### Step 1 : Receipt and entry to logbook

The REC secretariat receives Application for Review of Amendments Form and enters the date and pertinent information in the logbook of incoming documents

### Step 2 : Retrieval of pertinent protocol file

The Secretariat retrieves the corresponding protocol file for reference and guidance of the Chair and Reviewers.


### Step 3: Notification of Chair and Primary Reviewer

The Secretariat notifies within two days after receipt of the Application for Review of Amendments and sends the pertinent protocol file to the Chair and the previously assigned Primary Reviewers.

### Step 4 : Determination of type of review: expedited or full review; major or minor amendments

The Primary Reviewer recommends the type of review to the Chair and the Chair will determine the final type of review. The amendments will be classified as Major or Minor with the following criteria:

- Minor amendments - recommended amendments applying to protocols found to have particular aspect/s on its study or related document that do not impact on potential risks/benefits to participants and on the integrity of the research; no substantial change in study population, methodology and consent.
- Major amendments - recommended amendments on protocols (e.g. study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data, statistical analysis, mitigation of risk, protection of vulnerability, etc.) that increase risks/harms to participants and on the integrity of the research. Major amendments may include but are not limited to :
  1. Change in study design
  2. Additional treatments or the deletion of treatments
  3. Any changes in inclusion/exclusion criteria
  4. Change in method of dosage formulation (e.g. oral changed to intravenous)
  5. Significant change in number of subjects
  6. Significant increase/decrease in dosage amounts

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- Minor study protocol amendments that do not change the risk profile of study participants are classified for expedited review by the original Primary Reviewers. These are presented and discussed during the Expedited PR Review Meeting. Approved amendments are reported during the Full Board Review Meeting.
- Proposed major study protocol amendment that increases risk to study participants, as assessed by the RERC Chair and Primary Reviewers are classified for full board review. These are included in the Agenda of the Full Board Review Meeting for discussion and decision.

**Step 5: Communication of committee decision:** The REC communicates the committee action may be any of the following “approved”, “additional justification/information required”, “reconsent required” or disapproved. Staff prepares a draft of the committee decision based on either an expedited review report or minutes of a meeting. The Chair signs the decision letter (*See 4SOP 30- Communicating RERC Decisions*)

**Step 6: Filing of Amendment documents and committee decision and update of the database**

The Secretariat files the Amendment and a copy of the committee decision in the appropriate protocol folder then proceeds to update the pertinent protocol database.

**6.Forms**


Form 3.16.1 Amendment Form

Form 3.16.2 Letter of Approval of Amendment

Form 4.30.3 Letter of Document Receipt and Recommended Action

**7. History of SOP**

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
1	2015 October	Dr. Rhodora Madrid-Reyes	First draft
2	2016	Dr. Rhodora Madrid-Reyes	None
3	2017 February	Dr. Rhodora Madrid-Reyes	None
4	2020 October	Dr. Angelita B. Villena Dr. Donalyn Barcial	Revision of Review of Amendments

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			<b>Date of Approval:</b> June 04, 2021
			<b>Date of Effectivity:</b> June 04, 2021
5	2021 June	<i>Dr. Donalyn Barcial</i>  <i>Dinna P. Remo, CPA</i>	<i>Add in Policy Statement review classification for minor &amp; major amendments &amp; channel of review</i>  <i>Revise definition of minor &amp; major amendments</i>

## 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*


*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

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	<b>CHAPTER 3 POST APPROVAL PROCEDURES SOP 17 Review of Progress Report</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

### 1. Policy Statement

The REC shall require the submission of progress reports at a frequency based on the level of risk of the study as decided by the Primary reviewers and Chair of REC. This requirement shall be explicitly stated in the Approval Letter. BATMC RERC monitors the progress of research and accomplishment of goals of residents as required by the individual Departments' training program. Hence RERC requires them to report of the progress of their research work every 3 months or at intervals appropriate for the degree of risk and duration of the study protocol. . Frequency of submission of progress report is indicated in the Approval Letter *Form 4.30.1*. RERC Secretariat sends Reminder Letter *Form 4.30.2D* to the Principal Investigator at least thirty (30) days before due date.

### 2. Objective/s of the Activity

This activity aims to ensure that the conduct of the study is in compliance with the approved protocol and that the safety and welfare of study participants are promoted.

### 3. Scope


This SOP provides instructions for the review of progress reports that are required by the Batangas Medical Center RERC to be submitted by the PI to monitor the safety of participants enrolled in a study. Depending upon the degree of risk to the participants, the nature of the studies, and the vulnerability of the study participants and duration of the study, the RERC may choose to review or monitor the protocols more frequently. BATMC RERC may require more frequent submissions of progress reports of PI-RESIDENTS in training to monitor their progress of research and their accomplishments. It also describes the follow up of progress reports by the RERC Secretariat to the PIs as decided from the initial approval of the protocol by designated members of the RERC in compliance with ICH-GCP requirements. Failure to submit progress reports should be reported as PROTOCOL DEVIATION. This SOP begins with the receipt and entry to logbook of incoming documents and the protocol database and ends with filing of progress report and committee decision in the protocol file.

As a general rule, progress reports of Expedited Protocols will undergo Expedited Review while progress reports reviewed at Full Board should go through Full Board Review as well.

### 4. Workflow

ACTIVITY	RESPONSIBILITY
<b>Step 1:</b> Receipt and entry into logbook of the progress report (SOP on Management of Active Files (4SOP32)	RERC Staff



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		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021
<b>Step 2: Retrieval of pertinent protocol file</b>		
<b>Step 3: Notification of Chair and Primary Reviewers</b>		<i>RERC Staff</i>
<b>Step 4: Determination of type of review: expedited (SOP on Expedited Review (2SOP8) or full review (2SOP9)</b>		<i>Chair and Primary Reviewers</i>
<b>Step 5: Communication of committee action (SOP on Communication REC Decisions (4SOP 30)</b>		<i>Chair</i>
<b>Step 6: Filing of Progress report and decision letter and update of the protocol database. SOP on Management of Active Files (4SOP32)</b>		<i>RERC Staff</i>

## 5. Description of Procedures

### Step 1: Receipt and entry to logbook

The Secretariat receives the progress report written in the Progress Report *Form 3.17.1* and enters the date and pertinent information in the logbook of incoming documents

Only Progress Reports submitted on or before 12 noon of the LAST FRIDAY OF THE MONTH shall be included in the agenda for EXPEDITED REVIEW PR MEETING or FULL REVIEW BOARD MEETING.

### Step 2 : Retrieval of pertinent protocol file

The Secretariat retrieves the corresponding protocol file for reference and guidance of the Chair and Reviewers.


### Step 3 : Notification of Chair and Primary

The Secretariat notifies within one (1) day after receipt of the progress report and sends the pertinent protocol file to the Chair and the previously assigned Primary Reviewers.

### Step 4 : Determination of type of review: expedited or full review

The Chair shall determine the type of review based on the policy that progress reports of protocols that underwent Full review in its initial submission shall undergo Full review . Similarly, progress reports of protocols which underwent Expedited review shall undergo Expedited review. (*see 2SOP 8: Expedited Review and 2SOP9: Full Review*). The Primary Reviewers/member reviewers conduct review of the protocols if they are in accordance with the protocols and related documents approved by the RERC.

The primary reviewers/member reviewers recommend approval of the progress report if there is no deviation or violation of RERC approvals. If there is any deviation or violation of approvals given by the

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		<b>Date of Approval:</b> <b>June 04, 2021</b>
		<b>Date of Effectivity:</b> <b>June 04, 2021</b>

RERC, the Primary Reviewers recommend that appropriate action to be taken by the PI e.g. amendment of the protocol or consent form or explanation of deviation or violation.

Approval of progress reports reviewed by the Primary Reviewers by expedited procedure is reported during the Full Board meeting. For protocols subject to Full Review, these are included in the Agenda of the next Full Board Review Meeting for discussion and decision.

If amendments are recommended, PR will recommend submission of amendment report. Amendments may either be MINOR or MAJOR (*3SOP16 Review of Amendments*).

#### **Step 5 : Communication of committee decision**

The REC communicates the committee action, which may be “approved” or “additional information required” or “specific action/s required from the researcher”. Secretariat prepares a draft of the committee decision based on either an expedited review report or minutes of a meeting and have it signed and approved by the Chair.

#### **Step 6 : Filing of Progress Report and committee decision and update of the database**


The Secretariat files the progress report and a copy of the committee decision in the appropriate protocol folder and proceed to update the pertinent protocol database.

### **6.Forms**

- Form 3.17.1 Progress Report Form
- Form 4.30.2D Reminder Letter for Progress Report / Continuing Review / Final Report
- Form 4.30.3 Letter of Document Receipt and Recommended Action

### **7. History of SOP**

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
1	2015 October	Dr. Rhodora Madrid-Reyes	First draft
2	2016	Dr. Rhodora Madrid-Reyes	None
3	2017 February	Dr. Rhodora Madrid-Reyes	None
4	2020 October	Dr. Angelita B. Villena Dr. Donalyn Barcial	Revision of Review of Progress Report

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		<b>CHAPTER 3</b> <b>POST APPROVAL PROCEDURES</b> <b>SOP 17</b> <b>Review of Progress Report</b>	<b>Version No: 5</b>
			<b>Date of Approval:</b> June 04, 2021
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5	2021 June	<i>Dr. Donalyn Barcial</i>  <i>Dinna P. Remo, CPA</i>	<i>Included sending of Reminder Letters</i>  <i>Modify Activity on Determination of Type of Review</i>

## 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*


*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*


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	<b>CHAPTER 3 POST APPROVAL PROCEDURES SOP 18 Management of Protocol Deviation and Violations Report</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

## 1. Policy Statement

Researchers shall report protocol deviations and violations in the conduct of approved researches within a week of the event. Protocol deviations are protocol non-compliance without significant consequences. Protocol violation reduces the completeness or quality of the data, or impacts the subject's safety, rights or welfare. Deviations and violations are classified on scientific and ethical levels so that the RERC can adopt appropriate action (i.e. no action, site visit, training, withdrawal of patients, etc.).

Major protocol deviations and violations shall undergo a full board review; while minor protocol deviations and violations shall undergo expedited review by the original Primary Reviewers.

- a. The Principal Investigator(PI) should document, explain, and report to the BATMC-RERC any non-compliance from the approved protocol, whether minor or major, at the soonest possible time but not later than one (1) month from deviation.
- b. The PI may implement a deviation from the protocol to eliminate an immediate hazard(s) to study subjects without prior BATMC-RERC approval, but must submit as soon as possible but not later than one (1) month from event, a report of deviation or change, the reasons for it, and, if appropriate, an appropriate study protocol amendment/s.
- c. Reporting of study protocol noncompliance is facilitated through the submission of BATMC-RERC *Form 3.18.1: Deviation / Non-Compliance / Violation Report*, together with documents deemed necessary by the PI to clarify information indicated in the report. This comprises the study protocol non-compliance report package.
- d. Study protocol non-compliance report packages subject to full board review received within the cut-off period of twelve (12) calendar days before the scheduled BATMC-RERC full board meeting are sent to Primary Reviewers. These are included in the Agenda of the Full Board Review meeting for discussion and decision.
- e. Study protocol non-compliance under expedited review are presented and discussed during the Expedited PR Review Meeting. Resolution is reported during the Full Board Review Meeting.
- f. The Primary Reviewers accomplish and return the signed Batmc-Rerc Form 3.18.1: Deviation / Non-Compliance / Violation Report to the Secretariat on the day of the RERC Meeting together with the study protocol non-compliance report package.

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## 2. Objective/s of the Activity

The purpose of this SOP is to describe the BATMC-RERC review procedures for protocol violation/deviation. Review of protocol deviations and violations aims to ensure that the safety and welfare of human participants in the study are safeguarded and that the credibility and integrity of data are maintained.

## 3. Scope

This SOP applies to the review of reports of protocol deviations or violations in the conduct of previously approved studies. This begins with the receipt and documentation of the report of protocol violations and deviations in the logbook and ends with the filing of all related documents and update of the database.

This SOP provides instructions for taking action and maintaining records of various types of protocol deviation or violations which include any of the following:


- A. Failure of the investigators to comply with the procedures in the approved protocol.
- B. Failure of investigators to comply with national/ international guidelines for the conduct of human research, including those who fail to respond to the BATMC-RERC requests.
- C. It also covers action taken by the BATMC-RERC related to protocol violation/deviation reports submitted by the PI related to any event at the site that is not in compliance with the previously approved protocol documents.

### Responsibility

It is the responsibility of the BATMC-RERC Secretariat to receive protocol violation/deviation reports submitted. It is the responsibility of the board to take action related to protocol violation/deviation.

## 4. Workflow

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>STEP 1</b> Receive protocol violation/deviation reports	RERC Staff
<b>STEP 2</b> Retrieve pertinent protocol file and notify Chair of this report	RERC Staff

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<b>STEP 3</b> Chair and primary reviewers and decide on whether the deviations/violations are major or minor and whether these are for expedited or full review.	Chair/Member Secretary/ Asst Member Secretary	
<b>STEP 4</b> Discuss at Full Board and make a decision	Chair and Members	
<b>STEP 5</b> Notify the investigator	RERC Staff	
<b>STEP 6</b> Keeps records	RERC Staff	

## 5. Description of Procedures


**STEP 1:** The Secretariat receives the report on protocol deviation or violation in the appropriate report form (*Form 3.18.1*) and records this in the logbook for incoming documents.

**STEP 2:** The Secretariat retrieves the approved protocol and checks the identity of the primary reviewers for reference and guidance of the Chair in the selection/ designation of reviewers. The Secretariat checks the completeness of the documents. The Secretariat notifies and sends the protocol deviation or violation report and together with the retrieved pertinent documents to the Chair and the primary reviewers

**STEP 3:** The Chair and primary reviewers determine the type of review such that major protocol violations undergo full review. Otherwise, the protocol deviation undergoes expedited review. The protocol deviations/violations will be classified as Major or Minor with the following criteria:

- Minor Deviation/Violation – (*SIREB SOP p34 2.7.6.3*) are non systematic protocol non-compliance with minor consequence to the participant's rights, safety or welfare or integrity of study data; includes deviations that are administrative in nature
- Major Deviation/Violation - (*SIREB SOP p34 2.7.6.4*) are persistent protocol non-compliance with potentially serious consequences that could critically affect the data analysis or put the participant's safety at risk
- Minor deviations would require an expedited review by the previous Primary Reviewers.
- Major violations require a full board review.

(See *2SOP 8: Expedited Review* and *2SOP 9: Full Review*)

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**STEP 4:** The Chair includes the report on protocol deviation and violation in the Agenda of the next meeting if it is for Full review or the decision report if Expedited review. Expedited reviews are done by the primary reviewers, discussed and presented during the Expedited PR Review Meeting and make a report to Full Board Review Meeting.


Full board review of study protocol noncompliance report entails:

- a. The primary reviewers present the documents to BATMC-RERC members when study protocol non-compliance reports are deliberated on. The members deliberate on both the type and degree of non-compliance and take the appropriate action.
- b. The BATMC-RERC can recommend any of the following:
  - submission of additional information
  - submission of corrective action
  - invitation to a clarificatory interview
  - requirement for an amendment
  - requirement for a site visit
  - suspension of recruitment or study until the following are met:
    - Additional information is made available
    - RERC recommendations are implemented by the Principal Investigator and considered satisfactory by the RERC
    - withdrawal of ethical clearance due to repeated violation
  - Termination of The Study On The Basis Of One Or More Of The Following:
    - SAE reports indicate harm to participants
    - Breach of a previously approved conduct of research.
    - Major changes, deviations or amendments of the approved protocol without approval by the RERC
    - Revision in the Informed Consent form without approval by the RERC.
    - Repeated violation
    - Fraud.

**Step 5:** The Secretariat prepares the draft decision based on the report of the expedited review or the minutes of the meeting in the full review. The Secretariat collates and files the retrieved protocol documents, the report on protocol deviation and violation and the decision letter in the appropriate protocol file and updates the protocol database with the relevant information. *(See 4SOP 30-Communicating RERC Decisions and 4SOP 32 on Managing Active Study Files)*

- a. The PI is notified of the RERC decision on the study protocol noncompliance report through an action letter *(Form 4.30.3)*



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- b. For submissions under full board review, the BATMC-RERC decision will be sent to the PI within three (3) calendar days after the BATMC-RERC board meeting.
- c. For submissions under expedited review, action is finalized at the level of the RERC Chair within seven (7) calendar days.
- d. The PI may be requested to provide additional information, submit additional documents, or implement corrective action.
- e. The PI may file an Appeal using *Form 3.23.1* within 30days after the official decision letter of the RERC is received.

#### **STEP 6: Files management**

- a. The Secretariat stores the signed study protocol non-compliance report documents in the study protocol file folder.
- b. Files are managed in accordance with *4SOP 32: Active Study Files*.


#### **6. Forms**

- Form 3.18.1      DEVIATION / NON-COMPLIANCE / VIOLATION REPORT  
Form 4.30.1      Document receipt and Recommended Actions  
Form 4.27.2      Letter of Invitation for Clarificatory Meeting

#### **7. History of SOP**

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
1	2015 October	Dr. Rhodora Madrid-Reyes	First draft
2	2016	Dr. Rhodora Madrid-Reyes	None
3	2017 February	Dr. Rhodora Madrid-Reyes	None
4	2020 October	Dr. Rhodora Madrid-Reyes Dr. Allan E. Lanzon	Management of Protocol Deviation and Violations Report
5	2021 June	Dinna P. Remo, CPA	Revision in workflow with the insertion of the Expedited PR Review Meeting



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		<b>Date of Effectivity:</b> June 04, 2021

## 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*

*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*


*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*SJREB Consolidated SOPs (edited October 2020)*

*BatMC RERC SOP 2020*

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 3 POST APPROVAL PROCEDURES SOP 19 A Review of SAE and SUSAR Reports</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
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### 1. Policy Statement

The BATMC-REC shall require the submission of reports of SAEs and SUSARs by Sponsor/PI within four (4) weeks after the event has come to the attention of the principal investigator. The evaluation of the SAEs and SUSARs shall be conducted by the Primary Reviewers or SAE/SUSAR Reviewers, if any, whose recommendation shall be submitted to the BatMC RERC for final action for on-site. BATMC refers to *ICH TOPIC E2A- Clinical Data Management Definition and Standards of Safety Reporting* adopted by FDA( *Appendices- Reference No. 7* for harmonization of data for offsite and onsite cases as well as the *WHO-UMC Causality Assessment System ( Appendices- Reference No.8)* .

All on-site SAE/SUSAR cases undergo Full Board Review while all off-site SAE/SUSAR cases will undergo Expedited Review by the initial Primary Reviewers or appointed SAE Reviewers.

### 2. Objective/s of the Activity


Review of SAE and SUSAR reports aims to ensure that the safety and welfare of human participants in the study site are safeguarded and that information on SAEs and SUSARs are properly documented and evaluated.

### 3. Scope

This SOP applies to the review of reports of SAEs in various studies and SUSARs in clinical trials. This SOP begins with the receipt and documentation of submission of report of SAEs and SUSARs in the logbook and ends with the filing of all related documents and update of the protocol database.

### 4. Workflow

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1:</b> Receipt and documentation of submission of report of SAEs and SUSARs in the logbook.	RERC Staff
<b>Step 2:</b> Retrieval of pertinent protocol file	RERC Staff
<b>Step 3:</b> Notification of Chair	RERC Staff
<b>Step 4:</b> Submission of report to the SAE Subcommittee or the Primary reviewers	RERC Staff

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		<b>Date of Effectivity:</b> June 04, 2021
<b>Step 5:</b> <i>Inclusion of report of Primary Reviewers /Subcommittee in the agenda of the next regular REC meeting</i>		
<b>Step 6:</b> <i>Communication of REC action to the Principal Investigator/researcher (SOP on Communication of REC Decisions (4SOP30))</i>		
<b>Step 7:</b> <i>Filing of all related documents (4SOP32 Management of Active Files) and Update of the protocol database</i>		

## 5. Detailed Description of Procedures

### **ONSITE: Serious Adverse Event/s (SAE) and Suspected, Unexpected, Serious Adverse Reaction (SUSAR) Reports**

#### **Step 1**


The PI accomplishes the BATMC RERC Form 3.19A.1: *Serious Adverse Events Report Form* And BATMC-RERC Form 3.19A.2 : *SAE Report Summary* and submits to the secretariat within 24 to 48 hours from awareness of event. The Secretariat receives the accomplished SAE/SUSARs report forms and enters the submission into the logbook. The Secretariat notes whether the submission is within the required timeline. The secretariat informs the Chair of the submission. The secretariat forwards the SAE Report Package comprised of the following documents to the Chair and to the primary reviewers within 48 hours of receipt:

- BATMC-RERC FORM 3.19.1A: SAE & SUSAR REPORTS
- CIOMS Serious Adverse Reaction Form ( *Appendices- Reference No. 8*)
- BATMC-RERC FORM 3.19.2A: SAE & SUSAR REPORT SUMMARY (*On-Site*)
- Latest Investigator's Brochure
- Protocol Summary
- Other supporting documents, if any

#### **Step 2**

The Secretariat retrieves the identity of the primary reviewers (if there is no appointed SAE/SUSAR subcommittee / reviewers) and a tabulation of earlier SAE/SUSAR reports. If the primary reviewers assess that the report/s need/s immediate action, he/she will forward the report/s and his/her recommendation to the Chair for further assessment. The Chair will assess the recommendations for an immediate action either suspension of the study or recruitment.

#### **Step 3**

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	<b>CHAPTER 3</b> <b>POST APPROVAL PROCEDURES</b> <b>SOP 19 A</b> <b>Review of SAE and SUSAR Reports</b>	<b>Version No: 5</b>
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The Secretary notifies and sends the report and the retrieved documents to the Chair. The secretariat includes the SAE report/s on the agenda of the next meeting, provided that cut-off period for RERC meeting inclusion is 12 noon of the last Friday of the month prior to a full board meeting, in which the primary reviewer is required to attend.

#### Step 4

The Chair forwards the report and pertinent documents to the primary reviewers (or to the SAE/SUSAR Subcommittee) for action which should not be later than twelve (12) days prior to the next committee meeting.

Copies of the SERIOUS ADVERSE EVENT/S REPORT and SAE REPORT SUMMARY (*FORMS 3.19A.1 & FORM 3.19A.2*) are distributed to each RERC member together with the agenda.

#### Step 5

- The suggested action/decision of either the primary reviewer or the SAE/SUSAR Subcommittee is included in the Agenda of the next meeting (*see 4SOP 26 on Preparing the Meeting Agenda*) for ratification or discussion and final decision. During the meeting, the Chair calls for a decision on the SAE report/s with respect to the recommendation/s of Chair or reviewer assigned to the concerned study as presented by the RERC Chair/Secretary/Primary Reviewer. The committee may require any of the following actions:


##### *Decision Points:*

- No further action; documents for filing*
- Modification of participant inclusion or exclusion criteria to mitigate the newly identified risks or informed consent documents to include a description of newly recognized risks;*
- Recommend implementation of additional procedures for protecting/ safeguarding participants;*
- Suspension of enrollment of new participants or research procedures among participants who are currently enrolled (check consistency)*
- Request information*
- Recommend suspension of the entire study*

#### Step 6

Communication of BATMC-REC recommendation to the Principal Investigator/researcher.

(*See 4SOP 30 Communicating REC decisions:* )

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## Step 7

Filing of all related documents and update of the protocol database.

(See 4SOP 32 on Managing Active Files).

**OFFSITE:** Serious Adverse Event/s (SAE) and Suspected, Unexpected, Serious Adverse Reactions (SUSARs) Reports

## Step 1

The PI must submit the offsite SAE and SUSAR report every three (3) months.

The secretariat forwards the SAE Report Package to the primary reviewers and the chair which comprises of the following documents at least five (5) calendar days before the Expedited PR Review meeting:

- BATMC-RERC *FORM 3.19A.1: SAE & SUSAR REPORTS*
- CIOMS Suspect Adverse Reaction Form (*Appendices- Reference No. 8*)
- BATMC-RERC *FORM 3.19.3A: SAE & SUSAR REPORT SUMMARY (Off-Site)*
- Latest Investigator's Brochure
- Protocol Summary
- Other supporting documents, if any

## Step 2

The primary reviewers assigned to the particular study review and return the signed BATMC-RERC *FORM 3.19A.2: SERIOUS ADVERSE EVENTS REPORT SUMMARY* to the Secretariat together with the SAE report package.


## Step 3

The Chair and primary reviewers may recommend any of the following actions:

- *notation with no further action required,*
- *further information or action required or*
- *suspension of recruitment or suspension of the entire study*

## Step 4

The Chair submits the recommendations to the secretariat for inclusion in the agenda of the next Expedited PR Review meeting.

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### Step 5

The Secretariat Staff includes the SAE reports on the agenda. Copies of the SAE REPORT SUMMARY are distributed to each RERC member together with the agenda.

### Step 6

During the meeting, the Chair calls for a decision on the SAE report with respect to the recommendations of the Chair and the primary reviewers. The RERC can recommend any of the following actions:

- *No action required, study to continue;*
- *Modification of participant inclusion or exclusion criteria to mitigate the newly identified risks or informed consent documents to include a description of newly recognized risks;*
- *Recommend implementation of additional procedures for protecting/ safeguarding participants;*
- *Suspension of enrollment of new participants or research procedures among participants who are currently enrolled (check consistency)*

Protocols with reported Off-Site SAE/SUSARs and decision arrived at by expedited procedure are reported during the Full Board Review Meeting.

### Step 7


Communication of BATMC-REC recommendation to the Principal Investigator/researcher.  
(See 4SOP 30 on Communicating REC Decisions using Form 4.30.2.

### Step 8

Filing of all related documents and update of the protocol database.  
(See 4SOP 32 on Managing Active Files).

## 6. Forms

Form 3.19.0	SAE / SUSAR / RNE Submission Checklist
Form 3.19.1A	SAE & SUSAR Report
Form 3.19.2A	SAE & SUSAR Reports Summary (On-Site)
Form 3.19.3A	SAE & SUSAR Reports Summary (Off-Site)
Form 4.30.2	REC Decision Letter

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## 7. History of SOP

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
1	2015 October	Dr. Rhodora Madrid-Reyes	First draft
2	2016	Dr. Rhodora Madrid-Reyes	None
3	2017 February	Dr. Rhodora Madrid-Reyes	None
4	2020 October	Dr. Rhodora Madrid-Reyes Dr. Allan E. Lanzon	Revision of SAE/SUSAR Report Form
5	2021 June	Dr. Alfonso Syoei R. Yoshida Dr. Edralin M. Vidal Dinna P. Remo, CPA	Type of Reviews for On-Site and Off-Site SAE/SUSARs Deadline for submission of reports

## 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*


*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

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	<b>CHAPTER 3 POST APPROVAL PROCEDURES SOP 19 B Review of Reportable Negative Events (RNE) Reports</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

## 1. Policy Statement

The BATMC-REC shall require the submission of RNE reports, at the latest three (3) days after the event has come to the attention of the researcher. A special meeting shall be considered depending on the level of risk involved.

Reportable Negative Event (RNE) is an adverse event or incident that has the potential to be classified by the REC as an unanticipated problem posing risks to participants or others. An incident is determined to be reportable to the RERC when it is both: probably or definitely related to participation in the research. It occurs during the the implementation of a research that impact safety, dignity and well-being of participants and /or the study team and the integrity of data. These events need to be reported by PI or Safety (DSMB) personnel to the REC as essential to the continuing concern for a favorable balance of risks and benefits from the study.

## 2. Objective/s of the Activity

The review of RNE reports aims to ensure that the safety and welfare of human participants and the research team are safeguarded and that information on RNEs are properly documented and evaluated.


## 3. Scope

This SOP applies to the review of RNE reports. The SOP begins with the receipt and documentation of submission of RNE report in the logbook/database and ends with the filing of all related documents and update of the protocol database.

## 4. Workflow

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1:</b> <i>Receipt and documentation of submission of RNE report in the logbook.</i>	<i>RERC Staff</i>
<b>Step 2:</b> <i>Retrieval of pertinent protocol file</i>	<i>RERC Staff</i>
<b>Step 3:</b> <i>Notification of Chair</i>	<i>RERC Staff</i>
<b>Step 4:</b> <i>Call for a Special Meeting</i>	<i>Chair</i>
<b>Step 5:</b> <i>Deliberation on the RNE</i>	<i>REC members</i>



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		Date of Approval: June 04, 2021
		Date of Effectivity: June 04, 2021
Step 6: Communication of REC action to the researcher (4SOP 30 on Communication of REC Decisions) and to the Institutional authority		Chair
Step 7: Filing of all related documents (4SOP32 Management of Active Files) and Update of the protocol database		RERC Staff

## 5. DETAILED DESCRIPTION OF PROCEDURES

### Step 1 - Receipt and documentation of submission of the RNE report in the logbook/database:

The Staff receives the accomplished RNE report form (*Form 3.19B.1*) and enters the submission into the logbook. The Staff notes whether the submission is within the required timeline.

### Step 2 - Retrieval of pertinent protocol file:

The Staff retrieves the approved protocol file and checks the identity of the primary reviewers.

### Step 3 - Notification of Chair:

The Staff notifies and sends the report and the retrieved documents to the Chair who may decide to call for a special meeting.


### Step 4 - Call for a Special Meeting.

The staff prepares for a special full board meeting (*4SOP 28*). The principal investigator and other members of the study team may be invited for a clarificatory meeting (*Form 4.27.2*)

### Step 5 - Conduct of the Special Meeting.

The Chair leads the discussion of the special meeting, summarizes the RNE report and informs the REC members regarding the presence of the research team for clarificatory meeting. The safety issues are evaluated, i.e., identification of risks to the participants / research team, nature and effectivity of preliminary interventions with or without the help of community constituents/authority, impact on integrity of data and completion of the research. The research team is excused and the BATMC-REC members deliberate on possible options, as follows:

- *recommend suspension of the study until risk is resolved*
- *withdrawal of ethical clearance*
- *submission of a plan to mitigate risk/harm*
- *require an amendment to the protocol*
- *uphold original ethical clearance*

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 3 POST APPROVAL PROCEDURES SOP 19 B Review of Reportable Negative Events (RNE) Reports</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

**Step 6 - Communication of REC recommendation to the researcher:**

*See 4SOP 30 on Communicating REC decisions.*

**Step 7 - Filing of all related documents and update of the protocol database:**

*See 4SOP 32 on Managing Active Files.*

**6. Forms**

Form 3.19.1B	RNE Report
Form 4.28.1	Notice of Meeting
Form 4.30.2	Letter of Document Receipt and Recommended Action
Form 4.27.2	Letter for Clarificatory Meeting


**7. HISTORY OF SOP**

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
1	2015 October	Dr. Rhodora Madrid-Reyes	First draft
2	2016	Dr. Rhodora Madrid-Reyes	None
3	2017 February	Dr. Rhodora Madrid-Reyes	None
4	2020 October	Dr. Rhodora Madrid-Reyes Dr. Allan E. Lanzon	Review of RNE Reports
5	2021 June	Dinna P. Remo, CPA	Expanded definition of RNE  Define Special Meeting as Special Full Board Meeting

**8. References**

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 3 POST APPROVAL PROCEDURES SOP 19 B Review of Reportable Negative Events (RNE) Reports</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021


*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 3 POST APPROVAL PROCEDURES SOP 20 Review of Early Termination Reports</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021  <b>Date of Effectivity:</b> June 04, 2021

## 1. Policy Statement

Researches may be terminated early or prematurely because of various reasons, such as poor participant recruitment, frequent occurrence of adverse reactions, insufficient funding, etc. In these cases, early protocol termination may be recommended by the Data Safety Monitoring Board (DSMB), the scientific director, the sponsor, the PI, the RERC itself, and/or other authorized bodies. A plan for early termination shall include reason/s for termination and also strive to ensure the safety and privacy of already recruited participants. Applications for early termination shall undergo full board review.

## 2. Objective of the Activity


To review early termination reports and decide on how to proceed with the termination plan, with primary consideration on the safety and well-being of recruited study participants and adherence to the principles of fairness for all parties concerned.

## 3. Scope

This policy applies to the review of early termination reports. This SOP begins with the receipt of the application or recommendation for early termination and documentation in the logbook, and ends with the documentation of the final early termination report and updating of database.

## 4. Workflow

<b>Activity</b>	<b>Responsibility</b>
<b>Step 1:</b> Receive the application or recommendation for early termination and document in the logbook	RERC Staff
<b>Step 2:</b> Check approval given by RERC from the protocol files and collect relevant information	Primary Reviewer/Designated RERC Member
<b>Step 3:</b> Review the termination package and make recommendations	Primary Reviewer/Designated RERC Member
<b>Step 4:</b> Discuss with full board for appropriate decision	Members
<b>Step 5:</b> Communicate board decision to the PI	RERC Staff
<b>Step 6:</b> File copies of the final early termination report and update database	RERC Staff

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 3 POST APPROVAL PROCEDURES SOP 20 Review of Early Termination Reports</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021  <b>Date of Effectivity:</b> June 04, 2021

## 5. Description of Procedures

### Step 1: Receive the application or recommendation for early termination and document in the logbook

Application or recommendation for early termination from the DSMB, the scientific director, the sponsor, the PI, the RERC itself, and/or other authorized bodies shall be received by the Secretariat and documented in the logbook. The PI is informed to prepare and submit a protocol termination package. After submission of the package by the PI, it is checked for completeness by the Member Secretariat. The package should include the following:

- *Study termination form (Form 3.20.1)*
- *Progress report form (Form 3.17.1) up until application for early termination*
- *The request for termination memorandum should contain a brief written summary of the protocol, its results, and accrual data.*

### Step 2: Check approval given by RERC from the protocol files and collect relevant information

The primary reviewer of the approved protocol or a designated RERC member studies the retrieved protocol files and acquires other information pertinent to the study, particularly its current status.

### Step 3: Review the termination package and make recommendations


The primary reviewers/designated RERC members conduct a full review the contents of the early termination protocol package, and make recommendations on how study termination will be carried out. Of primary importance are the safety data for participants that have already been recruited, as well as a plan that includes steps and procedures on how the safety and well-being of these participants can be ensured moving forward.

### Step 4: Discuss with full board for appropriate decision

The full board of the RERC shall discuss the protocol at an RERC meeting. After taking into consideration all comments and recommendations from all members present in the meeting, the decision may be one of the following:

- *Acceptance of the decision for termination without further question or action*
- *Request for additional information regarding the application for termination*

The Secretariat prepares a draft of the full board decision based on the minutes of the meeting, which will then be signed by the Chair.

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 3 POST APPROVAL PROCEDURES SOP 20 Review of Early Termination Reports</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021  <b>Date of Effectivity:</b> June 04, 2021

#### Step 5: Communicate board decision to the PI

After the board makes a decision on the early termination of the protocol and officially signed by the Chair, the RERC Secretariat informs the PI of this decision.

#### Step 6: File copies of the final early termination report and update database

The Secretariat keeps copies of the finalized early termination report for documentation and updates the database accordingly.

### 6. Forms

Form 3.20.1 Early Study termination Form

Form 4.30.3 Form for Document Receipt and Recommended Action

### 7. History


<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
1	2015 October	Dr. Rhodora Madrid-Reyes	First draft
2	2016	Dr. Rhodora Madrid-Reyes	None
3	2017 February	Dr. Rhodora Madrid-Reyes	None
4	2020 October	Dr. Albert Joseph B. Lupisan Dr. Rogelio Acosta, Jr.	Format change and specification of early termination package and full board decision
5	2021 June	Dinna P. Remo, CPA	None

### 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*

*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*


	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 3 POST APPROVAL PROCEDURES SOP 20 Review of Early Termination Reports</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 3 POST APPROVAL PROCEDURE SOP 21 Management of an Application for Continuing Review</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

### 1. Policy Statement

The REC shall require the submission of an application for Continuing Review before the expiration of the ethical clearance of a protocol. Protocols that were previously classified Full review in its initial submission shall undergo Full review in its application for Continuing review. Similarly, protocols that were previously classified Expedited review shall undergo Expedited review in its application for Continuing review.

### 2. Objective/s of the Activity

This activity primarily aims to ensure that the conduct of the study is in compliance with the properly approved protocol and that the safety and welfare of study participants are promoted and the integrity and validity of data protected beyond the period of initial ethical clearance and up to the end of the study. Ethical clearance is given for one year from the date of approval of the protocol. Renewal of the ethical clearance must be secured one (1) month before its expiry. RERC Secretariat will send Reminder Letter for Continuing Review (*Form 4.30.2D*) to the PI two (2) months before the expiry of ethical clearance.

### 3. Scope


This SOP applies to the management of an application for Continuing review submitted by the proponent while the study is still on-going but whose ethical clearance is about to expire. This SOP begins with the receipt of an application for continuing review and ends with the entry to logbook and update to the protocol database.

### 4. Workflow

It is the responsibility of the Batangas Medical Center RERC Secretariat to remind proponents to apply for continuing review before the expiration of the ethical clearance from the initial ethical clearance.

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1:</b> Receipt of the application for Continuing Review and entry to logbook	RERC Staff
<b>Step 2:</b> Retrieval of pertinent protocol files	RERC Staff
<b>Step 3:</b> Notification of Chair and Primary Reviewers	RERC Staff



	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 3 POST APPROVAL PROCEDURE SOP 21 Management of an Application for Continuing Review</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021
<b>Step 4:</b> <i>Determination of type of review: expedited (2SOP 8 Expedited Review ) or full review (2SOP 9 Full Review)</i>		<i>Chair and Primary Reviewers</i>
<b>Step 5:</b> <i>Communication of committee action</i>		<i>Chair</i>
<b>Step 6:</b> <i>Filing of documents in the appropriate protocol folder and Update of the Protocol Database</i>		<i>RERC Staff</i>

## 5. Description of Procedures

Each of the identified steps in the workflow should be described in detail.

### **Step 1 : Receipt of the completely filled out application for continuing review form and entry to logbook.**

The Secretariat receives, logs and enters in the protocol database the information included in the application for Continuing review (*Form 3.21.1: Application for Continuing Review*). Updated GCP certificate of the PI must be submitted for monitoring of validity.

### **Step 2 : Retrieval of pertinent protocol file.**

The Secretariat retrieves the approved protocol and prepares a summary of the progress reports, protocol deviation/violation reports, SAE/SUSAR reports, report of negative events (RNEs) and corresponding decisions including the type of initial review during the period of effectivity of the initial ethical clearance.

### **Step 3 : Notification of Chair and Primary Reviewers.**

The Secretariat notifies the Chair and the Primary Reviewers via SMS or email regarding the submission and the summary of the reports submitted and decisions made during the period of effectivity of initial ethical clearance. The Chair and Primary reviewers shall be notified 2 weeks before monthly meeting BEFORE the last month of validity of the ethical clearance.

### **Step 4 : Determination of type of review: expedited or full review**

The Chair shall determine the type of review based on the policy that protocols that initially underwent Full review in its initial submission shall undergo full review in its application for Continuing review. Similarly, protocols which initially underwent expedited review shall undergo Expedited review in its application for Continuing review provided there is no elevation of risk (*see 2SOP 8: Expedited Review and 2SOP9: Full Review*). The Primary Reviewers/member reviewers conduct continuing

review of the protocols if they are in accordance with the protocols and related documents approved by the RERC.

The primary reviewers/member reviewers recommend approval of the application for continuing review if there is no deviation or violation of RERC approvals. If there is any deviation or violation of approvals given by the RERC, the Primary Reviewers recommend that appropriate action to be taken by the PI e.g. amendment of the protocol or consent form or explanation of deviation or violation. If amendments are recommended, PR will recommend submission of amendment report. Amendments may either be MINOR or MAJOR (*3SOP16 Review of Amendments*).

Approval or other recommendations by the PR for protocols subject to Expedited Review for Continuing Review is reported during the Full Board meeting. For protocols subject to Full Review, recommendations are discussed during Full Board meeting.

#### **Step 5 : Communication of committee action**

The Secretariat prepares the draft decision based on the report of the expedited review or the minutes of the meeting in the full review. The Chair finalizes and signs the decision letter (*Form 4.30.3*). Possible decisions include the following: Approval, Additional information required, submission of an explanation for failure to submit required reports or disapproval.

#### **Step 6 : Filing of documents in the appropriate protocol folder**


The Staff files the application for Continuing review, the recommendations of the reviewers and decision letter in the appropriate protocol folder.

### **6. Forms**

Form 3.21.1	Continuing Review Application Form
Form 4.30.2D	Reminder Letter for Progress Report / Continuing Review / Final Report
Form 4.30.3	Letter of Document Receipt and Recommended Action

### **7. History of SOP**

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
1	2015 October	Dr. Rhodora Madrid-Reyes	First draft
2	2016	Dr. Rhodora Madrid-Reyes	None
3	2017 February	Dr. Rhodora Madrid-Reyes	None
4	2020 October	Dr. Rogelio A. Acosta Jr. and Dr. Albert Joseph B. Lupisan	Revision of Management of an application for Continuing Review
5	2021 June	Dinna P. Remo, CPA	Inclusion of Reminder Letters for Continuing Review

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>		
	<b>CHAPTER 3 POST APPROVAL PROCEDURE SOP 21 Management of an Application for Continuing Review</b>		<b>Version No: 5</b>
			<b>Date of Approval:</b> June 04, 2021
			<b>Date of Effectivity:</b> June 04, 2021
			<i>Change in deadlines for submission of application</i>  <i>Requirement for submission of unexpired GCP certificate</i>  <i>Expand review process in case of deviations or violations</i>

## 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*


*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 3 POST APPROVAL PROCEDURES SOP 22 Review of Final Reports</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021  <b>Date of Effectivity:</b> June 04, 2021

## 1. Policy Statement

The BATMC RERC shall require the submission of the final report on or before the end of the study but not later than 4 weeks after the end of the study. “End of Study” is defined as follows :

- For BatMC-initiated protocols – “End of Study” refers to date of dissemination of Final Report by the Department.
- For Clinical Trials – “End of Study” refers to that which is defined on the terms of the Clinical Trial Agreement as applicable
- For non-BatMC initiated protocols other than clinical trials – “End of Study” will be based on the submitted Gantt Chart of the PI

Final reports shall undergo EXPEDITED REVIEW unless there are indications of deviations or violations of RERC approvals . Submission and review of final reports signal the completion of the study and its acceptance by the research ethics committee.

## 2. Objective/s of the Activity

This activity primarily aims to ensure that the conduct of the study was in compliance with the approved protocol and that the safety and welfare of study participants were promoted and the integrity of data protected until the end of the study.

## 3. Scope

This policy applies to the management and review of final reports submitted by the investigators at the end of the study. This SOP begins with the receipt and entry of the final report into the logbook and ends with an update of the protocol database.

## 4. Workflow

It is the responsibility of the Batangas Medical Center RERC Secretariat to remind investigators to submit the final reports at the end of the study and not later than one (1) month after the end of the study.

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1:</b> Receipt of final report and entry into logbook	RERC Staff
<b>Step 2:</b> Retrieval of pertinent protocol file	RERC Staff

<b>Step 3:</b> <i>Notification of Chair and Primary Reviewer</i>	<i>RERC Staff</i>
<b>Step 4:</b> <i>Expedited review (2SOP 8)</i>	<i>Chair Primary Reviewer Committee Members</i>
<b>Step 5:</b> <i>Communication of committee action</i>	<i>Chair</i>
<b>Step 6:</b> <i>Filing of the Final Report and related documents and update of the protocol files.</i>	<i>RERC Staff</i>

## 5. Description of Procedures

### Step 1 - Receipt and entry of final report into logbook .

The Staff receives and enters the date of receipt of the final report form (*Form 3.22.1*) into the logbook. Final Report will only be accepted when submitted together with the certification of approval and clearance from the Department's Research and Technical Review Committee.

### Step 2 - Retrieval of pertinent protocol file.

The staff retrieves the corresponding protocol file as reference in the review of the Final Report.

### Step 3 - Notification of Chair and Primary Reviewer.

The staff notifies the Chair and the primary reviewers of the receipt of the Final Report and awaits further instructions.

### Step 4 – Expedited review.


The Chair instructs the Secretariat to include the report in the agenda of the next meeting and to ensure that the Primary Reviewer is given the necessary documents to check if the research was conducted in accordance with the RERC approved protocol. The Primary Reviewers recommend approval of the final report if there is no deviation or violation of RERC approvals. If there is any deviation or violation of approvals given by the RERC, the Primary Reviewers may recommend for explanation of deviation or violation. Approval of the Final Report or other recommendations by the PR for protocols subject to Expedited Review is reported by the PR during Full Review Board Meeting.

### Step 5 - Communication of committee action.

It is suggested that the REC consider the following decisions in the review of a final report: acceptance of the Final Report or to require resubmission with corrections.

### Step 6 - Filing of the Final Report and related documents and update of the protocol database.

The REC secretariat files the Final Report and related documents in the appropriate folder and updates the protocol database.

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 3 POST APPROVAL PROCEDURES SOP 22 Review of Final Reports</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

## 6. Forms

Form 3.22.1 Review of Final Report

Form 4.30.2D Reminder Letter for Progress Report / Continuing Review / Final Report

## 7. History of SOP

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
1	2015 October	Dr. Rhodora Madrid-Reyes	First draft
2	2016	Dr. Rhodora Madrid-Reyes	None
3	2017 February	Dr. Rhodora Madrid-Reyes	None
4	2020 October	Dr. Rogelio A. Acosta Jr. and Dr. Albert Joseph B. Lupisan	Revision of Review of Final Report. Inclusion of timeline for submission of reports.
5	2021 June	Dinna P. Remo, CPA	Definition of "End of Study"  Clarification of Expedited Review under Step 4

## 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*


*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 3 POST APPROVAL PROCEDURES SOP 23 Management of Appeals</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

### 1. Policy Statement

The BATMC-RERC shall consider the perspective of the principal investigator regarding the feasibility and acceptability of REC recommendations including its disapproval. Appeals of researchers shall undergo full review and shall be resolved within thirty (30) calendar days upon receipt of the fully documented appeal.

### 2. Objective of the Activity

To describe the BATMC-RERC management of appeals to ensures fairness, transparency and comprehensiveness of ethics review that takes into consideration the perspective of the principal investigator.


To describe the reconsideration and appeal process of BATMC-RERC for unfavorable decisions rendered.

### 3. Scope

The SOP on Management of Appeals covers procedures that begin with the receipt of the appeal and ends with communicating the BATMC-RERC's action to the principal investigator/researcher and updating of the protocol.

### 4. Workflow

ACTIVITY	RESPONSIBILITY
<b>Step 1:</b> Receipt of an appeal	RERC Staff
<b>Step 2:</b> Retrieval of pertinent protocol file	RERC Staff
<b>Step 3:</b> Notification of Chair and Primary Reviewer/s	RERC Staff
<b>Step 4:</b> Inclusion in Agenda of the next regular meeting	Chair and Primary Reviewer
<b>Step 5:</b> Discussion of and deliberation on the appeal	Chair and REC Members
<b>Step 6:</b> Communication of committee action (4SOP30 Communicating REC Decisions)	Chair
<b>Step 7:</b> Filing of documents and updating of the protocol database	RERC Staff

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 3 POST APPROVAL PROCEDURES SOP 23 Management of Appeals</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

## 5. Description of Procedures

### Step 1: Receipt of an Appeal

The secretariat receives the letter of appeal of the principal investigator/researcher and enters the pertinent information into the logbook. Appeal requests must be submitted to the BATMC-RERC Chair in writing no later than thirty (30) calendar days after the RERC has rendered the written decision letter.

### Step 2: Retrieval of pertinent protocol file

The secretariat retrieves the pertinent file for reference in the review. The file includes the initially submitted protocol, ICF, research tools and other related documents.

### Step 3 : Notification of Chair and Primary reviewers

The secretariat notifies the Chair and the primary reviewers about the letter of appeal and awaits further instructions. The RERC Chair shall acknowledge the appeal request in writing no later than 7 days following receipt of the appeal request and will outline the appeal process and requirements.

### Step 4: Inclusion in the Agenda of the next regular meeting


The Chair instructs the secretariat to include the appeal in the agenda of the next Full Board Review Meeting, to ensure that the retrieved protocol and related documents are available during the meeting and to inform the principal investigator/researcher to be available on the scheduled meeting in case there is a need for further clarification.

### Step 5 : Discussion of and Deliberation on the Appeal

The primary reviewer summarizes the protocol and the previous discussion of the issues in the protocol as background to the appeal. The Chair presents the contents of the appeal and leads the discussion. The principal investigator/researcher may be called in for further clarification of issues. The principal investigator/researcher is asked to step out after the committee has taken up the issues for clarification. The committee then decides (by consensus) whether to accept any or all of the points raised in the appeal.

### Step 6: Communication of Committee Action



	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 3 POST APPROVAL PROCEDURES SOP 23 Management of Appeals</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

Based on the deliberations, the Chair summarizes the decision points and instructs the BATMC-RERC staff to prepare the draft decision letter (*BATMC-RERC Form 4.30.3 Letter of Document Receipt and Recommended Action*) for his/her finalization and forwarding to the principal investigator/researcher. (*4SOP 30 Communicating REC Decisions*). The principal investigator/researcher will receive a formal appeal decision letter and the principal investigator/researcher shall satisfactorily address all the conditions and concerns raised by the appeal board to receive ethics approval. The decision of BATMC-RERC shall be final and no further appeals will be granted.

#### Step 7: Filing of Documents and Update of Protocol Database

The secretariat files all the documents into the appropriate folder and updates the protocol database accordingly.

#### 6. Forms

Form 4.23.1 Letter of Appeal template


Form 4.30.3 Document Receipt and Recommended Action Form

#### 7. History of SOP

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
<b>1</b>	<i>2015 October</i>	<i>Dr. Rhodora Madrid-Reyes</i>	<i>First draft</i>
<b>2</b>	<i>2016</i>	<i>Dr. Rhodora Madrid-Reyes</i>	<i>None</i>
<b>3</b>	<i>2017 February</i>	<i>Dr. Rhodora Madrid-Reyes</i>	<i>None</i>
<b>4</b>	<i>2020 October</i>	<i>Dr. Rhodora Madrid Reyes Dr. Allan E. Lanzon</i>	<i>Management of Appeals</i>
<b>5</b>	<i>2021 June</i>	<i>Dinna P. Remo, CPA</i>	<i>Change submission of appeal from 1 month to 30 calendar days</i>

#### 8. References

*World Medical Association Declaration of Helsinki, 2013*

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 3 POST APPROVAL PROCEDURES SOP 23 Management of Appeals</b>	<b>Version No: 5</b>
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		<b>Date of Effectivity:</b> June 04, 2021

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*


*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 3 POST APPROVAL PROCEDURES SOP 24 Conduct of Site Visits</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021  <b>Date of Effectivity:</b> June 04, 2021

### 1. Policy Statement

The BATMC-ERC shall designate a team to conduct visits of selected sites of approved protocols that fall within the following established criteria for such visits: Site visits are part of BATMC RERC OVERSIGHT functions in the following conditions: high risk studies, receipt of significant number of protocol violations, receipt of complaints from participants and families, non-receipt of required after-approval reports, multiple studies conducted by a researcher

### 2. Objective of the Activity

Site visits are mechanisms with which the BATMC-REC monitors compliance with approved protocols, ICF process and continuing protection and promotion of participant's dignity, rights and well-being. Site visits may be initiated for a routine onsite evaluation of a study site for a routine audit

### 3. Scope

This SOP includes the steps in conducting visits to study sites for reasons set by the BATMC-REC. This begins with the selection of the site to be visited and ends with the draft of site visit report, presentation of report during the meeting, discussion of the recommendations, filing of Site-Visit Reports in the protocol folder and updating of the protocol database.

#### RESPONSIBILITIES


The Secretariat shall inform the PI of the scheduled site visit.

The Secretariat shall prepare, document, and communicate the action regarding the site monitoring and include it in the agenda for the next meeting.

The BATMC-RERC Chair shall form a site visit team and issue a report for presentation in the RERC meeting. The site visit team shall make a report after the site visit using BATMC-RERC *FORM 3.24.3: SITE VISIT REPORT FORM*.

The BATMC-RERC Members/Monitoring Team shall:

- Perform or designate members to perform on-site inspection of selected study sites of relevant projects.
- In consultation with the Chair, may initiate an on-site evaluation of a study site for cause or for a routine audit.

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#### 4. Workflow


<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<i>Step 1: Selection of site to visit; check protocol documents and prepare all relevant documents needed for adequate and comprehensive site visit</i>	<i>RERC Chair and PR</i>
<i>Step 2: Notification of principal investigator</i>	<i>RERC Staff</i>
<i>Step 3: Creation of Site Visit Team</i>	<i>Chair</i>
<i>Step 4: Conduct of site visit</i>	<i>Site Visit Team (members)</i>
<i>Step 5: Draft of report and presentation of report during meeting and discussion for recommendations</i>	<i>Site Visit Team (members)</i>
<i>Step 6: Transmittal of Final Report and Recommendations to the Researcher/Investigator</i>	<i>Chair/ RERC Staff</i>
<i>Step 7: Filing of Site-Visit Reports in the protocol folder and update of Protocol database</i>	<i>RERC Staff</i>

#### 5. Description of Procedures

##### Step 1: Selection of site to visit

The BATMC-REC Chair and Primary Reviewers shall decide which research site to visit based on the following criteria:

- high risk studies
- consistent non-submission or failure to submit after-approval submission requirements
- reports of major protocol noncompliance
- significant number of serious adverse events
- reports of complaints from study participants

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## Step 2: Notification of principal investigator

The Chair, through the Secretariat, informs the PI at least fifteen (15) calendar days before the scheduled visit through a letter (*BATMC-RERC FORM 3.24.2: NOTICE OF SITE VISIT TO THE PRINCIPAL INVESTIGATOR*). A copy of *BATMC-RERC FORM 3.24.3 : SITE VISIT REPORT FORM* is attached to this letter.

The letter provides Site Visit schedule details and instructions on what the PI needs to prepare that will be used for the Site Visit, as well as orderly preparation of the site. Documents to be prepared include: complete protocol document, informed consent being used, informed consent process, and all post-approval documents.

## Step 3: Creation of Site Visit Team

A Site Visit Team is created for each site visit.

The BATMC-RERC Chair assign members of the site visit team.

The Team should be composed of at least *three (3) people: two (2)* primary reviewers of the protocol, and the Chair/Vice-Chair or Member Secretary or 1 primary reviewer and 2 Member Officers


The Site Visit Team members are informed of their assignment through the issuance of *BATMC-RERC FORM 3.24.1 : NOTICE OF SITE VISIT TO BATMC RERC MEMBER*

The Secretariat prepares a Study Visit Package for each member of the Site Visit Team, inclusive of the *BATMC-RERC FORM 3.24.3: SITE VISIT REPORT FORM* and a copy of the approved study protocol and related documents.

## Step 4: Conduct of Site Visit

During the visit, the designated site visit team shall:

- Review the study protocol
- Review the informed consent documents and verify if the site is using the most recently approved version.
- Ask the PI or any member of the team to explain the informed consent process.
- Review the post-approval documents and verify if the site is using the most recently approved version.
- Ensure and document that the documents are being filed properly, securely and with confidentiality at the study site.
- Make an overall resolution of the protection of the rights, safety, and welfare of human participants in the study

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- g. At the end of the visit, the Site Visit Team will: discuss the findings with the research team, solicit feedback.

#### **Step 5: Draft of report and presentation of report during meeting and discussion for recommendations**

The Site Visit Team completes BATMC-RERC FORM 3.24.3: *SITE VISIT REPORT FORM* and submits it to Secretariat not later than seven (7) calendar days after the Site Visit.

The Secretariat logs the date of submission on the SUBMISSIONS LOG.

The Secretariat files a copy of the report on the study file and places the Site Visit Report in the agenda of the next meeting.

During the meeting, the Secretariat distributes the completed BATMC-RERC FORM 3.24.3: *SITE VISIT REPORT FORM* to RERC Members along with the meeting agenda.

The BATMC-RERC deliberates on the results of the Site Visit based on the rights, safety, and welfare of the study participants; and makes an overall conclusion of protocol compliance.

#### **Step 6: Transmittal of the Final Report and Recommendations to the Researcher/ Investigator**

The Secretariat notifies the PI of the BATMC-RERC action or recommendations through an action letter. *Form 4.30.3 (Letter of Document Receipt and Recommended Action)*

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

The PI may be requested to provide additional information, submit additional documents, or implement corrective action. The Secretariat follows-up the action taken by the Principal Investigator.


#### **STEP 7 Filing of the Site Visit documents and update of the Protocol database**

The Primary Reviewers, RERC Member-Secretary, and Chair sign the *BATMC-RERC FORM: SITE VISIT REPORT FORM (FORM 3.24.3)*.

The Secretariat files the Site Visit Report and the recommendations in the appropriate folder and updates the protocol database accordingly. (4SOP 32 Management of Active Files)

#### **6. Forms:**

- Form 3.24.1 Notice of Site Visit to BATMAC RERC Members
- Form 3.24.2 Notice of Site Visit to Principal Investigator
- Form 3.24.3 Site Visit Report

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## 7. History of SOP

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
1	2015 October	Dr. Rhodora Madrid-Reyes	First draft
2	2016	Dr. Rhodora Madrid-Reyes	None
3	2017 February	Dr. Rhodora Madrid-Reyes	None
4	2020 October	Dr. Rhodora Madrid Reyes Dr.Allan E. Lanzon	Revised Site Visit Report Form
5	2021 June	Dinna P. Remo	None

## 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*


*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*



*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*


*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

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Supersedes:	<b>Version 4</b>
Authored by:	Batangas Medical Center RERC
Effective Date:	June 04, 2021
Approved by:	Rhodora Madrid-Reyes MD, FPNA,FPSCOT Chairman 
Approved by:	Dr. Ramoncito C. MagnayeMD,FPCS,FPSGS,MHA 
Approval Date:	June 04, 2021



	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 4 DOCUMENTING AND ARCHIVING SOP 25 Preparing for a Meeting</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

## 1. Policy Statement

Meetings are one of the major activities of the research ethics committee. They are the venues for deliberation and decision making regarding ethical evaluation of study protocols and are opportunities for RERC to be informed and updated regarding its operations and relevant matters. It is important that the BatMC RERC conducts regular meetings.

The BatMC RERC shall hold two regular meetings every first Friday of the month for the review of expedited protocols and every second Friday of the month for the full board review of protocols classified as such.

Special meetings, to include clarificatory meetings, shall be held to resolve issues that require immediate attention such as safety of participants, protocol violation that impact research integrity. All meetings shall be held inside the institution or thru the BatMC official online platform.

## 2. Objective of the Activity


Preparation for a meeting aims to contribute to a smooth orderly and efficient conduct of meetings.

## 3. Scope

This SOP provides instruction related to the preparation of the BatMC RERC meeting agenda and its distribution to inform RERC members and other interested individuals about the items for discussion on a full board meeting. It is the responsibility of the RERC secretariat under the supervision of the member-Secretary to compile all documents/ information submitted to the RERC within the prescribed deadline to include them in the next full board meeting.

## 4. Workflow

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<i>Step 1: Preparation of the Agenda</i>	<i>RERC Staff/ Chair/ Member Secretary</i>
<i>Step 2: Coordination with physical plant</i>	<i>RERC Staff</i>
<i>Step 3: Preparation of the presentation Onsite or Online</i>	<i>RERC Staff</i>
<i>Step 4: Notification of RERC members and confirmation of the attendance</i>	<i>RERC Staff</i>

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		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

## 5. Description of Procedures

### Step 1: Preparation of the Agenda

Collect all documents submitted to the RERC at least one week prior to the scheduled meeting and put them in either expedited or full board agenda for the information of the RERC members.

### Step 2: Coordination with physical plant

The RERC secretariat secures the venue for the on-site meeting or coordinates with the Training Office for the online site to be utilized one week before the meeting.

### Step 3: Preparation of the presentation Onsite or Online

The secretariat ensures that the necessary equipment such as screen projector, laptop, and peripherals as well as food and beverages are available for onsite meeting. As for online meeting, the secretariat should ensure that laptop, files and the platform link are prepared.

### Step 4: Notification of RERC members and confirmation of the attendance

The Chair or member-secretary supervises the secretariat in the preparation of the *Notice of Meeting Form 4.26.1* that includes the provisional agenda. The support staff sends the Notice of Meeting to the members of the committee at least one week before the schedule and follow-ups the confirmation of attendance to ensure quorum. For the First Friday meeting, only the primary reviewers of the expedited protocols are required to attend. In case the primary reviewers for the expedited protocols cannot attend during the expedited protocol meeting, appropriate adjustments should be made. For the second Friday of the month, a full board is required to attend. In case the quorum cannot be met, the support staff informs the Chair and the member secretary so that appropriate adjustments can be made.


## 6. Forms

Form 4.26.1 Notice of Meeting

Form 4.26.2 Provisional Agenda of Meeting

## 7. History of SOP

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
1	2015 October	Dr. Rhodora Madrid-Reyes	First

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			<b>Date of Approval:</b> June 04, 2021
			<b>Date of Effectivity:</b> June 04, 2021
2	2016	Dr. Rhodora Madrid-Reyes	None
3	2017 February	Dr. Rhodora Madrid-Reyes	None
4	2020 October	Dr. Teresita Risalyn Villanueva Dr. Edralin Vidal	Inclusion of Online Meeting
5	2021 June	Dr. Teresita Risalyn Villanueva Dr. Edralin M. Vidal	Revision to include Expedited PR Review Meeting and Preparation for Two regular meetings in a month

## 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*


*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

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		<b>Date of Approval:</b> June 04, 2021  <b>Date of Effectivity:</b> June 04, 2021

### 1. Policy Statement

The meeting agenda serves as a guide in the conduct of meeting. The standard Notice of Meeting agenda includes the submitted protocols at least five (5) days before the scheduled regular meeting. It shall follow an established template for meeting agenda. The provisional agenda shall be included in the Notice of Meeting.

### 2. Objective/s of the Activity

The preparation of the meeting aims to ensure a smooth, orderly, inclusive and efficient conduct of meeting.

### 3. Scope

In this procedure, the RERC determines which protocols are to be included in the agenda for expedited review on the first Friday meeting, protocols for full board review on the second Friday meeting, and which topics/protocols are for special meetings. The SOP starts with preparation of the draft for the meeting agenda and ends with the filing of the final meeting agenda.

### 4. Workflow

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1:</b> Preparation of the draft meeting agenda	<i>Chair, Member Secretary or Secretariat</i>
<b>Step 2:</b> Preparation of the provisional meeting agenda	<i>Chair</i>
<b>Step 3:</b> Distribution of the provisional meeting agenda	<i>Secretariat</i>
<b>Step 4:</b> Approval of the provisional meeting agenda	<i>REC Members</i>
<b>Step 5:</b> Filing of the final meeting agenda	<i>Secretariat</i>

### 5. Description of the procedure

#### Step 1 – Preparation of the draft meeting agenda


The staff under the supervision of the Chair/ Member-Secretary prepares the draft agenda 1 week before the scheduled meeting, using the meeting agenda template. The agenda includes the following:

***Agenda Template for Expedited PR Review Meeting - Form 4.26.2a***

- ☐ Date of preparation
- ☐ Date, time and venue whether onsite or online
- ☐ Call to order
- ☐ Approval of the Provisional Agenda
- ☐ Disclosure of the Conflict of Interest
- ☐ New Business:
- ☐ PROTOCOL REVIEW – *All Expedited*
  - ◀ New Protocols
  - ◀ Review of Protocol Resubmission
  - ◀ Protocol Amendments
  - ◀ Progress Report
  - ◀ Protocol Deviations/Violations
  - ◀ Continuing Review
  - ◀ Final Report
- ☐ Other Matters

***Agenda Template for Full Board Review Meeting - Form 4.26.2b***

- ☐ Date of preparation
- ☐ Date, time and venue whether onsite or online
- ☐ Call to order
- ☐ Approval of the Provisional Agenda
- ☐ Disclosure of the Conflict of Interest
- ☐ Review and approval of the minutes of the previous meeting
- ☐ Business arising from the minutes
- ☐ New Business:
- ☐ PROTOCOL REVIEW
  - ◀ New Protocols under Full Review
  - ◀ Review of Protocol Resubmission
  - ◀ Protocol Amendments
  - ◀ Progress Report
  - ◀ Protocol Deviations / Violations
  - ◀ RNE Reports
  - ◀ SAE and SUSAR Report
  - ◀ Early Study Termination
  - ◀ Continuing Review
  - ◀ Final Reports
  - ◀ Management of Appeals
  - ◀ Site Visits Report
  - ◀ Queries or Complaints
  - ◀ Report of Protocols under Expedited Review
    - ◀ Approved Protocols
    - ◀ Approved Resubmitted Protocols
    - ◀ Approved Amendments (Minor)
    - ◀ Approved Progress Reports

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- ◀ Decisions on Protocol Deviations / Violations (Minor)
- ◀ Decision on Off-site SAE/SUSARs
- ◀ Decision on Continuing Review Applications
- ◀ Report of Final Reports
- ◀ Report on Exempt from Review Protocols
- ☐ Other Matters

### Step 2-Preparation of the provisional agenda

The Chair reviews the draft agenda within 1 week as the basis of preparing the provisional agenda for inclusion in the Notice of Meeting

### Step 3-Distribution of the provisional meeting agenda

The Chair instructs the staff secretary to distribute the meeting agenda to all members via email 1 week before the scheduled meeting.

### Step 4- Approval of the provisional meeting agenda

The RERC approves the provisional agenda during the meeting

### Step 5-Filing of the final meeting agenda


The staff secretary files the approved meeting agenda in a special folder that contains all meeting agenda in chronological order.

## 6. Forms

- Form 4.26.1 Notice of Meeting
- Form 4.26.2a Provisional Agenda for Expedited PR Review Meeting
- Form 4.26.2b Provisional Agenda for Full Board Review Meeting

## 7. History of SOP

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
1	2015 October	Dr. Rhodora Madrid-Reyes	First draft
2	2016	Dr. Rhodora Madrid-Reyes	None
3	2017 February	Dr. Rhodora Madrid-Reyes	None

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<b>CHAPTER 4</b> <b>DOCUMENTING AND ARCHIVING</b> <b>SOP 26</b> <b>Preparing the Notice of Meeting</b>			<b>Version No: 5</b>
			<b>Date of Approval:</b> June 04, 2021
			<b>Date of Effectivity:</b> June 04, 2021
4	2020 October	Dr. Teresita Risalyn Villanueva Dr. Edralin Vidal	Includes online platform, draft, provisional and final agenda approval
5	2021 June	Dr. Teresita Risalyn Villanueva Dr. Edralin M. Vidal	Separation of Provisional Agenda for Expedited PR Review Meeting and Full Board Review Meeting

## 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*


*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

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		<b>Date of Approval:</b> June 04, 2021
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## 1. Policy Statement

The Meetings shall be presided by the Chair or Vice Chair. The first Friday meetings for the Expedited review shall proceed when the primary reviewers are present. For the full board review during the second Friday, the meeting shall proceed only if a quorum has been declared and shall be guided by the meeting agenda. The presence of conflict of interest among its members shall be disclosed prior to discussion of protocols for review.

For the first Friday meeting, the Expedited review will be divided into: Initial Submissions for the new protocols, then expedited protocol for Resubmission, progress report, continuing review and all final report. For the second Friday meeting, the Full Board review will be divided into: Initial Submissions for the new protocols, then protocol for Resubmission and lastly, review of the post approval submissions including the report of the approved final report. Approvals and decisions or actions on post approval of protocols classified under Expedited Review will be reported during the Full Board Meeting. Exempt from review protocols should be reported after all post approval submissions. SJREB protocols shall be reviewed according to classification made by the chairman.

By policy, meetings will be conducted on-site or face to face. However, virtual meetings may be conducted when on-site or face to face meeting cannot be done. These guidelines shall likewise govern the RERC in allowing attendance, participation and voting of members not physically present through teleconferencing, video conferencing and other remote or electronic means of communication (virtual meeting) for the following reasons :


1. When face to face meetings cannot be held due to inclement weather, national disaster or calamities and other similar events preventing physical presence in the office;
2. When a member cannot physically attend nor vote but can participate and vote through remote communication.

## 2. Objective/s of the Activity

Meetings are conducted to provide an opportunity for the RERC to arrive at collegial decisions regarding study protocols and RERC operations and to be informed of pertinent administrative matters.

The setting of internal guidelines and policies for virtual meetings shall ensure that all members participating through remote communication have the opportunity to participate in the meeting (including an opportunity to read or hear the discussion substantially), and are able to participate and vote during the meeting. Further, setting up of internal policies for the conduct of virtual meetings



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shall ensure that submitted research protocols are reviewed and decided upon within the acceptable timeframe.


### 3. Scope

This SOP describes the manner by which the RERC conducts all its meetings. It covers the RERC actions and activities from the time the meeting is called to order and determine the presence of primary reviewers of expedited protocols on first Friday meeting and quorum has been declared during second Friday full board review to the time the meeting is adjourned. This SOP begins with the distribution of meeting materials and ends with the collection, storage and disposal of meeting materials.

This SOP includes guidelines to govern holding of virtual meetings and/or participation by absentia or through remote communication.

### 4. Workflow

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1: Distribution of meeting materials</b>  1.a Onsite meeting 1.b Online meeting	RERC Staff
<b>Step 2: Declaration of quorum</b>	Member Secretary
<b>Step 3: Approval of the provisional agenda</b>	Chair, Vice Chair or Presiding Officer
<b>Step 4: Declaration of Conflict of Interest</b>  4.a Onsite meeting 4.b Online meeting	REC Members
<b>Step 5: Approval of the minutes of the previous meeting</b>	REC Members
<b>Step 6: Discussion of " Business arising from the Minutes"</b>	Chair / Presiding Officer
<b>Step 7: Review of Protocols and protocol related submission</b>	REC Members
<b>Step 8: Report of result of expedited review and exempt from review protocols.</b>	Primary Reviewer

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	<b>CHAPTER 4 DOCUMENTING AND ARCHIVING SOP 27 Conduct of Meeting</b>	<b>Version No: 4</b>
		<b>Date of Approval:</b> October 19, 2020
		<b>Date of Effectivity:</b> November 02, 2020
<b>Step 9: Discussion of operations- related matters</b>		<i>Chair or Member Secretary</i>
<b>Step 10: Adjournment</b>		<i>REC Members</i>
<b>Step 11: Collection, storage and disposal of meeting materials</b>  11.a Onsite meeting 11.b Online meeting		<i>RERC Staff</i>

## 5. Description of Procedures

### Step 1: Distribution of meeting materials

**a. For onsite meetings** – those members who have confirmed their attendance will be given a hard copy of the minutes of the previous meeting and a hard copy of notice of the meeting or a soft copy of the aforementioned at least one week prior to the meeting for review


**b. For online meetings** – those members who have confirmed their attendance will be forwarded a soft copy of the minutes of the previous meeting as well as a copy of the notice of meeting at least one week before the scheduled meeting for review

All hard and soft copies were prepared by the staff secretary after approval by the Chair.

### Step 2: Declaration of quorum

Acknowledgment of presence of primary reviewers for expedited review on first Friday and declaration of quorum for full board review on second Friday. The member-secretary or an Assistant Member-Secretary notifies the members that the meeting will be recorded. He/She then proceeds to call on the names of the members and identifies them as medical or non-medical, institutional or non-institutional as well as guest or independent consultants. Acknowledgment of the presence of the primary reviewers of the expedited review is done and recorded. A quorum is not needed for the first Friday meeting. For the review of the full board classified protocols, a quorum is necessary and declared if 50% plus 1, inclusive of the presence of one (1) nonmedical and one (1) non-institutional member. This is recorded by the Member-secretary

**Step 3: Approval of the provisional agenda** – The Chair or the Vice-Chair is declared as presiding officer by the Member- secretary or Assistant Member Secreatry. The Presiding Officer invites the members to examine the provisional agenda and to propose addition or deletion.

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**Step 4: Declaration of Conflict of Interest** – At the onset, the presiding officer asks the members if there will be any Conflict of Interest. The Member will be ask to sign *Form 4.27.1 Declaration of Conflict of Interest by a Member*.

**a. On-site meeting** – the RERC member who declares a COI for a particular research will be asked to step out of the room just prior to the discussion until a decision for a research protocol has been declared.

**b. Online meeting** – the RERC member who declares a COI for a particular research will be asked to log out of the online platform prior to the discussion until a decision has been reached, after which the member can join the meeting.


The secretariat will record the time the members with COI stepped out of the room or logged out from the online discussion and the time he/she returned.

**Step 5: Approval of the minutes of the previous meeting** – The presiding officer will remind the RERC members that the previous minutes of the meeting has been sent via email and a page by page review will be done at the current meeting. Any correction, addition or deletion to the minutes of the meeting maybe raised by the RERC members. Approval will be asked by the presiding officer from the RERC members present;

**Step 6: Discussion of “Business arising from the Minutes”** - The presiding officer discusses any business arising from minutes and a consensus shall be met after discussion.

**Step 7: Review of Protocols and protocol related submissions** –The RERC member with any COI will be asked to leave once the research will be discussed. It is the primary reviewer who presents the protocol by giving a background (objectives, clinical significance, methods, outcomes, ethical considerations) about the study and their comments. The primary reviewers of the expedited protocol will then give the decision as follows: approved, minor modification, and major modification for which it will be discussed on the full board meeting. As for the full board review, after the presentation of the primary reviewers, other members may give their comments and a discussion will ensue, taking into consideration 3 key points: technical issue, ethical issues and informed consent issues. A clarificatory interview maybe scheduled with the Principal investigator during the current meeting or at later date as needed *Form 4.27.2( Letter of Invitation for a Clarificatory Meeting)*.

After all the issues and concerns have been discussed, the presiding officer request for a motion regarding the action for a protocol (approved, minor or major modification or disapproved). The presiding officer request for a show of hands regarding the motion and if a consensus has not been met, the RERC members who disagree will be asked to voice their opinions. Recommendations based

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on the unresolved issues will be summarized and sent to the PI. A board decision is arrived at when all RERC members agree in favor of the approval, major or minor modification or disapproval.

#### **Step 8: Report of result of expedited review and exempt from review protocols-**

The protocols which are set for expedited review will be discussed on the first Friday of the month as a regular meeting. Only the primary reviewers of expedited reviews are required to attend and make a report on the protocol. This is to inform the members of the findings and should there be a need to have a full board review on the protocol, it shall be discussed as such upon resubmission.

Report of exempt from review protocols are also presented and noted.

Report of approved final reports is done during full board meeting on the second Friday of the month.

**Step 9: Discussion of operations-related matters-** The operations-related matters include administrative issuances, schedule and assignment of member's schedules for RERC related workshops, lectures and conferences as well as any updates in the Policy and guidelines of PHREB, FERCAP and other accrediting bodies.

**Step 10: Adjournment-** Meeting must be adjourned after all items in the agenda have been discussed/ resolved.

A member must move for the adjournment of the meeting, and seconded for it to be declared.


#### **Step 11: Collection, storage and disposal of meeting materials**

**a. On site meetings** – all the hard copies of the minutes distributed must be given back to the staff secretary for disposal and the original hard copy is retained. It is placed in a separate folder and in the locked cabinet.

**b. Online meetings** – it is the responsibility of the RERC member to secure the soft copy of the minutes of the meeting in a secure folder in his email which should be password protected.

### **6. Forms**

Form 4.25.1 Notice of Meeting  
Form 4.26.1 Provisional Agenda of Meeting  
Form 4.29.1 Minutes of Meeting  
Form 2.14.1 Protocol Assessment Form  
Form 2.14.2 ICF Assessment Form  
Attendance Sheet Form

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## 7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2015 October	Dr. Rhodora Madrid-Reyes	First draft
2	2016	Dr. Rhodora Madrid-Reyes	None
3	2017 February	Dr. Rhodora Madrid-Reyes	None
4	2020 October	Dr. Teresita Risalyn V. Villanueva Dr. Edralin Vidal	addition of guideline for online meetings
5	2021 June	Dr. Teresita Risalyn V. Villanueva Dr. Edralin M. Vidal	Separation of regular meetings into Expedited Review and Full board review

## 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*


*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

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### 1. Policy Statement

Special meetings shall be held either onsite or online to resolve issues that require immediate attention, e.g. oversight problems involving safety of participants, protocol violation that impact research integrity, RNE clarificatory meetings, clarificatory interviews/dialogue with PI and urgent administrative and operational concerns of the RERC.

### 2. Objective/s of the Activity

Special meetings are conducted to provide an opportunity for the RERC to arrive at collegial decisions on issues requiring immediate attention about on-going study protocols and urgent administrative and operational concerns of the RERC.

### 3. Scope

This SOP describes the process in conducting special meetings. The SOP begins with the preparation for the special meeting and ends with the collection, storage and disposal of meeting materials.

### 4. Workflow


<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1 :</b> <i>Preparation for conduct of Special Meeting</i>	<i>Chair</i> <i>Member Secretary</i> <i>RERC Staff</i>
<b>Step 2 :</b> <i>Conduct of Special Meeting</i>	<i>Chair</i> <i>All members</i>
<b>Step 3 :</b> <i>Collection and storage or disposal of meeting materials</i>	<i>Member Secretary</i> <i>RERC Staff</i>

### 5. Description of Procedures

#### Step 1 – Preparation for conduct of Special Meeting:

A special meeting may be called by the Chair or is proposed by a member of the BatMC RERC

The decision to call a special meeting is based on the following criteria:

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- Oversight problems requiring immediate action if delay will affect or have impact on the safety of participants
- Protocol violations that impact on research integrity
- Occurrence of unexpected serious adverse events
- Urgent RERC activities such as but not limited to selection of new member or officer, approval of new or revised SOP, budget deliberation, accreditation applications, trainings and other unexpected administrative or operational events that would affect the RERC
- Clarificatory meetings / interview / dialogue

The Chair or Member Secretary or RERC Staff inform all members, including invited guests, if any, about the special meeting, date, time and venue, or if online, the platform link to be used, through various channels such as call, messaging, or through electronic mail. Confirmation of attendance will be noted to ensure availability of quorum during the special meeting. Notice of meeting and agenda will be sent through electronic mail (See online provisions on *4SOP 25 Preparing for a Meeting and 4SOP 26 Preparing the Meeting Agenda*).

#### **Step 2 – Conduct of the Special Meeting:**

Prior to the start of the meeting, members are notified that the meeting will be recorded. The Member Secretary determines the quorum and the number of votes to carry a decision. Confirmation of quorum is done at the start of the meeting and re-confirmation is done every time a decision needs to be made. Quorum is defined as the presence of at least 50% plus 1 member inclusive of at least one medical member, at least one non-medical member, at least one non-affiliated member and at least one female member.


For clarificatory interview/meeting, attendees may be composed of the Chair or Vice Chair, PRs, the PI and if necessary, an independent consultant.

A special meeting may be conducted between the members through electronic communication, i.e. tele or video conference.

The meeting is conducted in the same sequence as Full Board Review with similar corresponding actions (see *2SOP 9 Full Review; 2SOP 27 Conduct of Meetings*). Minutes of the special meeting shall follow the same sequence as regular meetings (see *4SOP 29 Preparation of the Minutes of the Meeting*). Resolution on the minutes of special meeting will be reported accordingly during the full board meeting.

Independent Consultants may be invited for a special meeting or during clarificatory interview( *Form 4.27.2 Invitation for a Clarificatory Meeting*) for purposes of clarifying study protocol related to their



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fields of expertise. As in the case of regular meeting, they will not be counted for quorum and are not allowed to vote for Full Board actions. (see 2SOP 9 Full Review)

### Step 3 – Collection and storage or disposal of meeting materials:

In case of face-to-face meetings, the RERC Staff collects all meeting materials, including documentation collected for the Minutes of the meeting. All meeting materials that must be stored are filed in the relevant study files in a manner prescribed in 4SOP 32 *Management of Active Files* and 4SOP 33 *Archiving of Terminate, Inactive and Completed Studies*.

In case of online meeting, the RERC staff shall save and store the digital files in cloud accordingly in the different folders in password protected google drive accessible only to the Chair and member secretary.

## 6. Forms

Form 4.26.1	Notice of Meeting
Form 4.29.2	Minutes of Meeting
Form 4.27.2	Letter of Invitation for a Clarificatory Meeting

## 7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2015 October	Dr. Rhodora Madrid-Reyes	First draft
2	2016	Dr. Rhodora Madrid-Reyes	None
3	2017 February	Dr. Rhodora Madrid-Reyes	None
4	2020 October	Dinna P. Remo, CPA	First draft
5	2021 June	Dr. Teresita Risalyn V. Villanueva Dr. Edralin M. Vidal	Addition of clarificatory meeting in the special meeting

## 8. References

*World Medical Association Declaration of Helsinki, 2013*



*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*


*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

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	<b>CHAPTER 4</b> <b>DOCUMENTING AND ARCHIVING</b> <b>SOP 29</b> <b>Preparation of the Minutes of Meeting</b>	<b>Version No: 5</b>
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### 1. Policy Statement

The Minutes of the Meeting shall be based on the approved agenda and shall be the basis of the decision letter on protocols

### 2. Objective/s of the Activity

The preparation of the minutes of the meeting ensures the proper documentation of the procedures and decision in an RERC meeting.

### 3. Scope

This SOP includes RERC actions related to the documentation of the proceedings of a meeting, the final output of which is the minutes of the meeting. This SOP begins with the entry of preliminary information on the minutes template and ends with the filing of the approved minutes.

### 4. Workflow


<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1:</b> <i>Entry of preliminary information on the minute's template</i>	<i>RERC Staff</i>
<b>Step 2:</b> <i>Preparation of the draft minutes</i> 2.a onsite meeting 2.b online meeting	<i>Chair or Member Secretary</i>
<b>Step 3:</b> <i>Notation of the draft meetings</i>	<i>Member Secretary or RERC Staff</i>
<b>Step 4:</b> <i>Approval of the minutes in the next RERC meeting</i>	<i>RERC Members</i>
<b>Step 5:</b> <i>Storage of the approved minutes</i>	<i>RERC Staff</i>

### 5. Description of Procedures

#### Step 1- Entry of Preliminary information on the minute's template

It is the RERC Staff under the supervision of the member secretary or chair who organizes the documents in the minute's template ahead of the meeting

#### Step 2 – Preparation of the draft minutes

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- On site meeting** – The staff secretary is tasked with the documentation of the proceedings in accordance with the agenda. The Chair/ Member-Secretary may do real time note-taking while the template of the agenda is projected on screen. The information that is included are the following: comments and recommendations on the scientific issues, ethical issues and informed consent form issues. It is understood that the opinions and actions included in the minutes are understood to be collective and should not be attributed to a specific member. The Chair ensures that the fulfillment of this task by the RERC staff secretary.
- Online meetings** – It is the Chair/Member-Secretary who are both institutional members who does the real time note taking on the agenda template projected on the online platform and screen shared.

### Step 3 – Notation of the draft meetings


If the staff secretary or Member-secretary prepared the draft minutes, then it will be forwarded to the Chair with 48 hours for checking and notation. In the general, the following items are included in the minutes of the meeting.

- ☐ Date and venue of meeting
- ☐ Members attendance (members present and absent)
- ☐ Presence of Independent consultants, primary investigators, guests and observers
- ☐ Time when the meeting was called to order
- ☐ Declaration of Quorum
- ☐ Name of presiding Officer
- ☐ Conflict of interest (COI) declaration
- ☐ Items discussed, issues raised and resolutions
- ☐ RERC decisions and recommendations
- ☐ Name and signature of person who prepared the minutes
- ☐ Name and signature of the chair and date of notation

### Step 4 – Approval of the minutes in the next RERC meeting

The approval of the minutes of the expedited review meeting and the full board meeting is done on the next month's second Friday meeting through a formal motion of any member and seconded accordingly.

### Step 5 – Storage of the approved minutes

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The RERC maintains a central file of all meeting minutes by year to facilitate retrieval and stored in a filing cabinet.

Digital copy of the minutes of the meeting are also filed by year in a password protected digital folder saved both in the external hard drive and cloud.

## 6. Form

Form 4.29.1a Minutes of Expedited PR Review Meeting

Form 4.29.1b Minutes of Full Board Review Meeting

## 7. History of the SOP

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
1	2015 October	Dr. Rhodora Madrid-Reyes	First draft
2	2016	Dr. Rhodora Madrid-Reyes	None
3	2017 February	Dr. Rhodora Madrid-Reyes	None
4	2020 October	Dr. Teresita Risalyn V. Villanueva Dr. Edralin Vidal	addition of guideline for online meetings
5	2021 June	Dr. Teresita Risalyn V. Villanueva Dr. Edralin M. Vidal	Add digital copy of minutes

## 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*


*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 4 DOCUMENTING AND ARCHIVING SOP 30 Communicating RERC Decisions</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021  <b>Date of Effectivity:</b> June 04, 2021

### 1. Policy Statement

The RERC shall communicate its decision to the researcher within 1 week after the expedited or full board meeting or deliberation as the case may be. The communication document shall include clear instructions/recommendations for guidance of the researcher and it must be written on an official stationery of the RERC and signed by the chair.

### 2. Objective of the Activity


The RERC secretariat ensures that all stakeholders are properly, correctly, and promptly informed of the results of deliberations of the RERC.

### 3. Scope

This SOP provides instructions related to the preparation of RERC communications (soft/hard copy) regarding its decisions. It also covers the transmittal of these communications and the management of its filing.

### 4. Workflow

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1:</b> A. For Full Review - Finalization of recommendations of the Committee (2SOP 9) B. For Expedited Review - Finalization of recommendations of reviewers (2SOP 8) C. For Exempt from Review – classification by RERC Chair	Chair
<b>Step 2</b> Transfer of information from meeting minutes to RERC decision forms or templates	RERC Staff Member Secretary
<b>Step 3:</b> Approval of the RERC prepared decision document	Chair
<b>Step 4</b> Transmittal of RERC decision to the researcher	RERC Staff
<b>Step 5</b> Filing of the decision document in the protocol file (SOP 32 Managing Active Files or SOP 33 Archiving of Terminated, Inactive or Completed Studies ) and Update of Protocol Database	RERC Staff

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	<b>CHAPTER 4 DOCUMENTING AND ARCHIVING SOP 30 Communicating RERC Decisions</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021  <b>Date of Effectivity:</b> June 04, 2021

## 5. Description of procedure

### Step 1 – A. Full Review – Finalization of recommendations of the committee

*See 2SOP 9*

#### B. Expedited Review - Finalization of Reviewers' Recommendations

*See 2SOP 8*

#### C. Exempt from Review – classification of RERC Chair

*See 2 SOP 10*

### Step 2 - Transfer of information from meeting minutes to REC decision forms or templates

After the finalization of the reviewers' recommendations and approval of the minutes, the RERC staff, under the supervision of member secretary, prepares the *Notification of RERC decision (Form 4.30.2A)*, *Letter for Modification (Form 4.30.2B)*; *Letter of Exemption from Ethical Review (Form 4.30.2C)*; *Reminder Letter for Continuing Review/Progress Report/Final Report (Form 4.30.2D)* ; *Approval Letter (Form 4.30.1)*; *Letter of Document Receipt and Recommended Action (Form 4.30.3)*

### Step 3 - Approval of the RERC decision documents

The RERC chair reviews, approves and signs the decision documents within 1 week from the decision of the committee for full review or the decision of the reviewers for expedited review.

### Step 4 - Transmittal of RERC decision to researcher


After the approval, the RERC staff sends the signed results of the review via email (online) and or the researcher gets the hard copy at the RERC office. The Process takes 3days after approval of the decision documents.

### Step 5 - Filing of the decision document in the protocol file and update of the protocol database

All meeting deliberations and decisions regarding a protocol are filed in the specific protocol folder. Likewise, copies of the assessment forms of that particular protocol are filed in this folder. Filing followed a protocol index or recording chronologically. This folder is then kept in a locked filing cabinet in the RERC office. Digital folder of each protocol of active documents are kept in a Protocol Box. Once the protocol is completed or terminated, this protocol is transferred to Google drive and hard drive. The RERC database is then updated.

## 6. Forms

Form 4.30.0	-	Notice of Receipt of Study Protocol & Assessment for Review Fee (For Non Institutional PI-Initiated Protocols)
Form 4.30.1	-	Action Letter Approval Letter
Form 4.30.2A	-	Notice of RERC Decision

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Form 4.30.2B	-	Letter for Modification
Form 4.30.2C	-	Letter of Exemption from Ethical Review
Form 4.30.2D	-	Reminder Letter for Continuing / Progress / Final Report
Form 4.30.3	-	Letter of document receipt and Recommended Action
Form 4.27.2	-	Letter of Invitation to a Clarificatory Meeting

## 7. History of SOP

In the BATMC RERC SOP 2017 or version 3, "Communicating RERC Decision" was incorporated in Chapter 2 pertaining to the initial reviews of expedited and full board protocols and chapter 3 pertaining to the Post-approval reviews.

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
1	2015 October	Dr. Rhodora Madrid-Reyes	First draft
2	2016	Dr. Rhodora Madrid-Reyes	None
3	2017 February	Dr. Rhodora Madrid-Reyes	None
4	2020 October	Dr. Teresita Risalyn V. Villanueva Dr. Edralin Vidal	addition of guideline for online meetings
5	2021 June	Dr. Teresita Risalyn V. Villanueva Dr. Edralin M. Vidal	Specify Expedited and Full Board Meetings in Policy Statement

## 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*


*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

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	<b>CHAPTER 4</b> <b>DOCUMENTING AND ARCHIVING</b> <b>SOP 31</b> <b>Management of Incoming/Outgoing Communications</b>	<b>Version No: 5</b>
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## 1. Policy Statement

RERC Communication refers to documented communication and can be in the form of hard copy letters or emails. It is encouraged that all RERC communications, received and issued are in this form to facilitate documentation of all actions, instructions and even responses to queries. All incoming and outgoing communications shall be recorded properly and correctly in a physical log book and electronic database. Communications pertaining to protocols are separated from administrative communications. Incoming communications shall be acted upon immediately.

## 2. Objective of the Activity

To describe the preparation and management of all RERC communication records and the filings of such records, thus, promoting effective monitoring and tracking system. This also promotes efficient operations of RERC and improves the quality of service.

## 3. Scope

The SOP provides instructions related to the preparation of RERC communication to various parties and management of such files. This begins with organizing all communications received and issued by the RERC and ends with the filing of these communication documents.


## 4. Workflow

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1:</b> <i>Organizing all the communications received and issued by the RERC</i>	<i>RERC Staff</i>
<b>Step 2:</b> <i>Recording of the details of incoming/outgoing communications</i>	<i>RERC Staff</i>
<b>Step 3:</b> <i>Acting on incoming communications</i>	<i>Chair or Member Secretary</i>
<b>Step 4:</b> <i>Filing of incoming/outgoing communications and Updating of respective Databases</i>	<i>RERC Staff</i>

## 5. Description of procedure

**Step 1 - Organizing all the communications received and issued by the RERC**



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The RERC Staff organizes both the incoming and outgoing communications. She sorts these communications as to follows:

- A. Administrative related
  - 1. Incoming
  - 2. Outgoing
- B. Protocol Related
  - 1. Incoming
  - 2. Outgoing

### **Step 2 - Recording of the details of incoming/outgoing communications**


The RERC staff, supervises by the member secretary, then records in a log which also functions as a log of submissions if the communication is protocol related and another log for administrative related. These logs should have at least the following elements:

- A. Administrative related
  - 1. Date of communication received / sent
  - 2. Name of RERC party contracted
  - 3. Content of communication
  - 4. Notation of any follow-up necessary
  - 5. Contact information (address, telephone number, and e-mail) of sending party
  - 6. Name and signature of individual who received the communication and completed the record
- B. Protocol related
  - 1. Date of communication submission
  - 2. Name of RERC party contracted
  - 3. Study information, i.e. sponsor, protocol number, principal investigator, etc.
  - 4. Content of communication or submission
  - 5. Notation of any follow-up if necessary
  - 6. Type of submission (if communication refers to a submission)
  - 7. Contact Information (address, telephone number, and email) of sending party
  - 8. Name and signature of individual who received the communication and completed the record

### **Step 3 - Acting on communications**

The Chair or the Member Secretary/Assistant Secretary, after being informed by the RERC staff, initiates and finalizes the response on incoming communications. The chair reviews and usually signs the outgoing communications.

### **Step 4 - Filing of incoming/outgoing communications and Updating of respective Databases**

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	<b>CHAPTER 4 DOCUMENTING AND ARCHIVING SOP 31 Management of Incoming/Outgoing Communications</b>	<b>Version No: 5</b>
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The RERC staff, with the supervision of the secretary member, files a copy of the communication in the:

- a. Protocol file folder – for protocol related communication
- b. Other appropriate RERC Communications folder – for administrative communication
- c. Digital Folder which is then filed in the hard drive and Google drive.

Communication is filed in each folder with the most recent on top of the previous communications.

## 6. Forms

### Administrative Logbook


- Incoming Communication Logbook
- Outgoing Communication Logbook

### Protocol Related Logbook

- Incoming Communication Logbook
- Outgoing Communication Logbook

## 7. History of SOP

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
1	2015 October	Dr. Rhodora Madrid-Reyes	NONE
2	2016	Dr. Rhodora Madrid-Reyes	NONE
3	2017 February	Dr. Rhodora Madrid-Reyes	NONE
4	2020 October	Dr. Teresita Risalyn Villanueva Dr. Edralin Vidal	Revised format Differentiate administrative and protocol related documents, and incoming and outgoing communications Revised workflow
5	2021 June	Dr. Edralin M. Vidal	None

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 4 DOCUMENTING AND ARCHIVING SOP 31 Management of Incoming/Outgoing Communications</b>	<b>Version No: 5</b>
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## 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*


*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 4 DOCUMENTING AND ARCHIVING SOP 32 Management of Active Files (Administrative and Study Files)</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021  <b>Date of Effectivity:</b> June 04, 2021

### 1. Policy Statement

Protocol files of Batangas Medical Center RERC approved protocols are considered active from the moment the protocol files are received for review until such time they are inactivated either by completion or termination. These files then shall be sorted, coded, secured in a locked cabinet and in a password protected digital protocol box, and arranged in a well-ordered manner that shall allow easy identification and retrieval.

### 2. Objective of the Activity


To describe the RERC procedure related to the management of active study files, documentations and records. This facilitates easy accessibility, retrieval and promotes confidentiality of files.

### 3. Scope

This SOP provides instructions related to the management of active study files originating from protocol submission and includes all documents that reflect all actions taken by the RERC before completion of the study.

### 4. Workflow

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1:</b> Design a standard coding system for all protocols submitted to RERC for review.	RERC Member Secretary
<b>Step 2:</b> File all submitted documents in individual protocol folder and chronologically organize the contents of the active study file according to time of receipt. Digital file should also be chronologically saved in each digital folder.	RERC Staff
<b>Step 3:</b> Update the active protocol regularly and ensure all actions are recorded regularly in the database.	RERC Staff
<b>Step 4:</b> Keep the active protocol files in a secured cabinet in the office. Keep the digital folder in a password protected protocol box.	RERC Staff

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
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		<b>Date of Approval:</b> June 04, 2021  <b>Date of Effectivity:</b> June 04, 2021

## 5. Description of procedure

### Step 1 - Design a standard coding system for all protocols submitted to RERC for review

RERC designs a unique identifier or code to refer to each active file for efficient file management.

Code active study files as follows: Batangas Medical Center RERC-(year) – number (chronological number based on order of receipt). For example, if Protocol entitled “First Clinical Drug Trial on Pediatric Patients” is the first protocol received in 2012, the code Batangas Medical Center RERC 2012-01 is the code that should be used to identify this protocol.


**Step 2 - File all submitted documents in individual protocol folder and chronologically organize the contents of the active study file according to time of receipt. Digital file should be also be chronologically saved in each digital folder.**

File protocol documents in sturdy file folders, using one folder per study protocol title.

File folders are labeled using the code of the study file. Soft copy of active protocol documents is filed in each labeled digital folder which is then saved in a secured protocol box. SJREB related protocol and files are separated from regular protocol files. Also Exempt Protocols are separately filed for documentation.

The study file folder contains the following documents and should have a protocol index:

- All versions of study protocol
- Related documents that came with the study protocol
- Principal investigator and co-investigators' CVs and other similar documents
- Reviewers' assessment forms
- Amendment reports
- Continuing review applications
- Serious Adverse Event Reports or Safety Notifications
- \* Suspected Unexpected Serious Adverse Reaction (SUSAR)
- Non-compliance (Deviation or Violation) reports
- Participant Queries

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
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- Site Visit Reports
- \* Early termination
- Approval letters
- Notifications of ERC Decision
- Miscellaneous communication
- Final report/Close out report


**Step 3 - Update the active protocol regularly and ensure all actions are recorded regularly in the database.**

Study file information is entered into a secured RERC database using its unique code. The Secretariat updates the study file folder and the database every week.

The database can be paper-based (logbook locked in the active files cabinet) or electronic (password protected) and should have at least the following fields:

- Protocol Code
- Protocol title
- Department
- PI and details
- Submission date
- Full board or Expedited Review date
- Reviewers
- Review decision
- Board meeting date
- Approval date
- Date for progress report

**Step 4 - Keep the active protocol files in a secured cabinet in the office. Keep the digital folder in a password protected protocol box.**

	<b>BATANGAS MEDICAL CENTER</b> <b>RESEARCH ETHICS REVIEW COMMITTEE</b>	
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Keep all active study files in a secure file cabinet, with access limited only to the chair, member secretary and secretariat and to whom the lock and key will be entrusted. Digital folder will be kept or saved in an

electronic protocol box the password of which is known only to the chair, member secretary, and the secretariat.

Active files can be accessed outside of regular protocol review in accordance with the SOP on Maintaining Confidentiality of Study Files and RERC Documents.

#### 6. Form:

Protocol Index

#### 7. History of SOP


<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
1	2015 October	Dr. Rhodora Madrid-Reyes	NONE
2	2016	Dr. Rhodora Madrid-Reyes	Revised Coding System
3	2017 February	Dr. Rhodora Madrid-Reyes	None
4	2020 October	Dr. Teresita Risalyn Villanueva Dr. Edralin Vidal	Revised format Revised list of documents to be included in the protocol file
5	2021 June	Dr. Edralin M. Vidal	None

#### 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*

*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
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		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021


*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*



	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 4 DOCUMENTING AND ARCHIVING SOP 33 Archiving of Terminated, Inactive or Completed Studies</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

## 1. Policy Statement

Files of study protocols which have been terminated or completed or declared inactive shall be archived and kept in a separate storage from THREE (3) years to FIVE (5) years depending on type of protocol beyond which these will be disposed in accordance with government rules.

Retention Rules:

INACTIVE - 3years;

COMPLETED/TERMINATED - 3years;

CLINICAL TRIAL -5years or as provided in the Clinical Trial Agreement, whichever is longer

## 2. Objective/s of the Activity


Archiving inactive, terminated, or completed protocols ensures efficient retrieval of information from the files for reference and compliance with national and international guidelines.

## 3. Scope

This SOP includes procedures related to storage and retrieval of protocols that are classified as inactive, terminated or completed. This SOP begins with the acceptance of final or early termination reports and identification of protocols as inactive and ends with the inclusion of the files in the archives and update of the protocols database and disposal .

## 4. Workflow

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1:</b> Acceptance of Final or Early Termination Reports (SOP 19 on Review of Final Reports, 3SOP 20 Review of Early Termination Reports), and Identification of a Protocol as Inactive.	RERC Staff Member Secretary Chairman
<b>Step 2:</b> Updating of corresponding protocol folder	RERC Staff
<b>Step 3:</b> Transfer of the protocol folder in the archives and Update of the protocol database	RERC Staff

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 4 DOCUMENTING AND ARCHIVING SOP 33 Archiving of Terminated, Inactive or Completed Studies</b>	<b>Version No: 4</b>
		<b>Date of Approval:</b> October 19, 2020
		<b>Date of Effectivity:</b> November 02, 2020
<b>Step 4 :</b> Retrieval of documents from Archive Section		<i>RERC Staff</i>
<b>Step 5 :</b> Disposal of archived protocol files		<i>RERC Staff</i>
<b>Step 6 :</b> Disposal of administrative records		<i>RERC Staff</i>

## 5. Description of Procedures

**Step 1 - Acceptance of Final or Early Termination Reports and Identification of an Inactive File:** The Committee members shall approve or accept the final report or early termination report of the protocol during a meeting (*3SOP 22 Review of Final Report; 3SOP 20 Review of an Early Termination Report*). In the identification of an *INACTIVE* File, the staff informs the Member Secretary of the failure of a concerned researcher/ proponent/ investigator to respond to the recommendations of the RERC in the last six (6) months during which time the researcher/proponent/investigator has been appropriately reminded of the requirement. This is included in the agenda of the next meeting where the protocol is declared inactive. Archiving notifications will be will be communicated to the Principal Investigator within seven (7) days after the board meeting.


**Step 2 - Updating of the corresponding active file:** The staff files the Final or Early termination report of the protocol in the corresponding protocol folder, including the excerpts of the minutes that approved the report or declared the protocol as inactive.

**Step 3 - Transfer of the Protocol Folder in the Archives and Update of the Protocol-Database:** The staff checks whether the documents listed in the protocol file index are complete and removes extraneous documents. The staff then transfers the folder to the archive section and updates the protocol database.

a. An archive number is assigned to the protocol by adding the / (year of archiving) as a suffix to the original protocol code. For example if the Final Report of Protocol Batangas Medical Center RERC 2010-002 is approved in 2012, the archiving code is Batangas medical Center RERC 2010-002/2012.

b. The archiving data should be entered accordingly in the protocol database and *Register of Archived Protocols (Form 4.33.1)* .

c. The archived protocols shall be placed in an envelope labeled with the BatMC RERC code, Surname of the Principal Investigator, and the date of Inactivation.

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
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**Step 4 – Retrieval of documents from Archive Section:** Only the RERC Secretariat Staff can retrieve documents either from the active study files or from the archives. Archived protocols can be retrieved within the three-year archiving period in accordance with the *4SOP 34 on Management of Access of Confidential Files*.

**Step 5 – Disposal of Archived Protocol Files :** Archived files must be reviewed at the end of the year.

- At the end of each year, the RERC Secretariat staff generates -
  1. List of inactive protocols that are beyond THREE (3) years past its date of inactivation from the Study Protocol Database;
  2. list of completed and terminated protocols that are beyond THREE (3) years past its date of archiving from the Study Protocol Database;
  3. list of Clinical Trial protocols that are beyond FIVE (5) years past its date of archiving from the Study Protocol Database or the retention period as indicated in the Clinical Trial Agreement whichever is later.
- The RERC Secretariat staff submits the list to the Chairman for review, verification and approval of disposal in accordance with government rules.
- The RERC Secretariat staff retrieves the archived protocols and disposes the files accordingly using paper shredder to be witnessed by an RERC member.
- The RERC Secretariat staff shall update the *Register of Archived Protocols (Form 4.33.2)* as to date of actual disposal and the *Register of Disposed Protocols (Form 4.33.3)*


**Step 6 – Disposal of Administrative Records :** Guidelines and references that have been superseded or outdated for three (3) years must be removed from the files and disposed of properly . Removed document files are shredded and permanently deleted from electronic and physical files.

## 6. Forms

Form 4.33.1	Archiving Notification
Form 4.33.2	Register of Archived Protocols
Form 4.33.3	Register of Disposed Protocols

## 7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2015 October	Rhodora M Reyes, MD	First draft
2	2016	Rhodora M Reyes, MD	None

		BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE	
		<b>CHAPTER 4</b> <b>DOCUMENTING AND ARCHIVING</b> <b>SOP 33</b> <b>Archiving of Terminated, Inactive or Completed Studies</b>	Version No: 5
			Date of Approval: June 04, 2021
			Date of Effectivity: June 04, 2021
3	2017 February	Rhodora M Reyes, MD	None
4	2020 October	Dinna P Remo, CPA Atty Jenn Krystel Zaraspe	New archiving period rules and retention period of archived files prior to disposal  New template for Archiving Notification  New template for Register of Archived Protocols  New template for Register of Disposed Protocols  Use of New Phreb Format
5	2021 June	Dinna P. Remo, CPA Atty. Jenn Krystel Zaraspe	Revision in retention rules  Addition of rule in disposal of administrative records

## 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*


*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 4 DOCUMENTING AND ARCHIVING SOP 34 Management of Access to Confidential Files</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

## 1. Policy Statement

Access to the RERC confidential files shall be regulated and limited to RERC members and staff. Other persons with legitimate interest in these files (e.g. institutional authorities, regulatory agencies, sponsors) shall be allowed limited access to specific files with proper justification. Researchers/Investigators shall be allowed access only to their own protocol files upon request.

## 2. Objectives of the Activity

Management of access to confidential files helps protect the intellectual property rights of researchers, compliance with the mandate of the Data Privacy Act of 2012 and enhances the credibility and integrity of the RERC.


## 3. Scope

This SOP consists of procedures for accessing confidential files including document handling and distribution. This SOP begins with the receipt of the request to access and ends with the return of the documents to the protocol study folder. BatMC RERC considers the following as confidential :

- Study Protocols
- Study Protocol-related documents (case report forms, informed consent documents, scientific documents, diary forms, expert opinions or reviews)
- Meeting Minutes
- Decisions, notice of board action / notification of BatMC RERC decision
- Certificate of Approvals
- Study protocol-related communications

## 4. Workflow

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1:</b> Receipt and logging of request for access to confidential files. <i>Form 4.34.1 Request Form</i>	RERC Staff
<b>Step 2:</b> Approval of requests for access and retrieval of documents	Member Secretary or Chair

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	<b>CHAPTER 4 DOCUMENTING AND ARCHIVING SOP 34 Management of Access to Confidential Files</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021
<b>Step 3:</b> <i>Supervision of use of retrieved document. For request for photocopies, receives copy of OR for payment of photocopying fees before release of copies.</i>		<i>RERC Staff</i>
<b>Step 4:</b> <i>Return of document to the files</i>		<i>RERC Staff</i>

## 5. Description of Procedures

**Step 1 - Receipt and logging of request for access to confidential files:** The staff receives the request (Form 4.34.1) to access specific files and refers this to the Chair or Member Secretary.

**Step 2 - Approval of requests for access and retrieval of documents:** The Chair or Member Secretary considers the indicated reason for the request and when found satisfactory shall approve it. The staff asks the individual requesting the document to sign the *Confidentiality Agreement and Conflict of Interest Disclosure* (Form 1.1.2) for RERC members/staff and in case of non REC members, the *Confidentiality Agreement Form for Non-members Requesting to Access Batangas Medical Center RERC Documents* (Form 4.34.4) and proceeds to retrieve the pertinent document.


Note : Regulatory authorities have full access to Batangas Medical Center RERC documents provided it is within their mandate (e.g. DOH, FDA), and upon reasonable notice to make the files available signed by the recognized official of the regulatory authority (e.g. DOH Secretary, FDA Director).

**Step 3 - Supervision of use of retrieved document:** The staff asks the user to sign the appropriate logbook, enforces the room-use restriction of documents and limits photocopying by RERC staff in behalf of concerned researchers/principal investigators or on special cases (Regulatory Authorities, RERC reviewers), if allowed by Chair, document may be brought outside the RERC office but must be returned within one (1) day from borrowing. *Refer to Form 4.34.2 Logbook of Request to Access and Form 4.34.3 Logbook of Request of Copies of Documents.* All borrowers must leave one up to date and unexpired government ID before they can take the records out of the office.

**Step 4 - Return of document to the files:** The staff returns the retrieved files to the protocol study file.

## 6. Forms

Form 4.34.1	Request To Access Form
Form 4.34.2	Logbook of Request to Access
Form 4.34.3	Logbook of Request of Copies of Documents
Form 4.34.4	Confidentiality Agreement Form For Non-Members Requesting To Access Batangas Medical Center RERC Documents

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
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		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

Form 1.1.2 Confidentiality Agreement and Conflict of Interest Disclosure Form For Members

## 7. History of SOP

<b>VERSION NO.</b>	<b>DATE</b>	<b>AUTHORS</b>	<b>MAIN CHANGE</b>
1	2015 October	Rhodora M Reyes, MD	First draft
2	2016	Rhodora M Reyes, MD	None
3	2017 February	Rhodora M Reyes, MD	None
4	2020 October	Dinna P Remo, CPA Atty Jenn Krystel Zaraspe	Revised wording of Confidentiality Agreement Form for Non RERC Members New template for Request to Access Document New template for Logbook of Request to Access New Template for Logbook of Request of Copies of Documents Use of New Phreb format
5	2021 June	Dinna P. Remo, CPA	None

## 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*

*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*


*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*



	<b>BATANGAS MEDICAL CENTER</b> <b>RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 4</b> <b>DOCUMENTING AND ARCHIVING</b> <b>SOP 35</b> <b>Management of Queries/Complaints</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021  <b>Date of Effectivity:</b> June 04, 2021

### 1. Policy Statement

Queries and complaints from clients, patients, or research participants shall be attended to promptly and appropriately while exercising due diligence. The nature of queries shall determine whether they can be answered by the RERC staff or referred to the primary reviewers of the specific protocol. All complaints shall be referred to the Chair who shall determine the level of risk involved. Complaints of minimal risk shall be referred to the primary reviewers for resolution. Complaints of more than minimal risk shall be taken up in a special meeting within 48 hours for deliberation by the committee en banc with the primary reviewers leading the discussion. The Primary Reviewers present all protocol-related resolved queries during the nearest Full Board Review Meeting.

### 2. Objective/s of the Activity

Managing queries and complaints aims to promote public trust and confidence in the institution, especially in the RERC and to ensure that the rights and well-being of participants are attended to. Communication of queries and complaints, especially from research participants, provide mechanisms that contribute both to maintaining transparency of BatMC RERC decision-making processes, as well as empowerment of study participants.


### 3. Scope

This SOP is limited to queries and complaints of research participants, or their families, in studies that have been issued an ethical approval by the RERC. BatMC RERC will also accept communications of queries, notifications and complaints from other parties provided these communications are relevant to BatMC RERC oversight. This SOP begins with the receipt, logging, and acknowledgement of queries and complaints and ends with the logging of the response and inclusion in the agenda of the RERC meeting.

### 4. Workflow

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1:</b> Receipt, Logging, And Acknowledgement Of Queries And Complaints (4SOP 31 Managing RERC Incoming And Outgoing	RERC Staff
<b>Step 2:</b> Referral of query or complaint to competent authority. 2.1 Referral of protocol-related query to primary reviewers.	RERC Staff



	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 4 DOCUMENTING AND ARCHIVING SOP 35 Management of Queries/Complaints</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021
2.2. Referral of all complaints (non-protocol related) to the RERC Chair		
<b>Step 3: Formulation of response</b>  3.1. Protocol-related queries  3.2. Minimal-risk complaints  3.3. More than minimal risk complaints : en-banc committee		Primary Reviewers Primary Reviewers Chair and RERC members
<b>Step 4: Communication of response (SOP 28 Communicating REC Decisions for protocol-related queries if applicable )</b>		RERC Staff
<b>Step 5: Logging of the response (SOP 29 Managing RERC Incoming and Outgoing Communications ) and inclusion in the agenda of the RERC meeting (SOP 24 Preparing the Meeting Agenda )</b>		RERC Staff
<b>Step 6 : File copies of Query/Complaint Form (Form 4.33.1) and Query/Complaint Response Form (Form 4.33.2) on relevant Protocol Folder</b>		RERC Staff

## 5. Description of Procedures


**Step 1 - Receipt, logging, and acknowledgement of queries and complaints:** The RERC will maintain a logbook dedicated to queries and complaints which will include date, time, name of concerned party, specific study protocol number and title and name of principal investigator, nature of query or complaint. Complainant shall accomplish Form 4.35.1 Query/Complaint Form to be properly coded by the RERC Staff.

### **Step 2 - Referral of query or complaint to competent authority:**

The staff refers queries related to specific protocols approved by the RERC to the primary reviewers.

On the other hand, the staff refer all complaints to the RERC Chair who determines the level of risk effected by the issue.

Minimal risk complaints are referred to the primary reviewers of the concerned protocol .

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
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		<b>Date of Approval:</b> June 04, 2021  <b>Date of Effectivity:</b> June 04, 2021

Complaints that involve more than minimal risk are referred to the Committee through a special meeting that shall be called within 48 hours. The staff notifies the concerned primary reviewers that they will lead the discussion such that pertinent materials are provided to them as reference.

**Step 3 - Formulation of response:**

For queries, the primary reviewers shall accomplish the portion on “Action Taken” on the *Form 4.35.1 Query/Complaints Form*.

For minimal risk complaints, the primary reviewers accomplish *Form 4.35.1 Query/Complaints Form*.

For more than minimal risk, the committee may choose any of the following options:

Constitute a site visiting team to gather more information, verification and clarification regarding the source and cause/s of the complaint for its early resolution.

Designate the primary reviewers to meet with the complainants and the researcher (preferably separately) for clarification of issues and obtain suggestions for resolution.


Formulate recommendation if satisfied with the adequacy of information –

- request for explanation/justification from researcher
- accept request/demand of participant
- suspension of further recruitment
- amendment of protocol and re-consent of participants
- others

**Step 4 - Communication of response:** RERC Staff prepares the official communication of response to queries and complaints using *Form 4.35.2 Query/Complaint Response Form* to be duly signed by the RERC Chair. See *SOP on Communicating RERC Decisions for protocol-related queries (4SOP 30)*, if applicable

**Step 5 – Logging of the response and inclusion in the agenda of the REC meeting:** See SOPs on Managing RERC Incoming/Outgoing Communications (4SOP 31 and Preparing the Meeting Agenda (4SOP 26).

**Step 6 – Filing of copies of Query/Complaint Form and Query/Complaint Response Form :** The RERC Secretariat Staff stores the signed forms in the study protocol folder.

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		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

## 6. Forms:

- Form 4.35.1 Query/Complaint Form
- Form 4.35.2 Query/Complaint Response Form
- Form 4.30.2 Notification of RERC Decision


## 7. History of SOP

<b>Version No.</b>	<b>Date</b>	<b>Authors</b>	<b>Main Change</b>
1	2015 October	Rhodora M Reyes, MD	First draft
2	2016	Rhodora M Reyes, MD	No change
3	2017 February	Rhodora M Reyes, MD	No change
4	2020 October	Dinna P. Remo, CPA Atty Jenn Krystel Zaraspe	Transferred from Chapter 3 in Revised SOP Format  Inclusion of Signature of Complainant & Primary Reviewer and RERC Chair on the Query/Complaint Form  New Template for Query/Complaint Response
5	2021 June	Dinna P. Remo, CPA Atty Jenn Krystel Zaraspe	Add in Policy Statement presentation of resolved queries in Full Board Meeting

## 8. References

World Medical Association Declaration of Helsinki, 2013

ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 4 DOCUMENTING AND ARCHIVING SOP 35 Management of Queries/Complaints</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021



*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*


*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*

Supersedes:	<b>Version 4</b>
Authored by:	Batangas Medical Center RERC
Effective Date:	June 04, 2021
Approved by:	Rhodora Madrid-Reyes MD, FPNA,FPSCOT Chairman 
Approved by:	Dr. Ramoncito C. MagnayeMD,FPCS,FPSGS,MHA 
Approval Date:	June 04, 2021

	<b>BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE</b>	
	<b>CHAPTER 5 SOP 36 Writing and Revising SOPs</b>	<b>Version No: 5</b>
		<b>Date of Approval:</b> June 04, 2021
		<b>Date of Effectivity:</b> June 04, 2021

## 1. Policy Statement

The SOP provides instruction on how the Batangas Medical Center RERC Standard Operation Procedures are prepared, approved and distributed. SOPs ensure efficiency, transparency, and consistency of RERC operations. The SOP manual needs to be periodically reviewed to determine the need for revision or new SOPs in order to respond to emerging operational issues of the RERC. The RERC shall designate a team to annually review its set of SOPs to determine its continuing relevance and effectiveness to its operations.

## 2. Objective/s of the Activity

Writing and revising SOPs ensures continuing quality assurance of RERC functions.


## 3. Scope

This SOP on Writing and Revising SOPs covers the procedures the RERC has put in place in order to be able to develop new and relevant SOPs and to revise and update old SOPs. This SOP applies to all RERC activities involved in the development of its SOPs and their revisions as published and distributed by the institution. This SOP begins with the proposal and approval for revision or writing of a new SOP and ends with the inclusion of the new or revised SOP in the SOP Manual and its dissemination.

## 4. Workflow

Steps and persons responsible involved in the process of writing, reviewing, approving and disseminating SOPs of the RERC.

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1:</b> Proposal and approval for revision or writing of a new SOP	Any RERC Member or Staff
<b>Step 2:</b> Designation of the SOP Team	Chair
<b>Step 3:</b> Drafting of the revision or new SOP	SOP Team
<b>Step 4:</b> Review and finalization of SOP	RERC Members
<b>Step 5:</b> Submission of finalized SOP to the institutional authority	Chair
<b>Step 6:</b> Inclusion of the new or revised SOP in the SOP Manual and its dissemination	RERC Staff

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## 5. Description of Procedures

**Step 1 - Proposal for a revision of an SOP or a new SOP and its approval:** Any member and staff of RERC can propose and it can be part of the agenda to be tackled during regular or special meeting and referendum.

**Step 2 - Designation of the SOP Team:** The Chair designates an SOP team. The Chair assigns members and non-members, as needed, to be part of the SOP Team. The Team receives an orientation from the Chair regarding duties and responsibilities and can organize SOP Team workshops to facilitate the drafting of SOPs.

**Step 3 - Drafting of the revision or new SOP:** The design the format and layout of an SOP is based on the following guidelines:

- (a) *Title, which is descriptive of contents*
- (b) *Policy statement*
- (c) *Objective/s of the activity, which defines the purpose and intended outcome*
- (d) *Scope, which defines the extent of coverage of the SOP and its limitations*
- (e) *Workflow provides a graphic representation of the essential steps to implement the SOP and the responsible person for each step.*
- (f) *Workflow provides a graphic representation of the essential steps to implement the SOP and the responsible person for each step.*
- (g) *Detailed instructions, which elaborates the steps listed in workflow*
- (h) *Glossary – acronyms and terms which need to be defined*
- (i) *Forms, documents to be accomplished by different parties as required by the SOP,*
- (j) *Document history which tabulates the different versions (from draft to final versions) of the document by author, version, date, and description of main changes*
- (k) *References, which lists the instruments use to draft the Guideline such as other SOPs, guidelines, or policies*

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Each SOP should be given a number and a title that is self explanatory and is easily understood. For the Batangas Medical Center RERC SOPs, the following format is used: Batangas Medical Center RERC SOP XXX where XXX is the number corresponding to a specific SOP. The header of each page of the SOP Manual will contain the the chapter number, SOP number and title of the SOP, the version number and dates of approval and effectivity of the version.


**Step 4 - Review and approval of SOP:** As the RERC sees fit, an existing SOP may be revised. A revision should be substantial (correction of grammatical errors is not considered substantial; a change in the identifier of an SOP is considered substantial). Minor changes refer to editorial, grammatical, or administrative changes that have no substantial effect on procedures. Major changes, on the other hand, are those that have a substantial effect on procedures, definitions, requirements, and similar considerations. When an SOP is difficult to understand or does not cover what it should, a revision may become necessary. When the need for a revision of SOP has been identified and agreed on, a draft will be written by a designated member of the RERC. A draft of the revised SOP will be discussed by the RERC members. The draft version will be reviewed by the Chair who will submit it to the Hospital Director for approval. Any member of the board may propose for the revision of the SOPs. Any proposal for revision must be written and submitted to the board for review, approval, coding, and inclusion into the document.

The proposal is discussed and acted upon through full board review. The SOP team drafts the revision, noting that the SOP identifier reflects the chronological number and date of the revision. If an SOP supersedes a previous version, indicate the previous SOP version and the main changes in the historical form. The Chair submits the draft to full board review where RERC members deliberate on the draft.

**Step 5 – Submission of the SOP to the institutional authority:** Upon full board approval, the Chair submits the approved draft to Medical Center Chief for final approval. The Batangas Medical Center Director approves the SOP by signing in the appropriate section in the cover page. The approved SOPs will be implemented from the date of formal approval of Dr. Ramoncito Magnaye

**Step 6 - Inclusion of the new or revised SOP in the SOP Manual and its dissemination:** Upon approval of Batangas Medical Center Chief, the Secretariat distributes SOP within thirty (30) days of approval by the head of the institution for hard copies and immediate for e-copies.

This will be distributed and forwarded to Batangas Medical Center RERC members, and published the SOP through the Hospital website. The Secretariat retains one complete originally signed SOPs copy and archives the superseded version of the SOP in the historical file maintained by the Batangas

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Medical Center RERC. Superseded SOPs are clearly marked “superseded” with year of archiving stamped in the cover page.

## 6. Forms

Form 5.36.1 Request for Creation/Revision of an SOP

Form 5.36.2 SOP Template

## 7. History of SOP

<b>Version No.</b>	<b>Date</b>	<b>Authors</b>	<b>Main Change</b>
1	2015 October	Dr. Rhodora M. Reyes	First Draft
2	2016	Dr. Rhodora M. Reyes	Updates on some procedures and policies
3	2017	Dr. Rhodora M. Reyes	Updates on some procedures and policies
4	2020 October	Dr. Anna Pineda Mark John Thomas Buquiz RN	Harmonizing SOP to PHREB Format
5	2021 June	Dinna P. Remo, CPA	Correction in SOP Numbering and header of SOP Manual

## 8. References

*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)2016*

*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*


*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*


*National Ethical Guidelines for Health and Health Related research 2017*


*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*BatMC RERC SOP 2020*



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Supersedes:	<b>Version 4</b>
Authored by:	Batangas Medical Center RERC
Effective Date:	June 04, 2021
Approved by:	Rhodora Madrid-Reyes MD, FPNA,FPSCOT Chairman 
Approved by:	Dr. Ramoncito C. MagnayeMD,FPCS,FPSGS,MHA Medical Center Chief II
Approval Date:	June 04, 2021

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*Active Study or Protocol* – is an ongoing study, implementation of which is within the period covered by ethics clearance.

*Adjournment* – Formal closure of the meeting. Motion for adjournment and record of the time are minuted.

*Administrative Documents* – documents that pertain to the operations of the RERC and are not directly related to a study or protocol.

*Administrative Issuance* – official communications or announcements from institutional authorities.

*After-approval reports* – are reports, e.g. progress report, protocol deviation/violation report, amendment, early termination report, final report, application for continuing review, required by the REC for submission by the researcher/investigator after the study has been approved for implementation.

*Agenda* - the list of topics or items to be taken up in a meeting arranged in a sequential manner. It is an outline of the meeting procedure and starts with a “Call to Order”.

*Alternate Members* – individuals who possess qualifications of specified regular members. They are called to attend a meeting and substitute for regular members to comply with the quorum requirement when the latter cannot attend the meeting.


*Amendment* – any change or revision made in the protocol after its approval.

*Anonymization* – process of removing the link between the research participant and the personally identifiable data, in such a way that the research participant cannot be determined nor traced.

*Appeal* – a request of a researcher/ investigator for a reconsideration of the RERC recommendation.

*Appointing authority*- the institutional official that has the power to designate or appoint individuals to specific offices or roles .

*Archived Study Protocol Files* – study files which are either (a) study protocols with approved final reports (*COMPLETED STUDIES 3SOP#22*); (b) study protocols with Ethical Clearance with early termination reports (*TERMINATED STUDIES 3SOP#20*); (c) approved study protocols are reclassified as *INACTIVE* if no communication is received from the study team within **one (1) year** from issuance of Ethical Clearance; (d) study protocols for initial review are reclassified as *INACTIVE* if without resubmissions or communication beyond **six (6) months** from date of notice of board action

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*Audio Conferencing* - is a conference in which people at different locations speak to each other via telephone or internet connections.

*Ballot* – voting (indicating the choice) by writing the choice on a form for the purpose. Ballots are subsequently counted to determine how the majority of members voted for decision-making.

*Benefits* – summary of probable positive or favorable outcomes ranging from benefit to the community (or society), indirect gains such as education, or direct therapeutic value

*Business Arising from the Minutes* – are matters generated from the discussions in the previous meeting that need continuing attention and require reporting.

*Clarificatory Meeting/ Interview* – is a face-to-face meeting or consultation of the REC with the researcher for the purpose of obtaining explanations or clarity regarding some research issues identified by the REC.

*Clinical Auditor* – an individual who systematically and independently examines trial related activities and documents at a particular period.

*Clinical Monitor* - an individual who oversees the progress of a clinical trial.

*Code* - a unique number assigned to a protocol indicating the year and series it was received.

*Collegial Decision* – a course of action arrived at after a group deliberation where members were considered of equal authority such that the course of action is considered a group action and is not ascribed to any one member.


*Competent Authority* –designated officer or member of the RERC with the authority to respond to queries and complaints regarding studies approved by the RERC.

*Complaint* – the act of expressing discontent or unease about certain events or arrangements in connection with a study.

*Computer Conferencing* - is teleconferencing supported by one or more computer.

*Confidentiality* - is the duty to refrain from freely disclosing private/ research information entrusted to an individual or organization.

*Conflict of Interest* – a situation in which aims or concerns of two (primary and secondary) different interests are not compatible such that decisions may adversely affect the official/primary duties.

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		<b>Date of Effectivity:</b> November 02, 2020

*Confidentiality* – is the duty to not freely disclose private/research information entrusted to an individual or organization.

*Conforme*- acceptance of or agreement to an assignment or designation.

*Consensus* – the process of arriving at a decision without voting but by generating the over all sentiment of a group such that deliberations continue until no more strong objection is registered.

*Continuing Review* - is the decision of the REC to extend the ethical clearance of a study based on an assessment that the research is proceeding according to the approved protocol and there is reasonable expectation of its completion.

*Database* – a collection of information that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

*Date of Effectivity* – date when the guidelines shall be enforced.

*Decision* – the result of the deliberations of the REC in the review of a protocol or other submissions.

*Device containing untested materials* - if a proposed device contains materials which have not previously been tested in contact with human subjects.

*Device materials used in a different location or for a different duration*- when existing materials are used and come in contact with new body locations or are used for a significantly longer duration.


*Device proposed for a new function* - where a device is being used for a new function outside of the manufacturer's indications for use/intended purpose.

*Draft Meeting Agenda* – the order of business that includes the list of topics or items recommended for discussion in a meeting. This is endorsed to the REC Chair for his/her approval.

*Draft Meeting Minutes* – Proceedings of the meeting prepared by the Secretariat under the supervision of the Member-Secretary.

*Drug or device* – health product used for diagnosis or treatment.

*Early Termination* - ending the implementation of a study before its completion, also commonly referred to as “withdrawn” or refers to the decision to end the implementation of a research protocol before its intended completion state.

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*Exemption from Review* – a decision made by the REC Chair or designated member of the committee regarding a submitted study proposal based on criteria in the NEGHR 2017 The Research Ethics Review Process Guideline 3.1.

*Exemption Report* – a list of protocols submitted for review that were deemed not to require the conduct of either expedited or full review. This report is presented during a regular committee meeting or as required by the institutional authority.

*Expedited Review* – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.

*Expedited Review Reports* – is an enumeration of protocols (including titles, code number, proponent, submission date, names of reviewers and decisions) that underwent expedited review for information of the REC members and for record viewers.

*Expertise* – a proficiency, skill or know-how possessed by experts in a certain academic or professional field.

*Final Meeting Agenda* - is the order of business that includes the list of topics or items approved for discussion in a meeting by the REC Members in a regular or special meeting.

*Final Meeting Minutes* – *Proceedings of the meeting that have been approved by the REC members.*


*Final Report / Close out Report* – is a summary of the outputs and outcomes of the study upon its completion. The RERC requires the accomplishment of the Final Report form within a reasonable period after the end of the study.

*Format*- general style or layout of the document

*Full Review* – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.

*High Risk Studies* – research where harm or danger resulting from the study intervention is very likely for participants.

*Honorarium / Honoraria* – a payment given for professional services that are rendered nominally without charge; alternately refers to *incentive* in this SOP.

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*Inactive Study or Protocol* – a study whose proponent has not communicated with the RERC with regard to issues pertaining to the approval or implementation of the study within **six (6) months** after receiving Notification Letter (Form 2.8.2) from the RERC.

*Incentive* - a thing that motivates or encourages someone to do something; alternately refers to *honoraum* in this SOP.

*Incoming Communications* – are documents which are directed to and received at the RERC office.

*Independent consultants* - Resource persons who are not members of the Research Ethics Committee, whose expertise is needed in the review of a research protocol/proposal and who may be invited to attend a committee meeting but are non-voting during the deliberations.

*Informed Consent Assessment Form* – detailed evaluation form of the relevant Informed Consent Form and other related documents if needed (such as Assent Form) to ensure that essential elements of informed consent are appropriately addressed, ensuring that vulnerability, recruitment process, and the process of obtaining informed consent are always assessed in the context of the study protocol and the participant.

*Initial Review* – ethical and technical review conducted on the initially-submitted study documents. It may be exempted, expedited or full.


*Initial Submission* – a set of documents consisting of the full proposal and other study-related documents that need to be submitted so that review can be conducted.

*Intellectual property* –refers to intangible creations of the human mind (such as inventions, literary and artistic works, designs, and symbols, names and images used in commerce, that are considered as owned by the one who thought of it. Intellectual property includes information and intellectual goods.

*Intellectual property right* – the exclusive right given to persons over the use of the creations of his/her mind for a certain period of time.

*Logbook* – a real-time chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signature of the Receiving Person and Action done

*Major Modification* – is a recommended revision of significant aspects/s of the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data, statistical analysis, mitigation of risks, protection of vulnerability, etc.) that impact on potential risks/harms to participants and on the integrity of the research.

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*Medical device – an instrument, material or software that was designed, manufactured and/or intendend for specific medical purpose(s) (see Scope and WHO definition<sup>1</sup> for details)*

*Medical Members – are individuals with academic degrees in the medical profession and a master’s in the nursing profession.*

*Meeting Agenda- the list of topics or items to be taken up in a meeting arranged in a sequential manner. It is an outline of the meeting procedure and starts with a “Call to Order”.*

*Meeting Minutes – narration of the proceedings of the assembly of RERC members.*

*Member Reviewer- a regular member of the Research Ethics Committee who is assigned to assess a research protocol, the Informed Consent, and other research-related submissions based on technical and ethical criteria established by the committee.*

*Minimal Risk - term used when the probability and magnitude of harm or discomfort anticipated in a research are not greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests*

*Minor Modification – is a recommended revision of particular aspect/s of the study or related documents that do not impact on potential risks/harms to participants and on the integrity of the research, e.g. incomplete documentation, incomplete IC elements, unsatisfactory IC format)*

*Modification of an existing device- if a device is modified significantly such that the safety and/or clinical performance may be affected.*


*More than Minimal Risk - term used when the probability and magnitude of harm or discomfort anticipated in a research are greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests*

*New devices - when a novel device is being used in human subjects for the first time where the device components, features and the methods of action are previously unknown.*

*Non-affiliated Member/s – are regular members who are not in the roster of personnel or staff of the Institution. They are not employees of the institution nor do they receive regular salary or stipend from the institution. Alternately referred to as *non-institutional* as used in this SOP manual.*

*Non-compliance report – any event that is not in accordance with the regulations or approval given by the RERC. It is either a deviation or a violation.*



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*Non-medical members*- are individuals without academic degrees in the medical profession nor a master's degree in the nursing profession; also alternately referred to as *non-scientific*.

*'Off-label' device* - relate to where a device is being used outside its existing intended purpose or indications for use for investigational purposes.

*Operations related Matters* – are items included in the agenda that are not directly related to any protocol under review.

*Outgoing Communications* – are documents from the RERC office sent to individuals or offices related to the operations of the RERC.

*PETRO Professional Education and Training Office* – unit within Batangas Medical Center that is in charge of the maintenance and use of physical facilities related to training.

*Post-approval Reports* – are accounts of the ongoing implementation of an approved study (e.g., progress report, amendment, safety report, protocol deviation/violation, early termination, final report, or application for continuing review) that are required be submitted by the researcher to the REC for monitoring purposes.

*Preliminary review* - review of the protocol conducted by the Chair/ Member Secretary/ Assistant Member Secretary to determine the type of review to be applied for the protocol submitted for initial review (Exempted from Review or for review as Expedited or Full).


*Primary Reviewers* – are members of the Research Ethics Committee (usually a scientist and a non-scientist) assigned to do an in-depth evaluation of the research-related documents using technical and ethical criteria established by the committee. The non-scientist member shall focus on the review of the Informed Consent process and form and reflect on community values, culture and tradition in order to recommend acceptance, non-acceptance or improvement of the informed consent process and form. The primary reviewers shall present their findings and recommendations during the meeting for discussion.

*Principal Investigator (PI)* - the lead person selected by the sponsor to be primarily responsible for the implementation of a study described in the protocol submitted.

*Progress Report* - description of how the implementation of the study is moving forward. This is done by accomplishing the Progress Report Form. The frequency of submission (e.g. quarterly, semi-annually or annually) is determined by the REC based on the level of risk.

*Protocol* – documentation of the study proposal that includes a presentation of the rationale and significance of the study, background and review of literature, study objectives, study design and



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methodology, data collection, dummy tables, plan for analysis of data, ethical consideration, and dissemination plan.

*Protocols for Full Review* – Study proposals that require an en banc ethical assessment because they entail more than minimal risks to the participants and/or that participation generates vulnerability issues.

*Protocol Database* – significant information about protocols that are organized systematically so that these can easily be accessed, managed, interpreted, analyzed and updated. It is usually in an electronic platform used for tracking and monitoring implementation of a study.

*Protocol Deviation* – non-compliance with the approved protocol that does not increase risk or decrease benefit to participants or does not significantly affect their rights, safety or welfare or the integrity of data. Example: missed visit, non-submission of a food diary on time.

*Protocol File/Folder* – is an organized physical or electronic compilation of all documents related to a protocol

*Protocol Index* – is a chronological record of the documents in the protocol file inside the cover page of the protocol folder. The protocol index is in table form indicating the date of filing, the nature of the document filed, the name and signature of the person who filed and an extra column to record any movement of the document.


*Protocol related Documents* - consists of all other documents aside from the proposal/protocol itself that required to be submitted for review, e.g., Informed Consent Form, Survey Questionnaire, CV of proponent, advertisements, In-depth Interview Guide Questions.

*Protocol related submissions*– other documents that are included (required) in the submission of the protocol, e.g., Informed Consent Forms, study tools (Interview guide, survey questionnaire, FGD guide) and CVs of the proponents and certificates of training.

*Protocol Violation* - non-compliance with the approved protocol that increases risk or decreases benefit to participants or significantly affects their rights, safety or welfare or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria.

*Provisional Meeting Agenda* – is the order of business that includes the list of topics or items approved for discussion in a meeting by the REC Chair.

*Provisional Meeting Minutes* – *Proceedings of the meeting that have been noted or approved by the Presiding officer.*

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**Quorum**– the minimum number (i.e., majority of the members) and type of members of the RERC that are required to be present in any meeting for the proceedings to be considered valid. International and national guidelines require the presence of at least 5 regular members including the non-affiliated and the non-scientist members. For BatMC RERC, a quorum is reached when there are at least 50% plus 1 RERC members present inclusive of at least one non-medical member, at least one non-affiliated member, at least one female member, and a member with experiences in scientific research.

**Query** – the act of asking for information or clarification about a study.

**Rapid Review of protocols** - facilitated review of protocols during a disease outbreak

**Real-time Recording** – the process of documenting the minutes of the meeting as the meeting proceeds simultaneously.

**Regular Meeting**– a periodically scheduled assembly of the REC.

**Regular Members** – are members constituting the research ethics committee, who receive official appointments from the institutional authority with specific terms and responsibilities including review of research proposals and attendance of meetings.

**Regulatory Authorities** – refer to government agencies or institutions that have oversight or control over the conduct of research, e.g., Department of Health, Food and Drug Administration, Research Institutions.


**Remote Communication** - means the transfer of data between two or more devices not located at the same site.

**Reportable Negative Events (RNE)** - are occurrences in the study site that indicate risks or actual harms to participants and to members of the research team and to integrity of data.

**RERC Operations**- the overall activities of the RERC that reflect performance of its functions and responsibilities.

**Research Protocol** – is a document that describes the background, rationale, objectives, design, methodology, statistical considerations, and organization of a clinical research project; also alternately referred to as “research study” for purposes of this SOP manual.

**Researcher** - is the individual primarily responsible for the conceptualization, planning and implementation of a study.

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*Researcher Initiated Studies* – are research activities whose conceptualization, protocol development and implementation are done by a researcher or group of individuals who may request for external funding support.

*Resubmission* - the revised study proposal at is forwarded to the REC in response to the recommendations given during the initial review.

*Risks* – summary of probable negative or unfavorable outcomes ranging from inconvenience, discomfort, or physical harm based on the protocol

*Room-use Restriction* – the rule that limits the use of a document within the designated premises.

*SAE or Serious Adverse Event* - ia an untoward medical occurrence in a patient or trial subject, which does not have causal relationship with the treatment and is : (1) fatal or results in death (2) life threatening (3) requires hospitalization (initial ) or prolonged existing hospitalization (4) results in persistent or significant disability, or incapacity or permanent damage (5) results in congenital anomaly or birth defect (6) required intervention to prevent permanent impairment or damage (devices) (7) other serious medical events

*SAE Subcommittee* – a group of individuals with the necessary expertise, assigned by the REC to review SAEs and SUSARs and provide the pertinent recommendation for action of the REC.


*SAR (Serious Adverse Reaction)* - when an SAE occurs during research with a medicinal product and there is a certain degree of probability that the SAE is a harmful and undesired reaction to the investigational medicinal product regardless of the administered dose.. If SAR is unexpected, it is called SUSAR (Suspected Unexpected SAR). "Unexpected" means that the nature and severity of the SAR do not match with the reference safety information (RSI) as included in the Investigator's Brochure.

*SADE - Serious Adverse Device Effect*; an SAE that occurs during research with a medical device

*Single Joint Ethics Review* – refers to reviews for the purpose of approving multi-site research that will be conducted in sites within the purview of the Department of Health. For Non-DOH hospitals, participation in this review is voluntary. (*Appendices : Reference 2 DOH Administrative Order 2017-0021*)

*Site Visit* – is an activity of the REC where an assigned team goes to the research site or office for specific monitoring purposes.

*Site Visiting Team*– members/staff of the REC (2-4 members) assigned by the RERC Chair to formally go to the research site, meet with the research team and evaluate compliance with the approved protocol and Informed Consent Form and Process, including other related research procedures to

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ensure promotion of the rights, dignity and well-being of participants and protection of integrity of data.

*Special Meeting* - an assembly of the Committee outside of the regular schedule of meetings for a specific purpose, usually to decide on an urgent matter like selection of officer, approval of a revised or new SOP, report of critical research problem that requires immediate action, oversight problems and other administrative or operational concerns of the RERC.

*Sponsor*- an individual, company, institution or organization which takes responsibility for the initiation, management, and financing of a clinical trial.

*Sponsored-Clinical Trials* – are a systematic study on pharmaceutical products in human subjects (including research participants and other volunteers), whose conceptualization, protocol development and support for their conduct are the responsibilities of sponsors who manufactured the products, in compliance with the requirements of regulatory authorities.

*Standard Operating Procedures* - are the step-by-step description of the different procedures done to accomplish the objective of an activity. They consist of clear, unambiguous instructions for ethical review to ensure quality and consistency.


*Status of participants* – summary of what happened to (condition of) participants recruited to the study, including those that completed the study, those that dropped out, or those withdrawn for specific reasons in accordance with the protocol

*Study Protocol Assessment Form* - detailed evaluation form to check the study protocol on the completeness of the documentation and information about the Principal Investigator, study site, study procedures and other documents. This includes evaluation of the scientific design and ethical considerations in the conduct of the study and all essential elements in securing informed consent from human participants.

*Study related Communications* – documents that refer to an exchange of information or opinions regarding a study, usually between the RERC and the researcher.

*Study Site* - physical location of where the study is being conducted, e.g., community, institutional facility.

*Support Staff* – institutional personnel assigned by administration to assist in the operations of the RERC.

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*SUSAR (Suspected Unexpected Serious Adverse Reaction)*- is a noxious response to a drug that is not described in the Investigator's Brochure nor in the drug insert; a serious event the nature and severity of which is not consistent with the applicable product information

*Teleconferencing* - is the holding of a conference among people remote from one another by means of telecommunication devices such as telephone or computer terminals.

*Term of office* – the specified length of time that a person serves in a particular designation /role.


*Termination package* – refers to the set of forms and documents required for the review of an application or recommendation for early termination of a study

*Unanimous* – a collective agreement.

*Video-conferencing* - is the holding of a conference among people in remote locations by means of transmitted audio and video signals.

*Voting* – the act of expressing opinions or making choices usually by casting ballots, spoken word or hand raising. The rule is majority wins.

*Vulnerable Groups* - participants or potential participants of a research study who may not have the full capacity to protect their interests and may be relatively or absolutely incapable of deciding for themselves whether or not to participate in the research. They may also be at a higher risk of being harmed or to be taken advantage.

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*World Medical Association Declaration of Helsinki, 2013*

*ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)*

*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016*

*National Ethical Guidelines for Health and Health Related research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

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*CIOMS. International ethical guidelines for health-related research involving humans. (Guideline 20: Research in disasters and disease outbreaks). Available at: <https://cioms.ch/publications/product/international-ethical-guidelines-for-health-related-research-involving-humans/>*

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