INTRODUCTION

In 2010 the VMMC-Institutional Review Board (VMMC-IRB) evolved from the Ethics Committee (established in 1979) by virtue of VMMC Memo Order # 58 dated 02 November 2010.

The VMMC-IRB is composed of medical/scientific professionals and non-medical/non-scientific members working together in a committee that safeguards the rights, safety, and well-being of all subjects involved in a clinical trial and providing public assurance of that protection.

Registered with the Philippine Health Research Ethics Review (PHREB) on August 13, 2013 (Registration No. 08-047).

Awarded a “Certificate of Accreditation as a Level 3 Ethics Review Committee by the Philippine National Health Research System (PNHRS) and Philippine Health Research Ethics Review (PHREB).

Awarded a “Certificate of Recognition” by Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) and Forum for Ethical Review Committees in Asia and the Western Pacific Region (FERCAP).
I. STRUCTURE AND COMPOSITION

1. Objectives
2. Scope
3. Responsibilities
4. Constitution and functions
5. Confidentiality/Conflict of Interest Agreement
6. Training of Members and Staff
7. Selection of Independent Consultants
8. Compensation of Members and Consultants
# I. STRUCTURE AND COMPOSITION

### DOCUMENT HISTORY

<table>
<thead>
<tr>
<th>Author</th>
<th>Version</th>
<th>Date</th>
<th>Describe the Main Change</th>
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</thead>
<tbody>
<tr>
<td>Dr. Tito C. Atienza Dr. Noemi Buensuceso Dr. Annielyn Beryl Ong-Cornel</td>
<td>1</td>
<td>15 May 2012</td>
<td>1st draft</td>
</tr>
</tbody>
</table>
| Dr. Tito C. Atienza Dr. Annielyn Beryl Ong-Cornel Dr. Noemi Buensuceso |         | 10 Jan 2013 | 1. Change of appointing body of members to Chief of Professional Staff  
2. Details on payment of honorarium of IRB Members and Independent Consultants (8.1)                                                                                                                                   |
| Dr. Tito C. Atienza Dr. Noemi Buensuceso Ms. Ma. Brenda Grace G. Benitez | 2       | 22 Feb 2013 | 2nd draft                                                                                                                                                                                                               |
| Dr. Tito C. Atienza Ms. Ma. Brenda Grace G. Benitez | 3       | 18 Oct 2013 | 3rd draft                                                                                                                                                                                                                |
| Dr. Tito C. Atienza Ms. Ma. Brenda Grace G. Benitez | 4       | 11 Nov 2014 | 4th draft                                                                                                                                                                                                                |
| Dr. Tito C. Atienza Dr. Noemi Buensuceso Ms. Ma. Brenda Grace G. Benitez | 5       | 10 May 2016 | 1) Minor changes (typographical errors)  
2) Inclusion of Chief of the Medical Professional Staff as one of the approving authority (8.1.1.)                                                                                                                          |
1. OBJECTIVES

The SOP describes the organizational framework for the structure and composition of the Veterans Memorial Medical Center - Institutional Review Board (VMMC-IRB). It supersedes the document known as “Veterans Memorial Medical Center - IRB Guidelines” which governed the functioning of the old Ethics Committee of the institution. This SOP also describes and provides the procedures, templates, and forms that are related to the nomination, appointment, training, and compensation of members of the Board, as well as identifying the persons who should read, agree to, sign and date these forms. Privacy and confidentiality documentation is likewise decided.

2. SCOPE

The SOP applies to the stated functions of the VMMC-IRB, as it carries out its task of providing an independent review of research protocols involving human participants that are submitted to the IRB by consultant-physicians, resident and fellow-trainees, students, hospital staff and employees of the VMMC for clinical trials or researches done within the hospital or institution alone.

This SOP describes the basic ethical principles and values on which the VMMC-IRB is based, the composition and appointment of the IRB members and the duties and responsibilities of IRB personnel, including attendance, training and disclosure of conflict of interest.

3. RESPONSIBILITIES

The Institution’s Office of the Chief Medical Professional Staff (CMPS) is responsible for constituting and establishing the VMMC-IRB. The VMMC Chief of Medical Professional Staff, with the approval of the Hospital Director, is also responsible for appointing the IRB Chair, its Members and Secretariat Staff, and providing the terms of reference for these appointments in accordance with prevailing hospital policies, guidelines, and regulations.

It is the responsibility of the VMMC-IRB Chair, Members and Secretariat Staff to study, comprehend, comply with, and respect the procedures and guidelines set forth by the VMMC-IRB.

It is the responsibility of all newly appointed VMMC-IRB Chair and Members (including the Chair) to read, understand, accept, and sign the required appointment forms at the start of their appointment or reappointment to the IRB. Refusal of any member to sign such agreement may be a ground for his/her disqualification from the Board.

It is the responsibility of new IRB to undergo training during the course of his/her appointment. Likewise, existing IRB personnel have to continuously update themselves and be trained on relevant knowledge and skills. To this end, the VMMC Administration is responsible for allocating an annual budget for specific training and other educational activities for the IRB Members.
4. CONSTITUTION AND FUNCTIONS

4.1. Organizational Structure of the VMMC-IRB

<table>
<thead>
<tr>
<th>Invite Member to the VMMC-IRB</th>
<th>VMMC-IRB Chair</th>
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<tbody>
<tr>
<td>Send members the following forms:</td>
<td>Secretariat Staff</td>
</tr>
<tr>
<td>- VMMC-IRB Form 1-A: Medical/Scientific Member Notification and Appointment</td>
<td></td>
</tr>
<tr>
<td>or VMMC-IRB Form 1-B: Non-Medical/Lay Member Notification and Appointment;</td>
<td></td>
</tr>
<tr>
<td>- VMMC-IRB Form 1-C: Curriculum Vitae;</td>
<td></td>
</tr>
<tr>
<td>- VMMC-IRB Form 1-D: Confidentiality Agreement and Conflict of Interest Disclosure and</td>
<td></td>
</tr>
<tr>
<td>- VMMC-IRB Form 1-E: Training Record</td>
<td></td>
</tr>
<tr>
<td>Return accomplished and signed forms</td>
<td>Member</td>
</tr>
<tr>
<td>Recommend members with signed conforme</td>
<td>Chair, IRB</td>
</tr>
<tr>
<td>Appoints member of the VMMC-IRB</td>
<td>Chief Medical Professional Staff</td>
</tr>
</tbody>
</table>

4.1.1. The Chief of Medical Professional Staff (CMPS) appoints the IRB and all members.

4.1.2. Only the Chief of Medical Professional Staff (CMPS) has the authority to dissolve the IRB after due process.

4.2. Composition of VMMC-IRB

4.2.1. VMMC-IRB is composed of the Chair and at least four (4) members. To the end that a quorum will be met during regular IRB meetings, it is highly encouraged that there should be eight (8) other members serving at any one time in the Board.

4.2.2. Members are selected according to their personal capacities, based on their interest, background, ethical, and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the work of VMMC-IRB.

4.2.3. All members are appointed for a fixed term of two (2) years, with no prejudice to the possibility of reappointment.

4.2.4. The Chief of Medical Professional Staff (CMPS) has the responsibility of appointing the Chair and the Members of the IRB.
4.2.5. To ensure continuity of policy structures of the Board, it is encouraged that after the initial appointment of two years, at least half of the membership of the Board should be reappointed.

4.2.6. The IRB members, in its first meeting, choose among themselves the Vice-Chair and member Secretary.

4.2.7. The IRB may be supported in its deliberation of specific protocols by Independent Consultants (see VMMC SOP I-7, Selection of Independent Consultants)

4.3. Resignation, Disqualification, and Replacement of Members

4.3.1. A member may resign his/her position by submitting a letter of resignation to the Chief of Medical Professional Staff (CMPS).

4.3.2. A member may not be reappointed if found non-compliant to assigned duties and responsibilities herein stated.

4.3.3. A member who has resigned and members who will not be reappointed will be replaced by new members upon recommendation by the Chief of Medical Professional Staff (CMPS).

4.4. General Duties and Responsibilities of VMMC-IRB Members and Staff

4.4.1. VMMC-IRB members and personnel should submit their properly signed and updated Curriculum Vitae [VMMC-IRB Form 1-C], which will be filed at the VMMC-IRB Membership File (which the CV, the Terms of Appointment, and copies of Training Certificate of each member)

4.4.2. Members are required to sign VMMC-IRB Form 1-D: Confidentiality Agreement and Conflict of Interest Disclosure at the start of their term. The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the IRB in the course of its work

4.4.3. Members should be willing to published their full name, profession, and affiliation to the VMMC-IRB upon request

4.4.4. Members must commit to record and make available, upon request or demand, all financial relationships, and any conflict of interest within or related to the IRB

4.5. Specific Duties and Functions of VMMC-IRB Personnel

4.5.1. VMMC-IRB Chair

4.5.1.1. Oversee the whole operations of the VMMC-IRB

4.5.1.2. Preside over monthly meetings
I. STRUCTURE AND COMPOSITION

4.5.1.3. Oversee the IRB protocols reviewed by Members and assign primary reviewers to review protocols submitted to the IRB

4.5.1.4. Prepare the budget and propose membership

4.5.1.5. Represent VMMC in national and international ethics fora

4.5.1.6. Ensure IRB compliance with international, national, and institutional policies governing human subject research and human subject protection.

4.5.1.7. Recommend updates in IRB policies and procedures in accordance with emerging national and international policy trends

4.5.1.8. Recommend policy amendments and changes

4.5.1.9. Prepare new IRB documents as needed

4.5.1.10. Maintain and update IRB manual of policies and standard operating procedures

4.5.1.11. Supervise the issuance of all IRB communication in respect of IRB decisions and actions

4.5.1.12. During IRB meetings, declare any conflict of interest in general and for specific protocols for review

4.5.1.13. Recommend to the appointing body any new Member of the IRB in case of vacancy

4.5.1.14. Initiate and schedule site visits as needed

4.5.1.15. Act on suggestions, complaints, and queries from stakeholders

4.5.2. VMMC-IRB Vice-Chair

4.5.2.1. Recommend the development, implementation, and monitoring of IRB policies and procedures to the IRB Chair

4.5.2.2. Manage the IRB office under the supervision of the IRB Chair

4.5.2.3. Ensure the basic training, orientation, and continuing education of IRB members and staff

4.5.2.4. Inform research investigators regarding IRB application processes
I. STRUCTURE AND COMPOSITION

4.5.2.5. Assist the IRB Chair in budget planning and the preparation and submission of midyear and annual reports to be submitted to the Hospital Director

4.5.2.6. Upon directive from the IRB Chair, schedule and lead the IRB in Site Visits or similar activities

4.5.2.7. During IRB meetings, declare any conflict of interest in general and for specific protocols for review

4.5.2.8. Participate in Site Visits and similar activities as needed

4.5.2.9. Perform other IRB-related tasks that may be assigned to him/her by the IRB Chair

4.5.3. VMMC-IRB Secretary

4.5.3.1. Assist the IRB Chair in overseeing the review of protocols by IRB Members and may, in the absence, on unavailability, of the Chair, assign primary reviewer/s for a submitted protocol

4.5.3.2. Oversee preparation and accuracy of the agenda and minutes of the meeting

4.5.3.3. Supervise the preparation of communication pertinent to protocol review-related actions to the Principal Investigator

4.5.3.4. Perform other IRB-related tasks that may be assigned to him/her by the IRB Chair

4.5.4. VMMC-IRB Member

4.5.4.1. Make timely and thorough review and decision regarding protocols given to him/her for evaluation (See SOP II: Protocol Review for timelines)

4.5.4.2. Familiarize him/herself with the SOPs of the IRB, his/her terms of reference, and the international and national guidelines on research ethics

4.5.4.3. Participate actively in the monthly meetings and other IRB meetings. It is expected that a member will have at least 75% attendance during the period of appointment because attendance is vital and integral to the effectiveness of the IRB as a review board.

4.5.4.4. Participate actively in the review of the progress reports, final reports, and other amendments presented during the IRB meeting.
I. STRUCTURE AND COMPOSITION

4.5.4.5. Participate in Site Visits and similar activities as needed.

4.5.4.6. Maintain confidentiality of the documents and deliberations of IRB meetings.

4.5.4.7. During IRB meetings, declare any conflict of interest in general and for specific protocols for review.

4.5.4.8. Participate in required training as stipulated in SOP I-6: Training of IRB Members and Personnel with proof of attendance in such training activity submitted to the Secretariat.

4.5.4.9. Submit an updated and signed curriculum vitae at the start of each calendar year.

4.5.4.10. Refer to the IRB Chair any suggestion, complaint, or grievance of research participants, PIs, and/or sponsors for appropriate discussion during the monthly IRB meeting.

4.5.4.11. Do other IRB-related duties that may be requested of him/her by the Chair.

4.5.5. VMMC-IRB Secretariat Staff

4.5.5.1. Manage protocol submissions

4.5.5.2. Organize an effective and efficient tracking procedure for each protocol received

4.5.5.3. Prepare and distribute protocol files for review

4.5.5.4. Maintain the VMMC-IRB Active Files and Archives, Communication Database [VMMC-IRB FORM 4-N], References and other document files, especially their security and confidentiality

4.5.5.5. Organize IRB meetings (see SOP II-5: Conduct of Full Board Meetings)

4.5.5.6. With the IRB Secretary, prepare and maintain meeting agenda and minutes

4.5.5.7. Facilitate requisition and procurement of office supplies and materials

4.5.5.8. Inform the IRB members and personnel about training workshops and arrange for the latter’s participation in such workshops

4.5.5.9. Organize the preparation, review, revision, and distribution of SOPs and guidelines
I. STRUCTURE AND COMPOSITION

4.5.5.10. Provide the necessary secretariat support for IRB-related activities like Site Visits and communicating decisions to the PIs

4.5.5.11. Perform other related functions that maybe assigned by the VMMC-IRB Chair

5. CONFIDENTIALITY/CONFLICT OF INTEREST AGREEMENT WORKFLOW

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>RESPONSIBILITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepare <strong>VMMC-IRB Form 1-D: Confidentiality Agreement and Conflict of Interest Disclosure</strong></td>
<td>Secretariat Staff</td>
</tr>
<tr>
<td>Accomplish <strong>VMMC-IRB Form 1-D: Confidentiality Agreement and Conflict of Interest Disclosure</strong></td>
<td>Chair, Vice-Chair, Secretary, Members, Secretariat Staff</td>
</tr>
<tr>
<td>Store Documents</td>
<td>Secretariat Staff</td>
</tr>
</tbody>
</table>

**DETAILLED INSTRUCTIONS:**

5.1. Preparation of Confidentiality Agreement (CA) and Conflict of Interest (COI) disclosure forms of the VMMC-IRB for Panel Members: The VMMC-IRB Secretariat provides a copy of **VMMC-IRB Form 1-D: Confidentiality Agreement and Conflict of Interest Disclosure** to new members of the VMMC-IRB panel as soon as they are appointed; these are renewed annually.

5.2. Accomplishment of Forms

5.2.1. A copy of **VMMC-IRB Form 1-D: Confidentiality Agreement and Conflict of Interest Disclosure** must be filled out and signed by all VMMC-IRB personnel. A COI does not necessary disqualify a person from becoming a member of the VMMC-IRB for as long as he/she declares it beforehand, understands his/her responsibility as a VMMC-IRB member (that is, to provide an unbiased review of a protocol for the protection of research participants), and declines from participating in protocol deliberations when his/her COI could affect the result of board decisions

5.2.2. The VMMC-IRB personnel reads, signs the forms, and dates his/her signature on the forms then submits them to the VMMC-IRB Secretariat Staff

5.2.3. The VMMC-IRB Secretariat Staff accepts the signed/unsigned form, makes duplicate copies of each, and files the originals together with the letter from the Chief, Medical Professional Staff about the member’s appointment, his/her CV and terms of reference, in the VMMC-IRB Membership Files.

5.2.4. The Secretariat Staff gives a copy of each signed and dated form to the VMMC-IRB Member who must keep them in his/her own personal files.
5.3. Storage of Signed Form in the VMMC-IRB Membership Files

5.3.1. The Secretariat Staff keeps one (1) copy of the signed and dated **VMMC-IRB Form 1-D: Confidentiality Agreement and Conflict of Interest Disclosure** in the VMMC-IRB Membership File.

5.3.2. This form is required to be updated when appointment is renewed.

6. TRAINING OF VMMC-IRB MEMBERS AND PERSONNEL WORKFLOW

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<thead>
<tr>
<th>ACTIVITY</th>
<th>RESPONSIBILITY</th>
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</thead>
<tbody>
<tr>
<td>Set training requirements</td>
<td>Vice-Chair</td>
</tr>
<tr>
<td>↓</td>
<td></td>
</tr>
<tr>
<td>Find available training, seminars, lectures, workshops</td>
<td>Members/Secretariat Staff</td>
</tr>
<tr>
<td>↓</td>
<td></td>
</tr>
<tr>
<td>Signify intention to attend training or the VMMC-IRB Chair instructs member/s to attend</td>
<td>Members/Secretariat Staff</td>
</tr>
<tr>
<td>↓</td>
<td></td>
</tr>
<tr>
<td>Attend training and keep the training record</td>
<td>Members/Secretariat Staff</td>
</tr>
<tr>
<td>↓</td>
<td></td>
</tr>
<tr>
<td>Store training record in VMMC-IRB Membership Files under Training of VMMC-IRB Members</td>
<td>Secretariat Staff</td>
</tr>
</tbody>
</table>

**DETAILED INSTRUCTIONS:**

6.1. Identification of Required Trainings, Seminars, and Workshops

6.1.1. The IRB Vice-Chair periodically reviews compliance with training requirements for VMMC-IRB Chair, Secretary, Members, and Secretariat Staff.

6.1.2. The 2 basic required course are:

- Basic Research Ethics & Good Clinical Practice
- VMMC-IRB Standard Operating Procedures

6.2. Attendance in the Training

6.2.1. The Member or Secretariat Staff attends the training and submits proof of attendance to the Coordinator, such as certificate of participation or completion.

6.2.2. The Coordinator verifies validity of submitted documents.
6.2.3. Attendees are encouraged to echo their experience and disseminate new knowledge and information to the VMMC-IRB.

6.3. Storage and Filing

6.3.1. The Secretariat Staff fills out VMMC-IRB Form 1-E: Training Record to document the training/workshop/conference activities in chronological order.

6.3.2. The Secretariat Staff makes a copy of the form and files the copy in the VMMC-IRB Membership File.

7. SELECTION OF INDEPENDENT CONSULTANTS WORKFLOW

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>RESPONSIBILITY</th>
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</thead>
<tbody>
<tr>
<td>Invite Independent Consultants to the VMMC-IRB</td>
<td>VMMC-IRB Chair</td>
</tr>
<tr>
<td>Sign conforme and VMMC-IRB Form 1-D: Confidentiality Agreement and Conflict of Interest Disclosure</td>
<td>Independent Consultant</td>
</tr>
<tr>
<td>Appoint the roster of Independent VMMC-IRB Chair Consultants</td>
<td>Chief, Medical Professional Staff</td>
</tr>
<tr>
<td>Store roster of Independent Consultants in the Independent Consultants File</td>
<td>Secretariat Staff</td>
</tr>
</tbody>
</table>

DETAILED INSTRUCTIONS:

7.1. Invitation of Independent Consultants

7.1.1. The VMMC-IRB Chair determines the external expertise requirements of the prospective Independent Consultant based on protocols submitted for review during previous years and the available expertise in the current VMMC-IRB composition.

7.1.2. The VMMC-IRB Chair sends invitations to various professionals with specific expertise to be part of the VMMC-IRB roster of Independent Consultants representing expertise not present in the current Board.

7.1.3. Similarly, in the course of protocol review, an IRB Member or the IRB Chair may determine that a protocol should also be reviewed by an Independent Consultant.
I. STRUCTURE AND COMPOSITION

7.1.4. The invitation includes the responsibilities and functions of the Independent Consultant as follows:

7.1.4.1. Accomplish the following forms when requested:

- VMMC-IRB Form 1-F: Service Agreement for Independent Consultants
- VMMC-IRB Form 1-D: Confidentiality Agreement and Conflict of Interest Disclosure
- VMMC-IRB Form 2-C: Study Protocol Assessment Form
- VMMC-IRB Form 2-D: Informed Consent Assessment Form

7.1.4.2. Review assigned protocols that concern his/her specialty using the VMMC-IRB Form 2-C: Study Protocol Assessment Form

7.1.4.3. Attend the VMMC-IRB meeting when invited where deliberations on said protocols will be made or alternatively, submit results of review to the VMMC-IRB Secretariat Staff, if unable to attend the meeting.

7.1.4.4. Return all protocol-related materials to the VMMC-IRB Secretariat Staff after review

7.1.4.5. Submit an updated and signed CV annually.

7.2. Confirmation of Invitation

7.2.1. The Independent Consultant signifies agreement to the invitation by signing the conforme attached to the letter of invitation

7.2.2. The signed conforme is submitted to the VMMC-IRB

7.3. Appointment of Independent Consultants

7.3.1. Any member of the VMMC-IRB recommends to the IRB Chair a roster of Independent Consultants who have been invited and who have accepted the invitation

7.3.2. The Chief Medical Professional Staff (CMPS) is informed of the appointment of an Independent Consultant. The Chief of the Professional Staff (CMPS) is regularly updated on the current roster of Independent Consultants.

7.3.3. The appointment is for two (2) years

7.3.4. Appointment may be terminated by either resignation of the consultant, or by the VMMC-IRB Chair
7.4. **Storage of Roster of Independent Consultants**

7.4.1. The VMMC-IRB Secretariat Staff files the appointment-related documents in the Independent Consultants File

7.4.2. The Independent Consultant’s File contains the appointee’s CV and the originally signed conforme representing the terms of reference of appointment

### 8. **COMPENSATING MEMBERS AND CONSULTANTS WORKFLOW**

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>RESPONSIBILITY</th>
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<tbody>
<tr>
<td>Recommend Honorarium</td>
<td>VMMC-IRB Chair</td>
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<td>↓</td>
<td></td>
</tr>
<tr>
<td>Approved Honorarium</td>
<td>Chief, Medical Professional Staff (CMPS)</td>
</tr>
<tr>
<td>Communicate Honorarium Information to Personnel and Independent Consultants</td>
<td>Secretariat Staff</td>
</tr>
</tbody>
</table>

#### 8.1. Recommendation of Honorarium

8.1.1. The VMMC-IRB Chair initiates the recommendation of honorarium, or increase thereof, after a dialogue with VMMC-IRB Members and subsequent approval by the Chief of the Medical Professional Staff and the Hospital Director

8.1.2. The compensation for IRB members covers a fixed amount for review of protocols, henceforth referred to as “Reviewers’ Fee”.

8.1.2.1. The amount of reviewers’ fee is determined and fixed by an existing memorandum issued by the CMPS and approved by the Hospital director

8.1.2.2. Only the IRB members who actually reviewed a submitted protocol and participated in the deliberation towards its ultimate approval or disapproval will receive a share of the reviewers’ fee.

8.1.2.3. The compensation may or may not include a fixed amount for attending meetings and other VMMC-IRB related-activities

8.1.3. The fee of independent consultant will be a fixed amount (PhP 1,500.00) that covers initial review and subsequent review of submitted documents for approval by the Board.

8.1.4. The recommendation for the honorarium of IRB members and Independent Consultants will be submitted to the Chief of Medical Professional Staff (CMPS) through submission of the IRB budget.
I. STRUCTURE AND COMPOSITION

8.2. Approval of Honorarium

8.2.1. The Chief of Medical Professional Staff (CMPS) may approve or disapprove the recommendation.

8.2.2. Approval or disapproval will be indicated in the approval of the IRB budget or amendment thereof.

8.3. Communication of Honorarium Information

8.3.1. The VMMC-IRB Members are informed of the honorarium package both upon appointment and whenever there are changes subject to the governing rules and regulations.

8.3.2. VMMC-IRB personnel and Independent Consultants acknowledge the information upon receipt of notification.
II. STUDY PROTOCOL REVIEW

1. Objectives

2. Scope

3. Responsibilities

4. Initial Review

5. Full Board Meeting

6. Special Meetings

Supersedes 05
Version 06
Authored By Tito C. Atienza, MD; Annielyn Beryl Ong-Cornel, MD; Noemi R. Buensuceso, MD; Johann Giovanni P. Mea, MD; Ms. Ma. Brenda Grace G. Benitez
Version Date 07 September 2016
Approved By Dominador M. Chiong Jr., MD
Approval Date 09 September 2016
## II. STUDY PROTOCOL REVIEW

### DOCUMENT HISTORY

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<td>Dr. Tito C. Atienza Dr. Annielyn Beryl Ong-Cornel Dr. Noemi R. Buensuceso</td>
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<td>29 Jun 2012</td>
<td>Criteria for expedited review (4.2.1)</td>
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<tr>
<td>Dr. Tito C. Atienza Dr. Annielyn Beryl Ong-Cornel Dr. Noemi R. Buensuceso Ms. Ma. Brenda Grace G. Benitez</td>
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<td>Dr. Tito C. Atienza Ms. Ma. Brenda Grace G. Benitez</td>
<td>3</td>
<td>18 Oct 2013</td>
<td>3&lt;sup&gt;rd&lt;/sup&gt; Draft</td>
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<tr>
<td>Dr. Annielyn Beryl Ong-Cornel</td>
<td>4</td>
<td>11 Nov 2014</td>
<td>Addition of provision for the need of post-trial access statement in any protocol reviewed</td>
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| Dr. Tito C. Atienza Dr. Noemi R. Buensuceso Ms. Ma. Brenda Grace G. Benitez Dr. Annielyn Beryl Ong-Cornel | 5       | 10 May 2016 | 1) Rephrased the first sentence on the “Scope” on Chapter II  
2) Deleted the word “referred by the Research Committee”  
3) Inclusion of “decision pending” on the action/decision of the Board.  
4) Correction in item 5.6.4. It should be Primary Reviewer not P.I.  
5) Change the word “scientific” to “medical” in item 5.6.5. |
| Dr. Annielyn Beryl Ong-Cornel Dr. Johann Giovanni P. Mea Ms. Ma. Brenda Grace G. Benitez | 6       | 07 Sep 2016 | 6<sup>th</sup> draft                                                                   |
1. OBJECTIVES

This SOP describes how the VMMC-IRB Secretariat manages study protocol submission packages from initial submission to resubmission in response to IRB questions, and including review classifications. This SOP aims to provide guidance as to how the reviewers evaluate a study protocol submitted to the VMMC-IRB either for the first time (initial submission) or with modifications per IRB recommendations (resubmissions).

2. SCOPE

The VMMC-IRB reviews global or local clinical trials and researches conducted by institution’s training residents & fellows, physicians or other employees. The VMMC-IRB, at the present time, does not accept protocols for ethics review if the Study Principal Investigator is not a VMMC employee. Except in certain cases deemed appropriate by the Chair and expressly approved by the Board (e.g. community-based clinical trials or research studies by training residents, fellows or consultants), the IRB will also not accept protocols for ethics review if the study is to be done outside the VMMC even if the Principal Investigator is a VMMC employee.

The SOP applies to IRB actions from the time of initial submission to the filing of the original study protocol package in the Active Study File cabinet and the preparation of copies of the package for distribution to the reviewers and deliberations during board meeting.

3. RESPONSIBILITIES

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

It is the responsibility of the IRB Chair to decide whether the study protocol is for full board or expedited review. The IRB Chair is also responsible for assigning primary reviewers. It is the responsibility of the IRB Secretary to inform the assigned primary reviewers of their assigned task, and to ensure that the deliberations and discussions are adequately documented during the meeting.

It is the responsibility of the assigned reviewers to check the completeness of the study protocol package delivered to them, systematically review the study protocol, write their comments after each item listed in the study protocol assessment forms and informed consent checklist, include consideration of relevant guidelines when doing the review, and present findings in the full board meeting (for full review study protocol).

The Principal Investigator (PI) is responsible for submitting a complete set of documents to the VMMC-IRB.
## II. STUDY PROTOCOL REVIEW

### 4. INITIAL REVIEW WORKFLOW

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>RESPONSIBILITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receive and manage study protocol submissions</td>
<td>IRB Secretariat Staff</td>
</tr>
<tr>
<td>Receive the proof of payment of institutional fee (deposited in the VMMC Trust Fund) with the submitted protocol</td>
<td>IRB Secretariat Staff</td>
</tr>
<tr>
<td>Classify submission as expedited or full Board review</td>
<td>IRB Chair</td>
</tr>
<tr>
<td>Assign primary reviewers</td>
<td>IRB Chair</td>
</tr>
<tr>
<td>Send study protocol package to primary reviewers with VMMC-IRB Form 2-A: Review Checklist for Initial Trial Application; VMMC-IRB Form 2-B: Registration and Application Form; VMMC-IRB Form 2-C: Study Protocol Assessment Form; and VMMC-IRB Form 2-D: Informed Consent Assessment Form</td>
<td>IRB Secretariat Staff</td>
</tr>
<tr>
<td>Review the protocol and return accomplished VMMC-IRB Form 2-C: Study Protocol Assessment Form and VMMC-IRB Form 2-D: Informed Consent Assessment Form to the Secretariat Staff</td>
<td>Primary Reviewers</td>
</tr>
</tbody>
</table>

**FULL BOARD REVIEW**

- Include the protocol in the agenda of the next full Board meeting
- Present review findings during full Board meeting
- Deliberates on Board action on the protocol
  - **1) If approved:** send approval letter to P.I.
  - **2) If minor modification/s:** send notification with recommendation to P.I., then process resubmission by expedited review
  - **3) If major modification/s:** send notification with recommendation to P.I., then process resubmission by full board review
  - **4) If disapproved:** send notification of decision with justification to P.I.

**EXPEDITED REVIEW**

- Include in the agenda of the next IRB meeting under the Expedited Review
- Present review findings during full Board meeting

- Secretariat Staff
- Primary Reviewer
- IRB Members
- Secretariat Staff
II. STUDY PROTOCOL REVIEW

**DETAILED INSTRUCTIONS:**

**a. Receipt and Management of Study Protocol Submission**

1. A study protocol is the developed study plan for conducting a clinical trial. It is created to protect the well-being of the participants and to establish the intent of the clinical trial to answer specific questions or needs. It defines the nature of study participants, the tests to be conducted, the procedures to be used, the time frame of the study and the medications and dosages to be given to participants.

2. A study protocol package for initial review must be received together with duly signed and accomplished forms and documents (as applicable) as enumerated in **VMMC-IRB Form 2-A: Review Checklist**.

3. The Secretariat Staff ensures completeness of submitted forms and documents using the above checklist.

4. The Secretariat Staff receiving the study protocol assigns a Control No. to the package and stamps in onto all the forms and documents submitted.

5. The Secretariat Staff signs **VMMC-IRB Form 2-A: Review Checklist** to document the receipt of study protocol package and gives one copy of duly signed form to the P.I. or designated representative submitting the package, and attaches another duly signed form to the study protocol package.

6. The Secretariat Staff logs the submission using **VMMC-IRB Form 4-N: Submission Log**.

7. Payment of the institutional fee must be made before the protocol package is submitted. Review of protocol will be done only on presentation (by the Principal Investigator or a representative of the clinical trial) to the IRB Secretariat of an official receipt from the VMMC Cash Section (formerly known as Finance Division) showing full payment of the institutional fee.

   1. The payment will be made in the name of VMMC Trust Fund, for the sole purpose of the moneys received being used for research purposes of the institution and the maintenance of the daily operational expenses and training activities of the VMMC-IRB.

   2. Research protocols by training residents and fellows for review by the IRB will be exempted from payment of the prescribed institutional fee.

**b. Classification of Submission**

1. The VMMC-IRB Chair classifies the study protocol review pathway as either Expedited Review or Full Board Review filtered through the following criteria for Expedited Review:
   - The research poses no more than minimal risk.
II. STUDY PROTOCOL REVIEW

- The study does not involve vulnerable populations.
- The study does not involve the collection of stigmatizing information.
- The study uses anonymized or archived samples.
- Continuing review of clinical trials that do not involve further recruitment of participants.
- Continuing review of studies previously classified under expedited review.
- Study protocol Amendments that are administrative in nature and do not affect the study protocol.

ii. Study protocols that do not meet the criteria for expedited review are classified under full board review.

c. Assignment of Primary Reviewers

i. The IRB Chair assigns two (2) scientific reviewers and one (1) non-scientific or lay member as primary reviewers of the study protocol. The reviewers are selected on the basis of their expertise. The scientific reviewer is tasked to review both technical soundness and related ethical issues of a study protocol and Informed Consent Form. The non-scientific reviewers is mainly tasked with the review of the Informed Consent process and form.

ii. The Secretariat Staff prepares a transmittal letter and sends the study protocol package to the assigned primary reviewers. The same protocol package is sent to IRB members who are not primary reviewers and they may or may not submit comments on the protocol under review.

iii. The Secretariat Staff files the study protocol package in a properly coded Study Protocol File folder and places it in the Active Study File cabinet.

d. Study Protocol Review

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

ii. Primary reviewers accomplish VMMC-IRB Form 2-C: Study Protocol Assessment Form and VMMC-IRB Form 2-D: Informed Consent Assessment Form completely and comprehensively, and check for completeness of the documentation and information about the PI, study site, and other documents (Basic and Study Specific) as required by the study protocol under review such those listed in SOP II-4.A: Receipt and Management of Study Protocol Submissions applicable to the study.
ii. **STUDY PROTOCOL REVIEW**

iii. A primary reviewer is given ten (10) calendar days before the next scheduled meeting within which time he/she must review make comments on and evaluate the study.

iv. The review of the study protocol and informed consent documents must be in accordance with the assessment points and elements detailed in **VMMC-IRB Form 2-C: Study Protocol Assessment Form** and **VMMC-IRB Form 2-D: Informed Assessment Form**

v. In addition to the review elements described above, the primary reviewers should ensure study protocol compliance with the National Ethical Guidelines for Health Research 2011 regarding the following matters:

1. Use of placebo
2. Involvement of minors and children as study participants
3. Appropriate and applicable memoranda of agreement (MOA),
4. If applicable, community involvement and impact/benefit of the study to community and/or the institution are examined and if relevant, noting the following: the impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn; an explicit assurance that no undue influence on the community is exerted in the informed consent taking process: involvement of local researchers and institutions in the study protocol design, analysis and publication of the results; contribution to development of local capacity for research and treatment; benefit to local communities; availability of study results, and benefit sharing.
5. It is acknowledged that some populations require special protection because of characteristics or situations that render them vulnerable. Vulnerable groups should not be included in research unless:
   
   (a) the research is necessary to promote the health of the population represented and
   
   (b) the research cannot be performed on legally competent persons

vi. Special considerations in the review process

1. The Board will ensure that the protocol to be reviewed has explicit statement/s regarding compensation for research participants. Compensation given to participants for lost earnings, transportation, and other expenses incurred in taking part in the study, and compensation for the inconvenience and time spent by those who do not have direct benefit from the research, should not be so large as to induce the prospective subject to consent to participate in the research against his better judgment.
II. STUDY PROTOCOL REVIEW

2. Compensation in whatever form should also be available to research participants should injury in their person occur in the course of the study.

3. There must be a statement in the protocol stating that the population in which the research is carried out will likely benefit from the research results. Likewise, the standard of care and other medical interventions must be offered to subjects after their study participation.

4. Post-trial access must be available to all study participants, i.e., the standard medical care, adequate medical advice and consultation including prescription of appropriate post-study medications and other medical intervention must be available and offered to subjects after their study participation.

vii. For full board study protocols, the primary reviewer accomplishes the aforementioned forms and returns them to the Secretariat Staff within three (3) calendar days prior to the meeting.

viii. For expedited review study protocols, the primary reviewer accomplishes the aforementioned forms, and returns them to the Secretariat Staff within seven (7) calendar days from receipt of package.

ix. The primary reviewers signify their decision by marking the appropriate section of the aforementioned forms and affixing their signature in the space provided. Decisions points are: Approval, Minor Modifications, Major Modifications, or Disapproval.

1. Minor modification is one where a proposed change in research related activities does not significantly affect an assessment of the risks and benefits of the study and does not substantially change the specific aims or design of the study.

2. Major modification is one where a proposed change in research related activities significantly affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study.

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

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

xii. For decisions on resubmission and post approval submissions, the Board may request information or clarificatory interview from PI, as the need arises.
## II. STUDY PROTOCOL REVIEW

### a. REVIEW WORKFLOW FOR RESUBMISSION

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>RESPONSIBILITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receive and manage study protocol resubmissions</td>
<td>IRB Secretariat Staff</td>
</tr>
<tr>
<td>Classify submission as expedited or full Board review</td>
<td>IRB Chair</td>
</tr>
</tbody>
</table>

**FULL BOARD REVIEW**

- Send study protocol resubmission to primary reviewers with
  - VMMC-IRB Form 2-A.2: Review Checklist for Resubmission and Amendment
  - VMMC-IRB Form 2-F: Review of Resubmitted Protocol Form

**EXPEDITED REVIEW**

- Send study protocol resubmission to Chair with
  - VMMC-IRB Form 2-A.2: Review Checklist for Resubmission and Amendment
  - VMMC-IRB Form 2-F: Review of Resubmitted Protocol Form

- Review the protocol and return accomplished VMMC-IRB Form 2-F: Review of Resubmitted Protocol Form to the Secretariat Staff

- Include the protocol in the agenda of the next full Board meeting

- Present review findings during full Board meeting

- Deliberates on Board action on the protocol

1) **If approved:** send approval letter to P.I.
2) **If minor modification/s:** send notification with recommendation to P.I., then process resubmission by expedited review
3) **If major modification/s:** send notification with recommendation to P.I., then process resubmission by full board review
4) **If disapproved:** send notification of decision with justification to P.I.

- Include in the agenda of the next IRB meeting under the Expedited Review

- Present review findings during full Board meeting

- Deliberates on Board action on the protocol

- If approved: send approval letter to P.I.
- If minor modification/s: send notification with recommendation to P.I., then process resubmission by expedited review
- If major modification/s: send notification with recommendation to P.I., then process resubmission by full board review
- If disapproved: send notification of decision with justification to P.I.
xiii. In the event that a PI or the Sponsor decides not to continue the application for ethics review, the PI must write a letter requesting for withdrawal of study protocol from the VMMC-IRB. All requests for withdrawal will be discussed during full Board meetings regardless of initial review classification. Upon approval of request, study protocol will be archived as stipulated in SOP IV-8: Archived (Inactive/Completed/Terminated) Files.

xiv. In the event that a PI or the Sponsor decides not to continue the conduct of a clinical trial which has been approved by the IRB, the PI must write a letter stating the reason for the decision and submission of accomplished VMMC-IRB Form 3-F: Early Study Termination Application Form. All information regarding approval protocol not being conducted will be discussed during the full Board meetings regardless of initial review classification. Board action to the non-continuation of a clinical trial with an already approved protocol will be based on the reason provided by the PI and will be relayed to him/her the soonest time possible. Upon approval of request, study protocol will be archived as stipulated in SOP IV-8: Archived (Inactive/Completed/Terminated) Files.

5. FULL BOARD MEETING WORKFLOW

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<tr>
<th>ACTIVITY</th>
<th>RESPONSIBILITY</th>
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</thead>
<tbody>
<tr>
<td>Set regular meeting schedule</td>
<td>IRB Chair and Members/Secretariat Staff</td>
</tr>
<tr>
<td>Distribute meeting agenda</td>
<td>IRB Secretariat Staff</td>
</tr>
<tr>
<td>Prepare meeting materials</td>
<td>IRB Secretariat Staff</td>
</tr>
<tr>
<td>Determine quorum</td>
<td>IRB Secretary</td>
</tr>
<tr>
<td>Call the meeting to order</td>
<td>IRB Chair</td>
</tr>
<tr>
<td>Confirm/Certify quorum</td>
<td>IRB Secretary</td>
</tr>
<tr>
<td>Declare conflict of interest</td>
<td>IRB Chair/IRB Secretary/IRB Members</td>
</tr>
<tr>
<td>Read and approve the minutes</td>
<td>IRB Chair/IRB Secretary/IRB Members</td>
</tr>
<tr>
<td>Review initial study protocol submissions and resubmissions</td>
<td>IRB Chair/IRB Secretary/IRB Members</td>
</tr>
<tr>
<td>Conduct clarificatory interview</td>
<td>IRB Chair/IRB Secretary/IRB Members</td>
</tr>
<tr>
<td>Review post-approval submissions (including SAEs)</td>
<td>IRB Chair/IRB Secretary/IRB Members</td>
</tr>
<tr>
<td>Review report of results of expedited review</td>
<td>IRB Chair/IRB Secretary/IRB Members</td>
</tr>
<tr>
<td>Adjourn meeting</td>
<td>IRB Chair</td>
</tr>
<tr>
<td>Collect, store and dispose meeting materials</td>
<td>IRB Secretariat Staff</td>
</tr>
</tbody>
</table>
II. STUDY PROTOCOL REVIEW

DETAILED INSTRUCTIONS:

a. Regular Meeting Schedule

i. The VMMC-IRB will have its regular monthly meeting every last Friday of the month. The meeting, however, for the last two (2) months of the year could be consolidated into only one meeting, depending on the number of items in the agenda that are to be discussed.

ii. The Secretariat Staff confirms the scheduled meeting date, time and venue at least three (3) days before the meeting.

iii. The Secretariat staff ensures that the venue, equipment and facilities are made available and in good working condition prior to the meeting day to allow ample time for equipment replacement or purchase of necessary supplies.

b. Distribution of the Meeting Agenda

i. The Secretariat Staff distributes (through email or messenger service) the VMMC-IRB Form 2-E: Meeting Agenda together with the related study documents that may be available to meeting attendees (members, invited PIs, independent consultants, and others) at least three (3) days before the meeting.

ii. Member should confirm their attendance within three (3) days of the meeting.

iii. The Secretariat Staff sends meeting reminders to all persons who will be in attendance, through mobile phone, email, or regular telephone the day before the meeting. Non-members who will be attending only specific portions of the meeting should be informed accordingly, as specified in formal invitation issued to them to attend the meeting.

c. Preparation of Members’ Meeting Folders, Study Protocols, and Study Protocol-Related Submission Scheduled for Review

i. The Secretariat Staff makes copies of the approved Minutes (VMMC-IRB Form 4-A: Format of the Minutes of the Meeting) of the previous meeting, for all members attending the meeting. For details regarding preparation of the Minutes, refer to SOP IV-4: Minutes of the Meeting.

ii. The Secretariat Staff distributes the folders containing meeting materials (such as agenda and minutes of previous meeting) at the start of the meeting. The folders are collected afterwards.

iii. During the actual meeting the IRB Members must bring all meeting-related materials sent to them to serve as their reference during the review.
d. Determination of Quorum

i. Quorum is defined as the presence of 50% plus 1 of all members, described as follows:
   - Scientific member(s) with expertise on the study protocols being reviewed
   - At least one (1) non-scientific or lay member
   - At least one (1) member independent of the institution (who can be represented by the lay member as the case may be)
   - Representation of both female and male members

ii. In studies involving children only, a pediatrician should be present.

iii. In case of anticipated lack of quorum, the VMMC-IRB Chair will search for a suitable corresponding alternate from the list of Independent Consultants.

iv. On the appointed meeting time, the IRB Secretary determines quorum viability and informs the IRB Chair to indicate readiness to call the meeting to order.

e. Calling the Meeting to Order and Complete Required Procedures prior to Review Proper

i. The IRB Chair, or a designated IRB member in the Chair’s absence, calls the meeting to order upon confirmation of quorum by the IRB Secretary.

ii. The VMMC-IRB also allows, at the discretion of the IRB Chair, guests (such as auditors or surveyors) or observers (such as students or trainees) to observe IRB meetings. Non-members (who are not PIs) attending any VMMC-IRB Meeting are required to sign a Confidentiality Agreement for Guests/Observers (VMMC-IRB 2-G).

iii. The Secretary documents the proceedings of the meeting, as soon as the meeting is called to order by the IRB Chair, noting the time of the meeting start. The Secretary documents the development of the agenda, specifically all board opinions and actions with respective reasons, for inclusion in the meeting minutes, and subsequent communication with the principal investigator. For details regarding preparation of the Minutes of the Meetings, refer to SOP IV-4: Minutes of the Meeting.

iv. The IRB Chair calls upon the Secretary to formally confirm quorum by citing the attendance requirements.

v. The IRB Chair calls for declaration of Conflict of Interest (COI) with respect to any study protocol or submission scheduled for review. Members declaring COI are documented by the Secretary. The IRB Chair instructs the members who declared COI to inhibit themselves from the deliberation of the respective study protocol for which the COI declaration was made.
II. STUDY PROTOCOL REVIEW

1. A conflict of interest arises when a member(s) of the IRB holds interests with respect to specific applications for review that may jeopardize his/her ability to provide free and independent evaluation of the research focused on the protection of the research participants. Conflict of interests may arise when an IRB member has financial, material, institutional or social ties to the research.

vi. The IRB Chair presides over the review of the Minutes of the previous meeting. Any member can declare a motion for approval, which any member can second. The IRB Chair then declares approval of the Minutes of the previous meeting.

vii. The IRB Chair proceeds to facilitate discussion of matters arising from the minutes, the results of which are noted by the Secretariat Staff for inclusion in the Minutes of the current meeting.

f. Discussion of Initial Study Protocol Submission and Resubmission

i. Full board review of study protocol and study protocol-related submissions typically includes review of the following in sequence:

- Initial Study Protocol Submissions
- Resubmission or Study Protocols for Modification
- Request for Clarificatory Interview
- Withdrawal of Study Protocol Applications
- Study Protocol Amendment Applications
- Continuing Review Application
- Final Reports
- Serious Adverse Event Reports
- Site Visit Reports
- Study Protocol Non-Compliance (Deviation or Violation) Reports
- Early Study Termination Applications
- Queries from Various Stakeholders

ii. The IRB Chair may allow some modification of the sequence of review in exigent circumstances. For example, if a clarificatory interview is included in the agenda, the Board may opt to move this up in the review sequence.

iii. The IRB Chair instructs the member who had previously declared conflict of interest (COI) to inhibit himself/herself from ensuing study protocol deliberation by leaving the room just before the respective study protocol is presented for deliberation. In some instances, such members may be called in by the Board to answer questions to assist in arriving at a Board action. Under no circumstances will IRB members who have declared COI be allowed to participate in the decision.
II. STUDY PROTOCOL REVIEW

iv. For initial review, the IRB Chair calls the primary reviewers to present findings on respective study protocols based on study protocol assessment points specified in VMMC-IRB Form 2-C: Study Protocol Assessment Form and elements detailed VMMC-IRB Form 2-D: Informed Consent Assessment Form. The primary reviewer is to present the following:

1. A summary/synopsis of the protocol
2. His/her findings on the scientific soundness of the protocol with emphasis on objectives, methodology, research design and others
3. His/her findings on ethical considerations like risk benefit rates, possible involvement of vulnerable subject, inclusion/exclusion criteria and issues that may come from considering them.
4. Evaluation of the informed consent with special emphasis on the clarity of the language to enable the subject to understand the contents of the form and thus give his/her voluntary consent.

v. The medical primary reviewer is instructed to focus presentation of findings on scientific soundness of the study protocol and its impact on human subject protection. The non-medical primary reviewer, on the other hand, is instructed to focus the presentation on the findings in the informed consent process and informed consent form (ICF) and its compliance with the requirements of international and national ethical guidelines, as well as national and institutional policies.

vi. Any IRB Member, who has been provided the submission package earlier, may offer his/her opinion on the soundness of either the technical or ethical aspects of a clinical protocol under deliberation. All IRB Members present in the meeting then deliberate on the study assessment points and informed consent elements as detailed in the aforementioned forms.

vii. For review of resubmissions, the IRB Chair calls the primary reviewers to present findings on the response of the PI to the previous recommendations of the board summarized in the VMMC-IRB Form 2-F: Review of Resubmitted Study Protocol.

viii. In case of unavailability of any primary reviewer to attend the meeting, he/she is required to forward the completed assessment forms to the Secretariat Staff three (3) days before the meeting. The findings summarized therein will be presented by the IRB Chair or his designee when the study protocol is deliberated on.

ix. For decision on either initial study protocol submission or resubmission, the IRB Chair calls for any of the following actions after due consideration of the assessments made by primary reviewers and the IRB members and after a process of actual voting:

- Approval
- Major Modification, which require full board deliberation
- Minor Modification, which can be expedited at the level of the Chair
- Disapproval
x. In case one primary reviewer is absent and has not submitted his/her review, discussion of the study protocol may still proceed at the discretion of IRB Chair. If the Chair feels that the present IRB composition does not have the expertise to proceed with the review, the discussion of the study protocol may be deferred till the next meeting. Also, the IRB may request comments or clarificatory interview from the PI at another meeting.

xi. The VMMC-IRB may allow investigators and other resource persons (such as an independent consultant commissioned by the IRB) of highly specialized areas to attend the part of the IRB meeting related to specific studies for purpose of clarifying issues related to the study protocol only, but not to present the study protocol to the board.

g. Conduct of Clarificatory Interview

i. If needed, the IRB conducts clarificatory interviews with PIs and/or study team members whose submissions raise ethical or technical issues that are better addressed by the PI himself/herself.

ii. The Secretariat Staff sends VMMC-IRB Form 4-D: Letter for Clarificatory Interview to PIs called for interview. PIs may also request a clarificatory interview with the Board by formally expressing their intention in writing.

iii. PIs or study team members to be interviewed by the IRB must sign VMMC-IRB Form 2-G: Confidentiality Agreement for Guests/Observers prior to the interview. They are allowed inside the meeting room only during the actual interview, after which they will be requested to leave.

iv. The IRB Chair calls for action depending on the type of submission (see SOP II-5.6 and SOP II-5.8). Decisions are based on the IRB’s assessment of the PI’s response to their queries.

h. Discussion of Post-Approval Submissions

i. The IRB Chair presents, if any, Study Protocol Amendment Submission Form (VMMC-IRB Form 3-A) that entail major amendments substantially affecting previous risk-benefit assessment on the study protocol. For details on classification of amendments and subsequent processing requirements, refer to SOP III-5: Study Protocol Amendment. The IRB Chair calls for any of the following actions:

- Approval
- Major Modification to the study protocol, subject to full Board review
- Minor Modification to the study protocol, subject to expedited review at the level of the Chair
- Disapproval
II. STUDY PROTOCOL REVIEW

ii. The IRB Chair presents, if any, submissions for Continuing Review of study protocols previously approved through full Board and any Continuing Review Applications Forms (VMMC-IRB Form 3-C) or Progress Report (VMMC-IRB Form 3-B) ascertained to have altered previous risk-benefit assessment on the study protocol. For details on how continuing review applications are processed, refer to SOP III-6: Continuing Review Application. The IRB Chair calls for any of the following actions:

- Uphold original approval with no further action
- Request information
- Recommend further action

iii. The IRB Chair presents, if any, Final Report Forms (VMMC-IRB 3-D) of completed studies. For details on how Final Reports are processed, refer to SOP III-7: Final Reports. The IRB Chair calls the Members to deliberate on the summary of findings and related ethical issues, including post-study management of study participants, and decide on board action such as:

- Approved
- Request information
- Recommend further action

iv. The IRB presents, if any, report on Serious Adverse Events (SAEs) submitted by PI’s. If there are serious issues related to the report of the adverse events in studies involving already marketed drugs, such reports will be transmitted to the institution’s Therapeutic Committee for information and appropriate action. The details on how Serious Adverse Events Reports are processed are detailed in SOP III-5: Serious Adverse Event Reports. The IRB Chair then calls the IRB members to deliberate on the matter and decide on appropriate action such as:

- Uphold original approval with no further action
- Recommend further action
- Forward to Therapeutic Committee

v. The IRB Chair, if any, reports on Site Visits (VMMC-IRB Form 3-G: Checklist for Site Visit). For details on how Site Visits are conducted and reported, refer to SOP III-11: Site Visit. The IRB Chair calls the IRB Members to recommend any of the following action:

- Uphold original approval with no further action
- Request information
- Recommend further action
vi. The IRB Chair presents, if any, **Study Protocol Deviation or Non-Compliance Report (VMMC-IRB 3-E)** of study protocols previously approved through full board. Noncompliance may be in the form of noncompliance with post-approval requirements. For details on how Study Protocol Non-Compliance (Deviation or Violation) Records are processed, refer to **SOP III-8: Study Protocol Non-Compliance (Deviation or Violation) Report**. The IRB Chair calls on the IRB Members to recommend any of the following actions:

- Uphold original approval with no further action
- Request information
- Recommend further action

vii. The IRB Chair presents, if any, **Early Study Termination Application Forms (VMMC-IRB Form 3-F)** of study protocols previously approved through full board. For details on how Early Study Termination Applications are processed, refer to **SOP III-9: Early Study Termination Application**. The IRB Chair calls on the IRB Members to recommend any of the following actions:

- Approval
- Request information
- Recommend further action

viii. The IRB Chair presents, if any, **Study Participant Queries or Complaints (VMMC-IRB 3-J)**. For details on how queries are processed, refer to **SOP III-10: Study Participant Queries or Complaints**. The IRB Chair calls on the IRB Members to recommend any of the following actions:

- Uphold original approval with no further action
- Request information
- Recommend further action

i. **Review of Results of Expedited Review**

i. The IRB Chair reports all the study protocols and study protocol-related submissions that were processed under expedited review.

ii. The submissions are reported in the same sequence as full board review with similar corresponding actions (see **SOP II-5.6** and **SOP II-5.8**).

j. **Discussion of Other Matters**: Before closing the meeting, the IRB Chair calls for any non-study protocol matters that need attention or action, as the need arises.

k. **Meeting Adjournment**: With no other matters for discussion, the IRB Chair formally adjourns the meeting, with the time noted by the Secretariat Staff who is documenting the meeting.
II. STUDY PROTOCOL REVIEW

I. Collections and Storage or Disposal of Meeting Materials

i. The Secretariat Staff collects all meeting materials, including the documentation collected for the Minutes of the meeting; mindful that these materials are confidential and must be handled in accordance with **SOP IV-9: Maintenance of Confidentiality of Study Files** and VMMC-IRB Documents.

ii. The Secretariat Staff files all meeting materials that must be stored in the relevant study files in a manner prescribed by instruction found in **SOP IV-7: Active Files and SOP IV-8: Archived (Inactive/Completed/Terminated) Files**.

6. SPECIAL MEETINGS

a. Preparation for Conduct of Special Meeting

i. A special meeting may be called by the IRB Chair as he determines the need for such or as it may be proposed by majority of the IRB members.

ii. The decision to call a special meeting is based on the:

- Urgency of issues at hand such that, if delayed, it may have a negative impact on public benefit
- Occurrence of unexpected serious adverse events
- Life and death situations
- Other similar situations or occurrences

iii. The Secretariat informs the IRB members, and invited persons, whose presence is determined as vital that the special meeting will be called.

iv. Quorum is defined as the presence of 50% plus 1 of all members, described as follows:

- At least one scientific member
- A non-scientific member
- At least one member not connected with the VMMC
- If needed, a member/or invited guest with expertise on the item to be discussed

v. The meeting conducted in the same sequence as full board review with similar corresponding actions (see **SOP II-5.6** and **SOP II-5.8**)

vi. The collection and storage or disposal of special meeting materials follow the procedures described in the regular meeting (see **SOP II-5.12**)
III. POST-APPROVAL REVIEW

1. Objectives

2. Scope

3. Responsibilities

4. Work Flow
   a. Study Protocol Amendments
   b. Continuing Review
   c. Final Report
   d. Non-Compliance: Deviation/Violation
   e. Early Study Termination
   f. Queries from Various Stakeholders

5. Serious Adverse Events

6. Site Visit

Supersedes | 05
Version | 06

Authored By | Tito C. Atienza, MD; Annielyn Beryl Ong-Cornel, MD; Noemi R. Buensuceso, MD; Johann Giovanni P. Mea, MD; Ms. Ma. Brenda Grace G. Benitez

Version Date | 07 September 2016
Approved By | Dominador M. Chiong Jr., MD
Approval Date | 09 September 2016
## DOCUMENT HISTORY

<table>
<thead>
<tr>
<th>Author</th>
<th>Version</th>
<th>Date</th>
<th>Describe the Main Change</th>
</tr>
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</table>
| Dr. Tito C. Atienza  
Dr. Annielyn Beryl Ong-Cornel  
Ms. Mercedita A. Parazo | 1       | 15 May 2012 | 1st draft                                                                            |
| Dr. Tito C. Atienza  
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| Dr. Annielyn Beryl Ong-Cornel  
Ms. Ma. Brenda Grace G. Benitez | 5       | 10 May 2016 | 5th draft                                                                            |
| Dr. Annielyn Beryl Ong-Cornel  
Dr. Johann Giovanni P. Mea  
Ms. Ma. Brenda Grace G. Benitez | 6       | 07 Sep 2016 | 6th draft                                                                            |
1. OBJECTIVES

This SOP describes how the VMMC-IRB processes post approval submissions by the Principal Investigators. Depending on the nature of the submissions, they may be processed by either “expedited” or “full board” review. This chapter describes submission procedures, required forms, documentation of board action, communication of board action to the PI, and filing of results.

2. SCOPE

This SOP applies to all study protocol-related submissions after initial approval has been issued for the study protocol-related documents. These submissions include request for amendments, continuing review applications, final reports, adverse event reports, deviation/non-compliance/violation reports, study participant queries, and site visit reports.

3. RESPONSIBILITIES

It is the responsibility of the Principal Investigator to comply with post-approval requirements such as submission of amendment applications if there are changes in the study protocol or informed consent form, continuing review reports within the prescribed period, serious adverse events reports, study protocol non-compliance (deviation/violation) or early study termination reports, and final reporting.

The Secretariat Staff is responsible for receiving and processing all submissions, including questions, queries and/or complaints from research participants. IRB members are responsible for reviewing these post-approval submissions related to study protocols for which they are primary reviewers.

In the event that a Site Visit becomes necessary, it is the responsibility of the Chair to form a Site Visit Team, the responsibility of the assigned members to conduct the Site Visit and issue a report for presentation in the Board meeting, and responsibility of the Secretariat Staff to organize the Site Visit.
III. POST-APPROVAL REVIEW

4. STUDY PROTOCOL AMENDMENTS, CONTINUING REVIEW APPLICATIONS, FINAL REPORTS, NONCOMPLIANCE REPORTS, EARLY STUDY TERMINATION APPLICATION, AND PARTICIPANT QUERIES OR COMPLAINTS WORKFLOW

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>RESPONSIBILITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receive and manage documents submission pertaining to study protocol amendments/continuing review applications/final reports/noncompliance reports/early study termination applications/participant queries or complaints</td>
<td>Secretariat Staff</td>
</tr>
<tr>
<td>Submit documents to the IRB Chair to determine classification of review as expedited or full board</td>
<td>Secretariat Staff</td>
</tr>
<tr>
<td>IRB Chair, Vice-Chair reviews submissions classified as expedited review (Expedited Review at the level of the Chair); Primary reviewers review submissions classified as full board review</td>
<td>IRB Chair, Vice Chair and Members/Reviewers</td>
</tr>
<tr>
<td>Review full board study protocols in IRB meeting</td>
<td>Members</td>
</tr>
<tr>
<td>Communicate results to Principal Investigator</td>
<td>Secretariat Staff</td>
</tr>
<tr>
<td>Manage study protocol files</td>
<td>Secretariat Staff</td>
</tr>
</tbody>
</table>

DETAILED INSTRUCTIONS:

a. Study Protocol Amendment

i. Receipt and management of Study Protocol Amendment package upon Submission

1. A study protocol amendment is a written description of a change to a protocol, informed consent document or any other study related material. Favourable opinion or approval should be obtained from the VMMC-IRB before an amendment can be implemented in the conduct of a study.

2. A study protocol amendment is facilitated through the submission of VMMC-IRB Form 3-A: Study Protocol Amendment Submission Form/VMMC-IRB Form 3-K: Additional Study Material for Approval Form with the amended study protocol and/or protocol-related documents by the principal investigator to the VMMC-IRB, which issued the initial ethical clearance or approval to the study protocol. This comprises the Study Protocol Amendment Package.

3. Upon receipt of the Study protocol amendment package, the Secretariat Staff logs the date of submission on the Submission Database (VMMC-IRB Form 4-N).
III. POST-APPROVAL REVIEW

4. The Secretariat Staff checks the submission for completeness and gives a receiving copy of VMMC-IRB Form 3-A: Study Protocol Amendment Submission Form/VMMC-IRB Form 3-K: Additional Study Materials for Approval Form to the PI or his/her representative.

5. The Secretariat Staff logs the date of submission on the Submissions Database (VMMC-IRB Form 4-N).

6. The Secretariat Staff ensures that sufficient copies for the IRB Members have been submitted by the PI for full board submissions.

ii. Classification of Review by the IRB Chair

1. The Secretariat Staff sends the Study Protocol Submission Package to the IRB Chair immediately for classification of review as expedited or full board.

2. A full board review is necessary if the proposed study protocol amendment increases risk to study participants, as assessed by the IRB Chair, such as a change in study design, which may include but is not limited to:
   - Additional treatments or the deletion of treatments
   - Any changes in inclusion/exclusion criteria
   - Change in method of dosage formulation, (e.g. oral changes to intravenous)
   - Significant change in the number of subjects
   - Significant decrease or increase in dosage amounts

iii. Review by IRB Chair and Primary Reviewers

1. For submission under expedited review, action is finalized at the level of the IRB Chair within seven (7) calendar days.

2. Study protocol amendment packages subject to full board review received within the cut-off period of fifteen (15) days before the IRB meeting are sent to Primary Reviewers ten (10) to twelve (12) calendar days before the IRB meeting.

3. The Secretariat Staff places the study protocol amendment request on the agenda for the next IRB meeting.

4. The Primary Reviewers accomplish the review and return the signed VMMC-IRB Form 3-A: Study Protocol Amendment Submission Form/VMMC-IRB Form 3-K: Additional Material for Study Use for Approval Form on the day of the IRB meeting together with the Study Protocol Amendment Package.
III. POST-APPROVAL REVIEW

iv. Full board review of Study Protocol Amendment Submission Package

1. The Secretariat Staff distributes the following Study Protocol Amendment Package to IRB Members along with the meeting agenda:

   - VMMC-IRB Form 3-A: Study Protocol Amendment Submission Form/VMMC-IRB Form 3-K: Additional Study Materials for Approval Form
   - Amended study protocol or protocol-related documents with amended section clearly indicated
   - Other documents that have been affected by the revision

2. The documents are presented to IRB Members when amendments are deliberated on. For detailed information on the conduct of full board review of study protocol amendments, see SOP II-5.8.

v. Communication of results

1. The PI is notified of the VMMC-IRB decision noting which amended documents are approved for use through an action letter.

2. The PI may be required to modify or clarify the amendment, provide additional information, or submit additional documents.

3. If the amendment is approved, the PI is requested to submit an amended study protocol or protocol-related document with a new version number and date, if such has not been included in the Study Protocol Amendment Package yet.

vi. Files management

1. The Secretariat Staff receives the amended study protocol or protocol-related documents with a new version number and date and marks it as “approved”, then affixes the approval date.

2. The newly approved documents will supersede previous versions of the study protocol or protocol related document.

3. The IRB Secretary and IRB Chair sign VMMC-IRB Form 3-A: Study Protocol Amendment Submission Form/ VMMC-IRB Form 3-K: Additional Material for Study Use for Approval Form

4. The Secretariat Staff stores the signed and approved documents in the study protocol folder/binder.
III. POST-APPROVAL REVIEW

b. Continuing Review Application/Progress Report

i. Receipt and management of the Continuing Review Application/Progress Report package upon submission

1. Ethical clearance or approval is granted for a period of one year. After approval, continuing review is required to be done at least once a year, depending on the risk assessment of the study protocol. The continuing review process is facilitated through the submission of VMMC-IRB Form 3-C: Continuing Review Application Form or VMMC-IRB Form 3-B: Progress Report Form.

2. The expiration of approval granted to a protocol and the frequency of continuing review are indicated in VMMC-IRB Form 4-B: Approval Letter to the Study Protocol, which is provided to the PI upon approval of the study.

3. For ethical clearance or approval approaching the one-year expiry date and requiring a renewal or extension, it is advisable to submit VMMC-IRB Form 3-C: Continuing Review Application Form 45 days prior to expiry date.

4. The Secretariat Staff looks through the Study Protocol Database for the titles of study protocols that are due for continuing review at the end of the month.

5. The Secretariat Staff informs the respective PIs at least 30 days in advance of the due date of submission by fax, e-mail or letter and by sending the VMMC-IRB Form 4-O: Reminder Letter for Progress Report or Continuing Review Application.

6. The continuing review of a study protocol is initiated by the submission by the P.I. of the VMMC-IRB Form 3-C: Continuing Review Application Form, together with the synopsis of the study protocol and current informed consent documents. This comprises the continuing review application package.

7. The Secretariat Staff checks the application package for completeness and gives a receiving copy of the VMMC-IRB Form 3-C: Continuing Review Application Form to the PI or his/her representative.

8. The Secretariat Staff logs the date of submission on the Submissions Database (VMMC-IRB Form 4-N).

9. The Secretariat Staff ensures that sufficient copies for the IRB Members have been submitted by the PI for full board submissions.
III. POST-APPROVAL REVIEW

ii. Classification of Review by the IRB Chair

1. The IRB Chair classifies the submission as either full board or expedited review.

2. Unless otherwise dictated by circumstances in and specifics of the submitted information, the classification of continuing review as expedited or full board is based on the initial review classification (i.e. continuing review of full board study protocols is done through full board review).

iii. Review by IRB Chair and Primary Reviewers

1. The continuing review application package is sent together with a copy of the study protocol to the IRB Chair for expedited review study protocols and to the Primary Reviewers and all other IRB members. In Full Board Review, the other IRB members (who are not primary reviewers) are provided with the study protocols, too; their opinions are considered during the deliberation process in the IRB meeting.

2. For submissions under expedited review, action is finalized at the level of the IRB Chair within seven (7) calendar days.

3. Continuing review application packages subject to full board review received within the cut-off period of fifteen (15) days before the IRB meeting are sent to Primary Reviewers as soon as they are received by the IRB or at least ten (10) calendar days before the meeting.

4. The Secretariat Staff places the continuing review application on the agenda for the next IRB meeting.

5. The Primary Reviewers accomplish the review and return the signed VMMC-IRB Form 3-C: Continuing Review Application Form on the day of the IRB meeting together with review application package.

iv. Full Board Review of Continuing Review Application

1. The Secretariat Staff distributes the following continuing review application package to IRB Members along with the meeting agenda:
   - VMMC-IRB Form 3-C: Continuing Review Application Form
   - Study protocol synopsis
   - Current informed consent documents

2. The documents are presented to IRB Members when continuing review applications are deliberated on. For detailed information on the conduct of full board review of continuing review application, see SOP II-5.8.2.
v. Communication of Results

1. The PI is notified of the decision noting board action on the continuing review application through a letter.

2. The PI may be requested to provide additional information or submit additional documents. The Board may also recommend further action on the continuing review application.

vi. Files management

1. The IRB Chair and IRB Secretary sign VMMC-IRB Form 3-C: Continuing Review Application Form.

2. The Secretariat Staff stores the signed continuing review application documents in the study protocol file folder.

c. Final Report

i. Management of the Final Report Package Upon Submission

1. Upon completion of the study, the investigator should provide the VMMC-IRB with a summary of the outcome of the study, especially of the human participants who were involved, in a form of an end of study report.

2. The end of study reporting is facilitated through the submission of VMMC-IRB Form 3-D: Final Report Form, together with the documents deemed relevant by the investigator to clarify information indicated in the final report. This comprises the final report package.

3. The Secretariat Staff checks the submission for completeness and gives a receiving copy of VMMC-IRB Form 3-D: Final Report Form, to PI or his/her representative.

4. The Secretariat Staff logs the date of submission on the Submissions Database (VMMC-IRB Form 4-N).

ii. Classification of Review by the IRB Chair

1. The IRB Chair classifies the submission as either full board or expedited review.

2. Generally, classification of review of final report as expedited or full board is based on the initial review classification (i.e. final report of full board study protocols is done through full board review); unless otherwise indicated by the specifics or details of the submitted information.
III. POST-APPROVAL REVIEW

iii. Review by Primary Reviewers

1. The Secretariat Staff sends the final report package together with a copy of the study protocol to the Primary Reviewers.

2. For submission under expedited review, action is finalized at the level of the Primary Reviewers within seven (7) calendar days.

3. Final Report packages subject to full board review received within the cut-off period of two (2) weeks or fourteen (14) calendar days before the IRB meeting are sent to Primary Reviewers ten (10) to twelve (12) calendar days before the meeting.

4. The Secretariat Staff places the final report submission on the agenda for the next IRB meeting.

5. The Primary Reviewers accomplish the review and return the signed VMMC-IRB Form 3-D: Final Report Form to the Secretariat Staff on the day of the IRB Meeting together with the final report package.

iv. Full Board Review of Final Report

1. The Secretariat Staff distributes the following final report package to IRB Members along with the meeting agenda:

   - VMMC-IRB Form 3-D: Final Report Form
   - Relevant documents or attachments

2. The documents are presented to IRB Members when final reports are deliberated on. For detailed information on the conduct of full board review reports, see SOP II-5.8.3.

v. Communication of Results

1. The PI is notified of the IRB decision, noting IRB action on the final report through an action letter.

2. The PI may be requested to provide additional information or submit additional documents, in which case the final report may be accepted, but action regarding archiving may be deferred pending submission of results of the study.

3. If the final report is approved, the PI is informed of the following:

   - The study protocol is now classified as inactive.
III. POST-APPROVAL REVIEW

- Ethical clearance is deemed expired effective on the day of the IRB meeting.
- Study Protocol records will be made available for three (3) years in the archives after the expiration date.

vi. Files Management

1. The IRB Secretary and IRB Chair sign VMMC-IRB Form 3-D: Final Report Form

2. The Secretariat Staff stores the signed final report documents in the study protocol file folder, upon approval of the final report, when no further action is expected from the PI.

3. The Secretariat Staff enters relevant study protocol data into the Study Protocol Database to signify the end of study.

4. The Secretariat Staff transfers the study protocol folder to the inactive files. See SOP IV-8: Archived (Inactive/Completed/ Terminated) Files for management of inactive files.

d. Study Protocol Deviation and Noncompliance Report

i. Management of the Study Protocol Noncompliance Reports Upon Submission

1. The investigator should document, explain, and report to the VMMC-IRB any noncompliance from the approved protocol, whether minor or major, on a quarterly basis.

2. The investigator may implement a deviation from the protocol to eliminate an immediate hazard(s) to study subjects without prior VMMC-IRB approval, but must submit as soon as possible, a report of deviation or change, the reasons for it, and, if appropriate, an appropriate study protocol amendment(s).

3. Any protocol deviation which results in a serious adverse event should be reported to the IRB within 48 hours (following the timelines of reporting on SAE).

4. Reporting of protocol noncompliance is facilitated by the submission of VMMC-IRB 3-E: Study Protocol Deviation or Non-Compliance Report, together with a documents deemed relevant by the investigator to clarify information indicated in the report. This comprised the study protocol noncompliance report package.

5. The Secretariat Staff checks the submission for completeness and gives a receiving copy of VMMC-IRB 3-E: Study Protocol Deviation or Non-Compliance Report to the P.I. or his/her representative.
6. The Secretariat Staff logs the date of submission on the Submissions Database (VMMC-IRB 4-N).

   ii. Classification of Review by the IRB Chair

   1. The IRB Chair classifies the submission as either full board or expedited review.

   2. Minor or administrative deviations that do not affect the scientific soundness of the study protocol nor compromise the rights, safety, or welfare of human participants in the study are classified under expedited review.

   3. Major deviations or protocol violations that consist of persistent protocol noncompliance with potentially serious consequences that could put patients’ safety at risk or could critically affect data analysis are classified under full board review.

   iii. Review by IRB Chair And Primary Reviewers

   1. For submissions under expedited review, action is finalized at the level of the IRB Chair within seven (7) calendar days.

   2. Study Protocol noncompliance report packages subject to full board review received within the cut-off period of two (2) weeks or fourteen (14) calendar days before the IRB meeting are sent to Primary Reviewers ten (10) calendar days before the IRB meeting.

   3. The Secretariat Staff places the study protocol noncompliance report on the agenda for the next IRB meeting.

   4. The Primary Reviewers accomplish the review and return the signed VMMC-IRB 3-E: Study Protocol Deviation or Non-Compliance Report to the Secretariat on the day of the IRB meeting together with the study protocol noncompliance report package.

   iv. Full Board Review of Study Protocol Noncompliance Report

   1. The Secretariat Staff distributes the following Study Protocol Noncompliance Report package to IRB Members along with the meeting agenda:

      - VMMC-IRB 3-E: Study Protocol Deviation or Non-Compliance Report
      - Documents related to the deviation

   2. The documents are presented to IRB members when study protocol noncompliance reports are deliberated on. The Board deliberates on both the type and degree of noncompliance and take the appropriate action.
III. POST-APPROVAL REVIEW

3. The IRB Panel can suspend ethical clearance or subject recruitment until noncompliance issues are addressed.

4. The IRB Panel may opt to withdraw ethical approval under following circumstances:
   - Fraud
   - Unresolved serious safety issues

5. For detailed information on full board review of study protocol noncompliance, see SOP II-5.8.6.

v. Communication of Results

1. The PI is notified of the IRB decision, noting appropriate action on the study protocol noncompliance report through an action letter.

2. The PI may be requested to provide additional information, submit additional documents, or implement corrective action.

vi. Files Management

1. The IRB Secretary and IRB Chair sign the VMMC-IRB 3-E: Study Protocol Deviation or Non-Compliance Report.

2. The Secretariat Staff stores the signed study protocol noncompliance report documents in the study protocol file folder.

e. Early Study Termination Application

i. Management of Early Study Termination Application Upon Submission

1. An application for early study termination is submitted when a study approved by the VMMC-IRB is being recommended for termination before its scheduled completion. This is done when the safety of the study participant is doubtful or at risk and also upon the request of the PI or the sponsor owing to the existence of unresolvable but valid complaints or circumstances.

2. Early study termination is facilitated through the submission of VMMC-IRB 3-F: Early Study Termination Application Form, together with documents deemed relevant by the investigator to support or clarify information indicated in the application. This comprises the early study termination application package.

3. The Secretariat Staff checks the submission for completeness and gives a receiving copy of VMMC-IRB 3-F: Early Study Termination Application Form to the PI or his/her representative.
III. POST-APPROVAL REVIEW

4. The Secretariat Staff logs the date of submission on the Submissions Database (VMMC-IRB 4-N).

   ii. Classification of Review by the IRB Chair

   1. The IRB Chair classifies the submission as either full board or expedited review.

   2. Generally, classification of review early termination applications as expedited or full board is based on the initial review classification (i.e. final report of full board study protocols is done through full board review); unless otherwise indicated by the specifics of the submitted information.

   iii. Review by IRB Chair and Primary Reviewers

   1. For submissions under expedited review, action is finalized at the level of IRB Chair within seven (7) calendar days.

   2. Early study termination application packages subject to full board review received within the cut off period of 2 weeks or fourteen (14) days before the IRB meeting are sent to Primary Reviewers at least ten (10) calendar days before the meeting.

   3. The Secretariat Staff places the early study termination application on the next IRB meeting.

   4. The Primary Reviewers accomplish the review and return the signed VMMC-IRB 3-F: Early Study Termination Application Form to the Secretariat on the day of the IRB meeting together with the early study termination application package.

   iv. Full Board Review of Early Termination Application

   1. The Secretariat Staff distributes the following early study termination application package to IRB Members along with the meeting agenda:
      • VMMC-IRB 3-F: Early Study Termination Application Form
      • Documents related to the early study termination

   2. The IRB deliberates on the implications of the application on the rights, safety, and welfare of the study participants, including adapting specific provisions for continued protection and dissemination of specific information to the study participants.

   3. The IRB may request information from the PI or invite the PI for clarificatory interview.
III. POST-APPROVAL REVIEW

4. For detailed information on full board review of early study termination application, see SOP II-5.8.7.

v. Communication of Results

1. The PI is notified of the IRB decision, noting Board action on the early study termination application through an action letter.

2. The PI may be requested to provide additional information or submit additional documents.

3. If the application is approved, the PI is requested to accomplish the VMMC-IRB Form 3-D: Final Report Form.

vi. Files Management

1. The IRB Secretary and IRB Chair sign the VMMC-IRB 3-F: Early Study Termination Application Form.

2. The Secretariat Staff stores the early termination application documents in the study protocol file folder.

f. Study Participant Queries or Complaints

i. Management of Submitted queries or complaints

1. Participant queries and complaints are major considerations because they provide mechanisms that contribute to study participant empowerment.

2. The IRB personnel can receive a query or complaints form a participant. Participant queries or complaints are managed through the documentation of queries and complaints using the VMMC-IRB Form 3-J: Study Participant Queries or Complaints, which has to be accomplished by an IRB personnel.

3. The above form has to be accompanied by a written disposition from the complainant.

4. Each query or complaint received will be individually entered into VMMC-IRB Form 3-J: Study Participant Queries or Complaints, by respective IRB personnel, and then forwarded to the Secretariat for processing.

5. The Secretariat Staff logs the query or complaint into the Submissions Database (VMMC-IRB 4-N).
III. POST-APPROVAL REVIEW

ii. Classification of Review by IRB Chair

1. The IRB Chair classifies queries as either full board or expedited review depending on the nature of query and response needed.

2. Complaints are always classified under full board review.

iii. Review by IRB Chair and Primary Reviewers.

1. For submission under expedited review, action is finalized at the level of the IRB Chair within seven (7) calendar days.

2. Queries and complaints subject to full board review received within the cut-off period of 2 weeks or fourteen (14) days before the IRB meeting

3. The Secretariat Staff places the query or complaint in the agenda of the next IRB meeting

4. The IRB Chair or Primary Reviewers review the information entered in VMMC-IRB Form 3-J: Study Participant Queries or Complaints.

5. If necessary, the PI will be contacted to provide information that will address the query or complain.

iv. Full Board Review of Study Participant Query or Complaint

1. The Secretariat Staff distributes the completed VMMC-IRB Form 3-J: Study Participant Queries or Complaints to IRB members along with the meeting agenda.

2. The IRB deliberates on how best to address the study participant’s concerns and recommend a course of action.

3. The IRB may request information from the PI, invite the PI for clarificatory interview, or require corrective action.

4. For detailed information on full board review of study participant queries or complaints, see SOP II-5.8.8.

v. Communication of Results

1. The IRB responds to the study participant in writing after a course of action of appropriate response is identified whether through expedited or full board review.
III. POST-APPROVAL REVIEW

2. The PI may be requested to provide additional information or submit additional documents in order to fulfil the study participant’s concerns.

vi. Files Management

1. The IRB Secretary and IRB Chair sign the VMMC-IRB Form 3-J: Study Participants Queries or Complaints

2. The Secretariat Staff stores the early termination application documents in the study protocol file folder.

5. SERIOUS ADVERSE EVENT REPORTS WORKFLOW

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>RESPONSIBILITY</th>
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<tbody>
<tr>
<td>Receive and manage serious adverse event/s report package</td>
<td>Secretariat Staff</td>
</tr>
<tr>
<td>Submit serious adverse event report package to the IRB Chair and Primary Reviewers for review</td>
<td>Secretariat Staff</td>
</tr>
<tr>
<td>Discuss serious adverse event report/s in IRB meeting</td>
<td>IRB Members</td>
</tr>
<tr>
<td>Communicate results of discussion and deliberation to PI</td>
<td>Secretariat Staff</td>
</tr>
<tr>
<td>Manage SAE report/s and related files</td>
<td>Secretariat Staff</td>
</tr>
</tbody>
</table>

**DETAILED INSTRUCTIONS:**

**a. Management of the SAE report upon submission**

i. Serious adverse events are events temporally associated with the subject’s participation in research that meets any of the following criteria:

- Results in death
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred)
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in a persistent or significant disability/incapacity
- Results in a congenital anomaly/birth defect
- Any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject’s health and may require medical or surgical intervention to prevent one of the outcomes listed in this definition

ii. The P.I. must report serious adverse event occurring in a patient enrolled in a study approved by the VMMC within 48 hours of its occurrence or the knowledge of the PI or any team member of the same.
iii. The SAEs that must be reported to the IRB within 48 hours are those which occur in a patient enrolled in a study being conducted in the VMMC. A collated report of SAE’s which happen in other (national, international) sites should be reported to the IRB every three months.

iv. If warranted by concerns of patient safety, the IRB receives the right to obligate the P.I. to make more frequent reporting of SAEs that occur outside the VMMC site.

v. Reporting of SAEs is facilitated through the submission of VMMC-IRB Form 3-H: Serious Adverse Event/s Report, together with a documents deemed relevant by the investigator to clarify information indicated in the report. This comprises the study protocol serious adverse event/s report package.

vi. The Secretariat Staff checks the submission for completeness and gives a receiving copy of VMMC-IRB Form 3-H: Serious Adverse Event/s Report to the PI or his/her representative.

vii. The Secretariat Staff logs the date of submission on the Submissions Log (VMMC-IRB Form 4-N).

viii. The Secretariat Staff collates all the serious adverse event/s report and encodes data in the Serious Adverse Events Database.

b. Review by Primary Reviewers

i. Serious adverse event/s report packages received within the cut-off period of 2 weeks or fourteen (14) days before the IRB meeting are sent to the Primary Reviewers ten (10) calendar days before the IRB meeting.

ii. The Secretariat Staff places the serious adverse event report on the agenda for the next IRB meeting.

iii. The Primary Reviewers accomplish the review and return the signed VMMC-IRB Form 3-H: Serious Adverse Event/s Report to the Secretariat on the day of the IRB meeting together with the serious adverse event/s report package.

c. Full Board Meeting

i. The Secretariat Staff distributes the following serious adverse event/s report package to IRB Members along with the meeting agenda:
   - VMMC-IRB Form 3-H: Serious Adverse Event/s Report
   - Relevant documents or attachment
III. POST-APPROVAL REVIEW

ii. The documents are presented to IRB Members when serious adverse event/s report are discussed and deliberated on. For detailed information on the conduct of full board review of serious adverse event/s reports, see SOP II-5.8.4.

d. The IRB may recommend any of the following actions:

i. Study to continue, with no other action required

ii. Modification of the protocol to mitigate the newly identified risks; informed consent to be modified to include a description of newly recognized risks;

iii. Recommend implementation of additional procedures for protecting/safeguarding participants;

iv. If there are serious issues related to the report of the adverse events in studies involving already marketed drugs, such reports will be transmitted to the institution’s Therapeutic Committee for information and appropriate action.

v. Temporary suspension of enrolment of new participants

vi. Recommend suspension of the entire study

1. In cases where the IRB recommendation is for the study to be suspended, the matter should be brought to the attention of the Chief of Medical Professional Staff and the Medical Director.

2. The P.I./or sponsor will be given ample time resolve the problem of SAE’s before any further action (after the suspension) on the study can be made.

e. Communication of Results

i. The PI is notified of the IRB decision, noting IRB action on the Serious Adverse Event/s Report through a letter.

ii. The PI may be requested to provide additional information, submit additional documents, or implement corrective action.

f. Files Management

i. The IRB Secretary and IRB Chair sign the VMMC-IRB Form 3-H: Serious Adverse Event/s Report.

ii. The Secretariat Staff stores the signed serious adverse event/s report in the study protocol file folder.
III. POST-APPROVAL REVIEW

6. SITE VISIT WORKFLOW

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>RESPONSIBILITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Select study sites to visit</td>
<td>IRB Chair and Members</td>
</tr>
<tr>
<td>Notify PI of date of “site visit”</td>
<td>IRB Chair and IRB</td>
</tr>
<tr>
<td>Create Site Visit Team</td>
<td>IRB Chair and IRB</td>
</tr>
<tr>
<td>Conduct Site Visit</td>
<td>Site Visit Team</td>
</tr>
<tr>
<td>Present findings during IRB meeting</td>
<td>IRB Chair</td>
</tr>
<tr>
<td>Communicate Results of Site Visit and subsequent IRB action to PI</td>
<td>Secretariat Staff</td>
</tr>
<tr>
<td>Manage Site Visit documents</td>
<td>Secretariat Staff</td>
</tr>
</tbody>
</table>

DETAILED INSTRUCTIONS:

a. Selection of Study Sites

i. Study sites may be selected for Site Visits based on the following criteria

- A study considered a high-risk one.
- Frequent non-submission or failure to submit continuing review requirements
- Reports of major protocol noncompliance or deviations
- Significant number of serious adverse events
- Reports of complaints from study participants

ii. A decision for Site Visit is deliberated on during a full board meeting of the IRB.

b. Notification of PI of Date of Site Visit

i. The IRB Chair, through the Secretariat, informs the PI at least two (2) weeks before the scheduled visit through a letter. A copy of VMMC-IRB Form 3-G: Site Visit Report Form is attached to this letter.

ii. The letter provides Site Visit schedule details and instructions on what the PI needs to prepare such as documents and files that will be used for the Site Visit, as well as orderly preparation of the site.

c. Creation of a Site Visit Team

i. A Site Visit Team is organized for each site visit.

ii. The members of this team are assigned by the IRB Chair.
III. POST-APPROVAL REVIEW

iii. The Site Visit Team should be composed of at least three (3) people: two (2) of the three (3) primary reviewers and another IRB member who is not a primary reviewer.

iv. Each member of the Site Visit Team are informed of their assignment through the issuance of VMMC-IRB Form 3-G: Notice of Site Visit.

v. The Secretariat Staff prepares a Study Visit Package for each members of the Site Visit Team, inclusive of the VMMC-IRB Form 3-G: Site Visit Report Form and a copy of the approved study protocol and related documents.

vi. The Site Visit Team prepares for the activity by reviewing the contents of the study file and the requirements of VMMC-IRB Form 3-G: Site Visit Report Form.

d. Conduct of Site Visit

i. Upon arrival in the study site, the Site Visit Team uses VMMC-IRB Form 3-G: Site Visit Report Form to do the following:

- 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 staff to explain the informed consent process
- Review the post-approval documents and verify if the site is using the most recently approved version, or that these have been approved
- Verify security, privacy, and confidentiality of the documents at the study site
- Observe facilities in the study site
- Make an overall determination of the protection of the rights, safety, and welfare of human participants in the study

ii. At the end of the visit, the Site Visit Team will:

- Discuss the findings with the research team
- Solicit feedback

e. Presentation of Findings at IRB meeting

i. One of the members of Site Visit Team completes VMMC-IRB Form 3-G: Site Visit Report Form which should reflect the consensus opinion of the Site Visit Team members, and submits it to the Secretariat not later than seven (7) calendar days after the Site Visit.

ii. The Secretariat Staff logs the date of submission on the Submissions Log (VMMC-IRB Form 4-N).

iii. The Secretariat Staff places the Site Visit Report in the agenda of the next IRB meeting.
III. POST-APPROVAL REVIEW

iv. During the meeting, the Secretariat Staff distributes the completed VMMC-IRB Form 3-G: Site Visit Report Form to IRB members along with the meeting agenda.

v. The IRB deliberates on the implications of results of the Site Visit on the rights, safety, and welfare of the study participants; and makes an overall determination of protocol compliance in the study site.

vi. For detailed information on full board review of Site Visit Reports, see SOP II-5.8.5.

f. Communication of Results

i. The PI is notified of the IRB action or recommendations through a letter.

ii. The PI may be requested to provide additional information, submit additional documents, or implement corrective action.

g. Site Visit Files Management

i. The Primary Reviewer, IRB Secretary and IRB Chair sign the VMMC-IRB Form 3-G: Site Visit Report Form.

ii. The Secretariat Staff stores the Site Visit documents in the study protocol file folder.
IV. DOCUMENTATION AND ARCHIVING

1. Objectives

2. Scope

3. Responsibilities

4. Minutes of the Meeting

5. Protocol Communication Records

6. Administrative Records

7. Active Files

8. Archived (Inactive/Completed/Terminated) Files

9. Confidentiality of Study Files and VMMC-IRB Documents
## IV. DOCUMENTATION AND ARCHIVING

### DOCUMENT HISTORY

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<td>30 Nov 2012</td>
<td>Completion and Finalization of VMMC-IRB Forms</td>
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1. OBJECTIVES

This SOP describes how the VMMC-IRB manages documentation and communication of the review process, such as:

(1) how the minutes of the meetings are to be prepared, used, distributed, and filed;

(2) how to ensure proper completion, distribution, and filing of written study protocol- or review-process-related communication

(3) how administrative records and IRB administrative documents (exclusive of study protocol files) are processed, stored, or disposed of;

(4) how active and inactive or archived study protocol files (including amendments) are maintained; and

(5) how original documents and copies of documents are handled in order to protect confidentiality of documents.

2. SCOPE

This SOP applies to the minutes of the meeting, all communication records related to study protocols with VMMC-IRB approval or undergoing IRB review; to administrative documents, active study protocol files, and inactive study protocol files that are retained or archived for at least three (3) years after completion of the research so that the records are accessible for auditors and inspectors. This SOP applies to all kinds of handling, distribution, and storage of submitted study protocols, IRB documents, and correspondences.

3. RESPONSIBILITIES

The Secretariat Staff, under the supervision of the IRB Secretary, has the primary responsibility for study protocol and administrative documentation and archiving. The IRB Chair is responsible for final approval of documents prior to archiving.
IV. DOCUMENTATION AND ARCHIVING

4. MINUTES OF THE MEETING WORKFLOW

<table>
<thead>
<tr>
<th>ACTIVITY</th>
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<td>Prepare the template of the Minutes of the Meeting</td>
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<tr>
<td>Prepare draft of Minutes</td>
<td>Secretariat Staff, IRB</td>
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<td>Secretary</td>
</tr>
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<td>Approved the Minutes</td>
<td>IRB Chair and IRB</td>
</tr>
<tr>
<td>↓</td>
<td>Secretary</td>
</tr>
<tr>
<td>Store the approved Minutes</td>
<td>Secretariat Staff</td>
</tr>
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</table>

**DETAILED INSTRUCTIONS:**

a. **Preparation of the Template of the Minutes of the Meeting**

i. The IRB Secretary and Secretariat Staff uses the **VMMC-IRB Form 4-A. Format of the Minutes of the Meeting** to organize a template of the minutes ahead of the meeting date.

ii. All the relevant identifying information should be filled out such as standard text in the regular sections and relevant study protocol information.

iii. The minutes of the meeting is generated as the meeting progresses. The Secretariat Staff in charge of documentation notes all boards opinions and actions in all specific sections of the agenda, as the agenda is developed and discussed, with respective reasons in the case of study protocol-related actions.

b. **Preparation of the Draft of the Minutes**

i. Opinions and actions included in the minutes are collective in nature and need not to be attributed to specific members.

ii. The Secretariat Staff in charge of documentation submits complete draft of the minutes to the IRB Secretary within seven (7) days after the meeting for form and content corrections and finalization. The finalized draft is sent to the IRB Chair immediately for approval.

iii. The following information must be indicated in the minutes:
   - Date and venue of meeting
   - Members attendance (members present and absent)
   - Guests and observers attendance
   - Time when the meeting was called to order
   - Presiding officer
   - Items discussed per Meeting Agenda
   - Name and signature of person who prepared the Minutes
IV. DOCUMENTATION AND ARCHIVING

- Date of completion
- Name and signature of the IRB Secretary to indicate that the contents have been verified and corrected
- Name and signature of the IRB Chair to indicate approval
- Date of approval by the IRB Chair

c. Approval of the Minutes

i. The IRB Chair approved the Minutes by affixing his/her signature and the date the minutes was signed.

ii. Upon approval of the minutes, the contents of the Conclusions and Recommendations section (per study protocol discussed) are transferred into:

1. Approval letter a study protocol

2. Action letter or notification letter in response to specific kind of application submitted to the IRB

   a. VMMC-IRB Form 4-C: Action Letter to Study Protocol Submissions/Resubmissions/Amendments

   b. VMMC-IRB Form 4-D: Letter for Clarificatory Interview

   c. VMMC-IRB Form 4-E: Approval Letter for Study Protocol Amendment Request

   d. VMMC-IRB Form 4-F: Notification Letter (Request Information) to Continuing Review Application/Final Report/Deviation/Site Visit

   e. VMMC-IRB Form 4-G: Archiving Notification

   f. VMMC-IRB Form 4-M: Notification Letter (Uphold Approval) for Continuing Review Application, Deviation/Non-Compliance/Violation Report/SAE or SUSAR Report/Site Visit Report

   g. Certification of Board Action (VMMC-IRB Form 4-L) is issued to study protocols of clinical trial

d. Storage of the Minutes

i. The Secretariat Staff files the original copy of the Minutes in the Minutes Folder

ii. The Secretariat Staff makes copies of the minutes approved by the IRB Chair.
iii. The Minutes approved by the IRB Chair is distributed to the members within 3 weeks after the meeting.

iv. The approved minutes will be presented in the next full board meeting for approval.

5. STUDY PROTOCOL COMMUNICATION RECORDS WORKFLOW

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>RESPONSIBILITY</th>
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</thead>
<tbody>
<tr>
<td>Sort all communication received and issued by the VMMC-IRB</td>
<td>Secretariat Staff</td>
</tr>
<tr>
<td>Record the details of the communication</td>
<td>Secretariat Staff</td>
</tr>
<tr>
<td>Store communication files</td>
<td>Secretariat Staff</td>
</tr>
</tbody>
</table>

**DETAILED INSTRUCTIONS:**

a. Sorting of all communication received and issued by the VMMC-IRB

i. Communications can come in the form of letters, official memoranda, or emails.

ii. The Secretariat Staff sorts all communication received and prepares them for recording.

b. Recording of the Details of the Communication

i. Study protocol-related communications received by the VMMC-IRB are recorded in the *Submissions Log (VMMC-IRB 4-N)*. This form is updated as each submission is received. The record should contain, but not limited to, the following:

- Date Received
- Study Code
- Title
- Principal Investigator
- Submitting Person
- Receiving Person
- Date of Document
- Type of Submission
- Content of Submission
- Action Taken by IRB
- Further Action Required
c. Storage of Communication Records

i. Upon completion of the Submission Log (VMMC-IRB Form 4-N) the Secretariat Staff files a copy of the communication in the study file.

ii. The Secretariat Staff then writes in the protocol folder contents index as each communication is filed.

6. ADMINISTRATIVE RECORDS WORKFLOW

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>RESPONSIBILITY</th>
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</thead>
<tbody>
<tr>
<td>Compile administrative documents and/or records</td>
<td>Secretariat Staff/ Members/IRB Chair</td>
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<tr>
<td>∴</td>
<td></td>
</tr>
<tr>
<td>Sort and store documents</td>
<td>Secretariat Staff</td>
</tr>
<tr>
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<td></td>
</tr>
<tr>
<td>Dispose unnecessary copies</td>
<td>Secretariat Staff</td>
</tr>
</tbody>
</table>

DETAILED INSTRUCTIONS:

a. Compilation of Administrative Records

i. The Secretariat Staff maintains administrative documents not related to specific study protocols, but used in daily operation of the VMMC-IRB such as:

- Reference materials and guidelines
- Standard Operating Procedures
- Communication issued to and received from persons other than principal investigators, on matters that are not related to any study protocols
- VMMC-IRB members and staff files (CVs, Appointment letters, Signed Confidentiality Agreement and Conflict of Interest Disclosure (VMMC-IRB Form 1-D), Training Records (VMMC-IRB Form 1-E), Certificates of Training
- Forms

ii. These documents are maintained separately from study protocol-related documents.

b. Sorting and Storage of Documents

i. The Secretariat Staff labels and files administrative documents sequentially.

ii. Guidelines are filed numerically by subject and by subject alphabetically.

iii. SOP Manuals are filed chronologically.

iv. Important communications are filed in the communications folder and recorded chronologically in the Submissions Log (VMMC-IRB Form 4-N).
IV. DOCUMENTATION AND ARCHIVING

v. Members’ and staff files are filed alphabetically by last name.

vi. Only the most recently updated Curriculum Vitae (VMMC-IRB Form 1-C) are filed in the individual member’s or staff’s file.

vii. Signed Confidentiality Agreement and Conflict of Interest Disclosure (VMMC-IRB Form 1-D) and training certificates are filed chronologically under every member’s or staff’s file.

viii. Training Records (VMMC-IRB Form 1-E) must be updated as each training certificate is submitted by the member or staff for filing.

ix. Active VMMC-IRB blank forms are kept in individually labelled folders or envelopes. The folders or envelopes are files numerically with a list or index of forms written as:

- Form number
- Subject of form

c. Disposal of Unnecessary copies

i. Guidelines and references that have been superseded or outdated for three (3) years are removed from the files and disposed of properly.

ii. Removed document files are shredded and permanently deleted from physical files.

7. ACTIVE FILES WORKFLOW

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>RESPONSIBILITY</th>
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</thead>
<tbody>
<tr>
<td>Create a coding system for active files</td>
<td>VMMC-IRB</td>
</tr>
<tr>
<td>Organize the contents of the active study files</td>
<td>Secretariat Staff</td>
</tr>
<tr>
<td>Maintain the active study files</td>
<td>Secretariat Staff</td>
</tr>
</tbody>
</table>

DETAILED INSTRUCTIONS:

a. Creation of Coding System for Active Study Files

i. Active files are study protocols that have been received by the VMMC-IRB Secretariat and are either undergoing review (full board or expedited) or has been approved by the respective VMMC-IRB.
iv. Active study files are given a control number upon receipt by the IRB. The control number is coded as follows VMMC-YYYY-NNN where YYYY represents the year of the study protocol was submitted for review and NNN represents the chronological or sequential study protocol number (as it is received by the IRB Secretariat). NNN begins with 001 at the beginning of each year.

iii. The assigned control number code should appear permanently on the study protocol folder.

b. Organization of Contents of Active Study Files

i. Study files are encoded into the Study Protocol Database, which contains the following information:

- Control No.
- Study Title & No.
- Principal Investigator
- Sponsor
- Primary Reviewers
- Date Received
- Date of VMMC-IRB Review
- Date of Resubmission
- Date of Approval
- Date of Progress Report Submission
- Date of Continuing Review Application
- Date of Submission of Amendment(s)
- Date of Study Closure/Termination
- Status

ii. The Secretariat Staff puts study protocol files in file folders upon processing of the submission of the study protocol, ensuring that one folder contains documents for one study protocol and labelled with the title and code of the study protocol.

iii. Folders are then kept in secured cabinets labelled as “Active Files”.

iv. Cabinets labelled as “Active Files” should contain study file folders classified as “active”.

v. A study file folder contains the following documents, as applicable:

- 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
- Board action in the form of excerpts from minutes
- Amendment reports
c. **Maintenance of Active Study Protocol Files**

i. The Secretariat Staff files all the aforementioned documents in the study folder as they come.

ii. The Secretariat Staff stamps the receiving date on all documents before putting them in the folders.

iii. All Active File Folders are maintained in the “Active Files” cabinet until the **Final Report Form (VMMC-IRB Form 3-D)** is approved by the VMMC-IRB.

iv. The Secretariat Staff maintains Active Files cabinets under the supervision of the IRB Secretary.

8. **ARCHIVED (INACTIVE/COMPLETED/Terminated) FILES WORKFLOW**

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<thead>
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<th>ACTIVITY</th>
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<td>Manage completed/inactive/terminated study files</td>
<td>Secretariat Staff</td>
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<tr>
<td>Sort administrative documents to be archived</td>
<td>Secretariat Staff</td>
</tr>
<tr>
<td>Establish archived documents retrieval process</td>
<td>Secretariat Staff</td>
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</table>

**DETAILED INSTRUCTIONS:**

a. **Management of Archived (inactive/completed/terminated) Study Files**

i. Archived (inactive/completed/terminated) study files are either:
   - Study protocols with approved (by the VMMC-IRB) final reports, or
   - Study protocols declared Inactive by the Board if no communication is received from the study team for a period of twelve months
   - Study protocols submitted to the IRB but withdrawn by the PI or sponsor before approval is obtained
   - Study protocols submitted to and approved by the IRB but withdrawn by P.I. or sponsor before actual study start
iv. Upon approval of the **VMMC-IRB Form 3-D: Final Report Form**, the Secretariat Staff removes the contents of the entire file form the active study filing area and verifies that all documents are present in an organized manner.

v. Correspondingly, the data about the study and the year when archive should be entered on the Study Protocol Database.

### b. Sorting of Archived Administrative Documents

i. The Secretariat Staff should perform inventories of miscellaneous administrative documents yearly.

Administrative documents that are related to any fund or money released by the IRB are required to be archived in a manner that allows easy retrieval for audit purposes. These include documents that specify issuance of honorarium, receipt of paid institutional fee (money which is passed or directly to the institution’s Cash Section), approved annual budget and similar expense reports. One set of such documents are stored in the appropriate storage container/cabinet for archived administrative files.

ii. Unnecessary copies are disposed of accordingly (see section 6.3 above).

### c. Retrieval of Documents

i. Only authorized VMMC-IRB Secretariat Staff can retrieve documents either from active study files or from the archives.

ii. Active or inactive study files can be borrowed, upon written request by the PI or the VMMC-IRB personnel, and only for room use.

iii. A **Borrowers Log (VMMC-IRB 4-I)** is placed in a pocket on the study file folder cover, and contains the following information:

- Study file code
- Study title
- Date when borrowed
- Borrower
- Signature of borrower
- Signature of Secretariat Staff upon return of document to file box
9. MAINTAINING CONFIDENTIALITY (OF STUDY FILES AND VMMC-IRB DOCUMENTS) WORKFLOW

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<th>ACTIVITY</th>
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<td>Request access to VMMC-IRB documents</td>
<td>Members, Non-Members</td>
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<td>Reproduce confidential documents</td>
<td>Secretariat Staff</td>
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<tr>
<td>Maintain log of copies issued</td>
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DETAILED INSTRUCTIONS:

a. Classification of Documents as Confidential

i. Access to confidential documents is restricted by the VMMC-IRB to members and staff, but limited access can be provided to non-members who have a legitimate purpose to access the documents.

ii. The VMMC-IRB considers the following as confidential:
   - Study protocols
   - Study protocols-related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)
   - Minutes of meetings
   - Decisions, action letters/notification of VMMC-IRB decision, approval letters
   - Study protocol-related communications

b. Access to Confidential VMMC-IRB Documents

i. All IRB members and the staff with a signed Confidentiality Agreement and Conflict of Interest Disclosure (VMMC-IRB Form 1-D) can have access to IRB confidential documents upon request.

ii. Non-members can access specific documents upon formal request and completion/signing of Confidentiality Agreement for Non-Members Requesting Copies of VMMC-IRB Documents (VMMC-IRB Form 4-J). The form requires the approval of the IRB Chair. Regulatory authorities have full access to VMMC-IRB files provided it is within said authorities’ mandate, and the request made in advance (at least 30 days notice) to make the files available.

iii. All requests for access are recorded by the Secretariat Staff in the Log of Request for Copies of Documents (VMMC-IRB Form 4-K) before the documents are releases.
c. Reproduction of Confidential Documents

i. The request to make copies of any confidential documents should have been made in advance and should be approved by the IRB Chair.

ii. The Secretariat makes only the exact number of copies requested.

iii. The recipient signs for the copies requested in the Log of Request for Copies of Documents (VMMC-IRB Form 4-K) upon receipt of the copies.

d. Maintenance of Log of Copies

i. The Secretariat Staff ensures the diligent recording of all document copies issued in the Log of Request for Copies of Documents (VMMC-IRB Form 4-K)

ii. This log is filed in a separate folder labelled Log of Copies Issued.
STANDARD OPERATING PROCEDURES

V. PREPARING STANDARD OPERATING PROCEDURES (SOPS)

1. Objectives

2. Scope

3. Responsibilities

4. Preparing Standard Operating Procedures (SOPs)

5. Writing and Reviewing of new SOP

6. Presentation of new/revised SOP

7. Decision of VMMC-IRB Action

8. Approval

9. Distribution and Storage
## V. PREPARING STANDARD OPERATING PROCEDURES (SOPS)

### DOCUMENT HISTORY

<table>
<thead>
<tr>
<th>Author</th>
<th>Version</th>
<th>Date</th>
<th>Describe the Main Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Tito C. Atienza</td>
<td>01</td>
<td>30 Dec 2012</td>
<td>1st draft</td>
</tr>
<tr>
<td>Dr. Tito C. Atienza   Dr. Annielyn Beryl Ong-Cornel   Ms. Ma. Brenda Grace G. Benitez</td>
<td>01</td>
<td>30 Sep 2013</td>
<td>2nd draft: Completion of appendices (list of forms, acronyms, glossary, references)</td>
</tr>
<tr>
<td>Dr. Tito C. Atienza   Dr. Annielyn Beryl Ong-Cornel   Ms. Ma. Brenda Grace G. Benitez</td>
<td>01</td>
<td>18 Oct 2013</td>
<td>Final Version approved and ratified in the VMMC-IRB Workshop/SOP Forum</td>
</tr>
<tr>
<td>Dr. Tito C. Atienza   Ms. Ma. Brenda Grace G. Benitez</td>
<td>4</td>
<td>11 Nov 2014</td>
<td>4th draft</td>
</tr>
<tr>
<td>Dr. Tito C. Atienza   Dr. Noemi Buensuceso   Ms. Ma. Brenda Grace G. Benitez   Dr. Annielyn Beryl Ong-Cornel</td>
<td>5</td>
<td>10 May 2016</td>
<td>5th draft</td>
</tr>
<tr>
<td>Dr. Annielyn Beryl Ong-Cornel   Dr. Johann Giovanni P. Mea   Ms. Ma. Brenda Grace G. Benitez</td>
<td>6</td>
<td>07 Sep 2016</td>
<td>6th draft</td>
</tr>
</tbody>
</table>
1. **OBJECTIVES**

The Standard Operating Procedure (SOP) defines the process for writing, reviewing, distributing, amending, and storing VMMC-IRB SOPs.

2. **SCOPE**

This SOP applies to any item in the VMMC-IRB SOP and their amended versions as published and distributed by the VMMC-IRB.

3. **RESPONSIBILITIES**

The VMMC-IRB Chair and Vice-Chair are jointly responsible for ascertaining the need for new SOPs and amendments to existing ones based on changes in international and national guidelines and policies or requests from various stakeholders including VMMC-IRB Members. The VMMC-IRB Chair is responsible for designing an SOP Team, which drafts new SOPs and amends them as needed. The team is responsible for proposing design and format as well as the substantial contents of the SOP. VMMC-IRB members are responsible for consensus action on the proposed SOP, the outcome of which is endorsed by the VMMC-IRB Chair to the Chief of Medical Professional Staff for approval. The Chief, Medical Professional Staff is responsible for the final approval of all SOPs. The VMMC-IRB Secretariat Staff is responsible for storing and distribution.
4. PREPARING STANDARD OPERATING PROCEDURES (SOPS)

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>RESPONSIBILITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design SOP format, coding and layout</td>
<td>SOP Team</td>
</tr>
<tr>
<td>Write new/review existing SOP</td>
<td>SOP Team</td>
</tr>
<tr>
<td>Present new/revised SOP to the VMMC-IRB</td>
<td>VMMC-IRB Chair</td>
</tr>
<tr>
<td>Decide on VMMC-IRB action</td>
<td>VMMC-IRB Members</td>
</tr>
<tr>
<td>Approved new/revised SOP</td>
<td>Chief, Professional Staff, VMMC</td>
</tr>
<tr>
<td>Distribute and store new SOP</td>
<td>Secretariat Staff</td>
</tr>
</tbody>
</table>

DETAILED INSTRUCTIONS:

a. Design of the Format, Coding (using an identifier), and layout

i. An SOP follows the format:

- **Number and version**, which follows the SOP on coding SOPs
- **Title**, which is descriptive of contents
- **Objectives**, which defines the purpose and intended outcome
- **Scope**, which defines the extent of coverage of the SOP and its limitations
- **Responsibilities**, which delineates tasking and accountabilities for SOP implementation
- **Workflow**, when necessary, which provides a graphic representation of the essential steps to implement the SOP
- **Detailed instructions**, which elaborates the steps outlines in the workflow
- **VMMC-IRB Form 5-D: Document History**, which tabulates the different version (from draft to final version) of the document by author, version, date, and description of main changes
- **Forms**, which are documents to be filled out or accomplished by different parties as required by the SOP, with a list of forms
- **References**, which lists the instruments use to draft the Guideline such as other SOPs, guidelines, or policies
- **Appendices**, which provide elaborations or clarifications of specific sections including glossary and list of abbreviations
V. PREPARING STANDARD OPERATING PROCEDURES (SOPS)

ii. Each SOP is alphanumerically coded: VMMC-IRB SOP XXX/YY-W-ZZZZ, where XXX is a three-digit number corresponding to the chapter, YY is a two-digit number identifying the version of the SOPs, and W is one-digit number identifying the version of SOP with minor changes in the SOP, and ZZZZ refers to the year the SOP was first drafted. YY (version) starts from 01 and W will be 0 if without change, 1 if with changes already. Thus, the SOP on writing of SOPs is identified with the code VMMC-IRB SOP 005/01-0-2012, signifying that this SOP can be seen in Chapter 5, it is the first version (005/01-1), and has minor changes, (05/01-0) as of 2012 (when it was first drafted).

iii. The layout of a typical SOP (VMMC-IRB Form 5-A: SOP Template) uses a header with the following elements:

- Institutional seal or logo
- Name of institution
- SOP code
- SOP title
- Effective date
- Page number
- SOP content

iv. The SOP is introduced by a cover page (VMMC-IRB Form 5-B: SOP Cover Page) laid out as a typical SOP page with the following additional items included:

- Summary content after the title
- Institutional contact details (address, telephone numbers, facsimile number, email address)
- Date of the previous version: if not applicable, the date of previous issue is indicated by “N/A” (not applicable)
- Name of the authors/editors
- Approval information such as approving authorities and offices

5. WRITING AND REVIEW OF NEW SOP

a. SOPs are issued by the VMMC-IRB in order to facilitate transparent, clear, and systematic implementation of its functions.

b. New SOPs may be issued in not less than three-year intervals; unless regulations on which these documents are based have significantly changes in the interim.

c. Existing SOPs are reviewed every three (3) years; unless situations or circumstances dictate more frequent review and revision or when the regulations on which these documents are based have significantly changed in the interim.
d. Any amendment or revision must be written and submitted to the VMMC-IRB Chair for compilation and processing by respective parties, such as VMMC-IRB Members, in preparation for the next round of SOP review.

e. A request for amendment or revision is accomplished by filling out VMMC-IRB Form 5-C: Request for Amendment of an SOP. The VMMC-IRB Chair is responsible for initial review of the request, procurement of relevant information, recommendation of further action as follows:

- Confirm need for amendment or revision, forward to SOP Team
- Request further information
- Forward to content expert for opinion

f. When the need for a new SOP has been identified and agreed on, the VMMC-IRB Chair will organize the writing process whereby a draft will be written by SOP Team designated by himself/herself. The draft is regarded as a consensus issuance by the SOP Team, and may be a result of consultation with other stakeholders prior to completion.

6. PRESENTATION OF NEW/REVISED SOP TO THE VMMC-IRB

a. The draft version is submitted by the SOP Team to the VMMC Chair

b. The VMMC-IRB Chair organizes an IRB forum, which is expected to be attended by majority of the IRB members.

c. The IRB Chair presents the new/revised SOP to the IRB during this forum and presides over deliberation.

7. DECISION OF VMMC-IRB ACTION ON NEW/REVISED SOP

a. The IRB members will deliberate on the proposed draft and arrive at a consensus action.

b. If a consensus cannot be achieved, the matter is put to a vote. Favourable action by voting requires a vote of two-thirds plus one of the members present in the meeting.

c. Action can be deferred if recommendations for further amendments or revisions are lodged during the forum, in which case, the IRB Chair will supervise the documentation of requested amendments or revisions and call for a subsequent meeting, no more than thirty (30) days from the date of this forum.
8. APPROVAL OF NEW/REVISED SOP FOR IMPLEMENTATION

a. Upon favourable action by VMMC-IRB, the approved SOP is endorsed by the IRB Chair to the Chief of Professional Staff, VMMC for final approval.

b. The approval is indicated by the dated signature of the Chief of Medical Professional Staff (CMPS), VMMC on the cover page of the document.

c. The effective date of the document is reckoned as the date when the Chief of Medical Professional Staff (CMPS), VMMC signs the document. However, in the interest of continuity of IRB work, SOP documents may be regarded as functionally approved as of the date of favourable action by the VMMC-IRB.

d. The printed copy of the approved SOPs will be distributed to VMMC-IRB Members and VMMC authorities (Hospital Director, Assistant Director, Chief of Medical Professional Staff, Administrative Officer) within thirty (30) days of approval by the Chief of Medical Professional Staff.

e. An electronic copy of the SOP will be published as soon as possible in the VMMC-IRB website.

9. MAINTAINING CONFIDENTIALITY (OF STUDY FILES AND VMMC-IRB DOCUMENTS) WORKFLOW

a. One (1) complete originally signed set of current SOPs is maintained by the VMMC-IRB Secretariat Staff, which can be reproduced as needed.

b. In case of amended or revised SOP documents, the old version will undergo archiving procedure by the Secretariat Staff. The word “SUPERSEDED” is stamped on all pages of one complete set of the old version, after which it is stored separately from the current version.

c. Superseded versions are indicated in the VMMC-IRB 5-D,2012: Document History of the new version by the Secretariat Staff prior to storage.
<p>| <strong>Adverse drug reaction (ADR)</strong> | In the pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established, all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase responses to medicinal product means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, that is, the relationship cannot be ruled out. Regarding marketed medicinal products, a response to a drug which is noxious and unintended and which occurs at doses normally used in human prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function. Current reporting required by the FDA in <a href="http://umis.doh.gov.ph/adverse">http://umis.doh.gov.ph/adverse</a>. See also adverse event, unexpected adverse event and suspected unexpected serious adverse reaction. |
| <strong>Adverse event (AE)</strong> | Any untoward or undesirable medical occurrence in a patient or participant in clinical investigation after use or administration of an investigational product. The AE may or may not be related to the investigational product. |
| <strong>Amendment to the protocol</strong> | A written description of a change(s) to, or formal clarification of a protocol and changes on any other supporting documentation made from the originally approved protocol by the research ethics review body after the study has begun. See protocol amendment. |
| <strong>Anonymized sample or data</strong> | Biological sample or data that cannot be linked to an identifiable person through destruction of that link to any identifying information about the person who provided the sample or data. |
| <strong>Approved Protocols</strong> | Protocols that have been reviewed by the VMM-IRB and approved without stipulations or after stipulations/recommendations by the IRB have been complied with. |
| <strong>Archives</strong> | A storage for completed studies, inactive files or terminated documents that have not been updated within the last five (5) years. |
| <strong>Assent</strong> | Authorization for one’s own participation in research given by a minor or another participant who lacks the capability to give informed consent. The assent is a requirement for research, in addition to consent, given by a parent or legal guardian. It is an agreement by an individual not competent to give legally valid informed consent like a child or cognitively impaired to participate in research. See also child’s assent |
| <strong>Assent forms</strong> | Forms asked of minor-aged children who are participants of a research or trial, aside from parent’s or legal guardian’s consent. The objectives of the study and procedures are explained to the child participants in a language understandable to them. See Chapter IV and IRB Form 3-C for additional information re “Assent”. |
| <strong>Bias</strong> | The systematic tendency of any factors associated with the design, conduct, analysis and evaluation of the results of a clinical trial to make the estimate of a treatment effect deviate from its true value. |</p>
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child's assent</td>
<td>An agreement or expressed willingness of a minor to take part in the research when a child cannot give full consent. Children often can understand some, but not all parts of a study. Assent is the child’s way of saying that he/she agrees to take part in the research to the degree that he/she understand it. It differs from consent since consent is the permission given by a parent or guardian to a child to take part in the research. Older children or youth may give their own consent if they are mature enough to completely or totally understand the research, and the consent or decision to participate is freely given with the premise that they are given enough information to make a choice and they understood the information provided to them.</td>
</tr>
<tr>
<td>Clinical trial</td>
<td>A planned scientific research or study among human volunteers to determine the effects of treatment or diagnostic test on their safety, efficacy, and its effect on quality of life. It is also a systematic study on pharmaceutical products in human subjects (including patients and other volunteers) in order to discover or verify the effects of and/or identify any adverse reactions to investigational products, and/or to study the absorption, distribution, metabolism, and excretion of the products with the object of ascertaining their efficacy and safety.</td>
</tr>
<tr>
<td>Compensation</td>
<td>Payment and/or medical care received or provided to subjects injured in research. Payment received by the research participants may include reimbursement for lost earnings, travel costs and other expenses incurred reimbursement for lost earnings, travel costs and other expenses incurred as a study participant, as recompense for inconvenience and time spent. It does not include renumeration for participating in the study.</td>
</tr>
<tr>
<td>Competence</td>
<td>Technically, a legal term, used to denote capacity to act on one’s own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice.</td>
</tr>
<tr>
<td>Completed Study</td>
<td>A study that was accomplished according to the protocol and where a final report of the study had been submitted and approved.</td>
</tr>
<tr>
<td>Confidentiality</td>
<td>The expectation from respondents and research participants that data or information relayed or communicated are kept secret. Also, the non-disclosure of IRB information and documents to other than an authorized individual.</td>
</tr>
<tr>
<td>Conflict of interest (COI)</td>
<td>A conflict of interest arises when a member(s) of the IRB holds interests with respect to specific applications for review that may jeopardize his/her ability to provide free and independent evaluation of the research focused on the protection of the research participants. Conflict of interests may arise when an IRB member has financial, material, institutional or social ties to the research. Potential conflicts of interest must be described and managed as per policy.</td>
</tr>
<tr>
<td>Deviation/non-compliance/</td>
<td>Occurs whenever the submitted and approved protocol is not complied with to the letter, or as approved.</td>
</tr>
<tr>
<td>violation</td>
<td></td>
</tr>
<tr>
<td>Glossary Term</td>
<td>Definition</td>
</tr>
<tr>
<td>----------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Diagnostic</td>
<td>Procedure or technique used in the identification of a disease or determination of the health status of an individual.</td>
</tr>
<tr>
<td>Direct benefits</td>
<td>Gain or advantage or good effect derived by a research subject immediately or closely arising from the use of an experimental substances or device. See also benefits.</td>
</tr>
<tr>
<td>Disapproval</td>
<td>A negative action of the IRB on the protocol. The study cannot be implemented if it has been disapproved by the Board.</td>
</tr>
<tr>
<td>Disclosure of data</td>
<td>The giving of information in connection with proposed research undertaking or the sharing of the results of the study especially as they pertain to the individuals or the family's health situation.</td>
</tr>
<tr>
<td>Discontinuation/Termination</td>
<td>The deed of terminating participation in a clinical trial by a research subject (dropout) earlier than the completion of all protocol-required terms. In some case, the discontinuation may be initiated by the investigator for a cause or inability to locate or follow up subject or by the sponsor.</td>
</tr>
</tbody>
</table>
| Document             | Hard copies of studies, proceedings, communications, that include the following:  
  - Study protocols and related documents (such as case report forms, informed consent, diary forms, scientific documents, report, records, expert opinion or reviews);  
  - IRB documents (SOPs, meeting minutes, advice and decisions);  
  - Correspondence with experts, auditors, study participants, principal investigators, officials of the VMMC or those of other related institutions, agencies and committees; or  
  - Any other forms of communications such as printed or written papers, hard copies, electronic mails (e-mail), faxes, audio or video tapes, etc.                                                                                                                                                                                                                                                                 |
| Drug                 | A substance used as medication or used in the diagnosis, cure, mitigation, treatment or prevention of disease.                                                                                                                                                                                                                                                                                                                                                                                   |
| Ethical clearance    | A certification that a research proposal has complied with ethical requirements; action of an ethics or institutional review committee on a research protocol that signifies approval and permission to proceed with the research. See also approval.                                                                                                                                                                                                                                                                 |
| Ethics review        | The evaluation of a research protocol by an ethics review committee to promote the safety and protection of the dignity of human participants. This is a systematic process by which this independent committee evaluates a study protocol to determine if it follows ethical and scientific standards for carrying out biomedical research on human participants. It checks if the protocol complies with the guidelines to ensure that the dignity, rights, safety and well-being of research participants are promoted. |
| Expedited approval   | An ERB approval granted only by the Chair of the IRB or a designated board member (not the full Board) for minor changes to current ERB-approved research activities and for research which involves no more than minimal risk.                                                                                                                                                                                                                                                  |
| **Expeditied review** | An ethics review of research protocol by the IRB chair or a designated voting member or subgroup of voting members rather than by the entire IRB. This is done for some research involving no more than minimal risk and maybe for minor changes in approved research, annual renewals of approved projects, approval of protocol amendments, research conducting health record review, and for confirming changes required by the ethics committee for approval of the protocol. |
| **Full board review** | Review of proposed research at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in non-scientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting and not by less than five (5) members. |
| **Good clinical practice (GCP) guidelines** | An international ethical and scientific quality standards for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with these standards provide public assurance that the rights, safety, and well-being of trial subjects are protected, consistent with the principles that have their origin in the International Declaration of Helsinki, and that the clinical trial data are credible (CPMP/ICH/135/95). These are standards and procedures for clinical trials that encompass the design, protocol approval, monitoring, termination, audit, analyses, reporting, and documentation of human studies. It defines the responsibilities and activities of the sponsor, principal investigators and monitor involved in the clinical trials. The GCP ensures that the studies are scientifically and ethically sound, and all the clinical properties of the product under investigation are properly documented. |
| **Guardian** | One who is legally responsible for the care and management of the person or property of an incompetent person or a minor or someone who can make important personal decisions in behalf of another person. |
| **High-risk group** | Social group known to have a high prevalence of a health problem because of shared environmental, occupational, nutritional or genetic factors including practices that contribute to ill-health. |
| **Incapacity** | A person’s mental status and means, inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Often used as a synonym for incompetence. |
| **Incompetence** | Technically, a legal term meaning inability to manage one’s own affairs. Often used as a synonym for incapacity. |
| **Independent consultant** | An expert who gives advice(s), comment(s) and suggestion(s) upon review of the study protocols with no affiliation to the institute(s) or investigator(s) proposing the research proposal. |
| **Indirect benefits** | An unintended or unlikely gain or advantage or good effect from participating in a research. |
## Informed consent
The process of obtaining approval to participate in an investigative study or permission to a medical intervention. Consent must be freely given in verbal, video or written form. An important part of the process is the adequacy, appropriateness, and timeliness of the information for decision-making; It is “a decision to participate in research, taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation.”

## Informed Consent Document (ICD) or Informed Consent Form (ICF)
A written, signed, and dated form confirming a competent participant’s willingness to voluntarily participate in a particular trial or research, after having been informed of all aspects that are relevant to the participant’s decision to participate and given time to reflect on the decision.

## Initial Review
A first time review of a new protocol for its technical completeness and ethical considerations. This is usually done by three to five individual reviewers of a team in advance of the full IRB meeting. Comments of the reviewers will be reported to the full Board meeting.

## Institutional Ethics Review Board
Ethics review committee organized in a particular institution to ensure that health research is conducted according to international ethical principles, national and institutional guidelines. This is an independent body constituted of medical, scientific, and non-scientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

## Investigator
A person responsible for the conduct of the clinical trial at a trial site. If trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and be called the principal investigator. It is a person responsible for the trial and for the rights, health and welfare of the subjects in the trial. The investigator should have qualifications and competence in accordance with local laws and regulations as evidenced by an up-to-date curriculum vitae and other credentials. Decision relating to, and to provisions of, medical or dental care must always be the responsibility of a clinically competent person legally allowed to practice medicine or dentistry. The investigator must be a qualified scientist who undertakes scientific and ethical responsibility, either on his/her behalf or on behalf of an organization, for the ethical and scientific integrity of a research project at a specific site group of sites. See principal investigator

## Minimal risk
A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.
<table>
<thead>
<tr>
<th><strong>Minors</strong></th>
<th>Person who have not yet reached the age of majority, 18 years old.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Monitor</strong></td>
<td>A person appointed by and responsible to the sponsor or contract research organization for monitoring and reporting progress of the trial and for verification of data (WHO, Guidelines for Good Clinical Practice for Trials of Pharmaceutical Products).</td>
</tr>
<tr>
<td><strong>Monitoring visit</strong></td>
<td>An action taken by the VMMC-IRB or its representatives which involves going to a study site to assess how the principal investigators and the institute are conducting researches, taking care of participants, recording data and reporting their observations, especially serious adverse events found during the studies.</td>
</tr>
<tr>
<td><strong>More that minimal risk</strong></td>
<td>Occurs when the participants in the course of the research would be exposed to more than a remote possibility of a “substantial or prolonged pain, discomfort, distress” or “clinically significant deterioration of a medical condition”</td>
</tr>
<tr>
<td><strong>Placebo</strong></td>
<td>A substance that is not biologically active, does not interact with other substances nor is it expected to affect the health status of an individual. It is an inactive pill, liquid, or powder that has no treatment value. In clinical trial, experimental treatments are often compared with placebos to assess the experimental treatment’s effectiveness. In some studies, the participants in the control group will receive a placebo instead of an active drug or experimental treatment.</td>
</tr>
<tr>
<td><strong>Primary reviewer</strong></td>
<td>A reviewer – member of the Institutional Review Board or ethics review committee to whom is assigned the function of full review of a study protocol and all submitted study materials with the aim of effecting a thorough review of them. The primary reviewer presents his/her review of the study protocol at the convened IRB meeting after which, discussion with other IRB members is made and finally, a vote for an action is taken.</td>
</tr>
<tr>
<td><strong>Principal investigator</strong></td>
<td>The chief or person primarily responsible for the implementation or a research project. See also investigator.</td>
</tr>
<tr>
<td><strong>Privacy</strong></td>
<td>The right or claim or state or ability or condition of an individual or group or institution to conceal or seclude or hide themselves or information about themselves and thus reveal or expose themselves selectively. It is a conceptual space defining the individual’s boundary as a person, intrusion of which is limited by human rights and by law. It is right to determine when, how, and to what extent information about someone is communicated to others.</td>
</tr>
<tr>
<td><strong>Protocol</strong></td>
<td>A document which states the background, rationale, and objectives of the trial (investigation, research, study) and describes its design, methodology, and organization including statistical considerations and the conditions under which it is to be performed and managed. The protocol should be dated and signed by the Principal Investigator.</td>
</tr>
<tr>
<td><strong>Protocol amendment</strong></td>
<td>A written description of change(s) to, or formal clarification of a protocol. See also amendment to protocol.</td>
</tr>
<tr>
<td>Glossary Term</td>
<td>Definition</td>
</tr>
<tr>
<td>---------------</td>
<td>------------</td>
</tr>
<tr>
<td><strong>Protocol approval by sponsor</strong></td>
<td>The affirmative action of the sponsor on the protocol development when the technical and ethical reviewers have finally approved all the changes of the protocol. This usually act as the signal for the submission of the protocol and the other required documents to an IRB, national regulatory authorities and research sites as applicable. <em>See also approval.</em></td>
</tr>
<tr>
<td><strong>Protocol package or protocol dossier</strong></td>
<td>Protocol plus accompanying communications, registration forms and other documents relevant to the protocol.</td>
</tr>
<tr>
<td><strong>Quorum</strong></td>
<td>Number of members required to act on any motion presented for action during a meeting. This is usually a one-half-plus-one majority.</td>
</tr>
<tr>
<td><strong>Regulatory requirements</strong></td>
<td>Necessary prerequisites for the approval and conduct of clinical trial by a national regulatory authority. For example, for pharmaceutical and biologic products, it means obtaining a “permit for clinical investigational use” which is a “registration document issued by the FDA for the purpose of allowing the conduct of Phase I, Phase II, and Phase III clinical trials of investigational biologic products in the country”.</td>
</tr>
<tr>
<td><strong>Rescue medication</strong></td>
<td>Quick-relief or fast-acting medications or procedure used to immediately manage or relieve symptoms when they occur.</td>
</tr>
<tr>
<td><strong>Research</strong></td>
<td>Organized set of activities intended to generate data that are generalizable into new knowledge, principle or technology. Investigative work undertaken on a systematic and rigorous basis using quantitative and qualitative methods to generate new knowledge.</td>
</tr>
<tr>
<td><strong>Research ethics committee</strong></td>
<td>An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favorable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.</td>
</tr>
<tr>
<td><strong>Research participants or subjects</strong></td>
<td>An individual who participates in a biomedical research project, either as the direct recipient of an intervention (e.g., study product or invasive procedure), as a control, or through observation. The individual may be a healthy person who volunteers to participate in the research, or a person with a condition unrelated to the research carried out who volunteers to participate, or a person (usually a patient) whose condition is relevant to the use of the study product or questions being investigated.</td>
</tr>
<tr>
<td><strong>Research protocol</strong></td>
<td>A document that provides the background rationale and objective(s) of a biomedical research project and describes its design, methodology and organization, including ethical and statistical considerations. Some of these considerations may be provided in other documents referred to in the protocol. <em>See also protocol.</em></td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
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<tr>
<td>Risk</td>
<td>The probability of discomfort or harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Risks to research participants must be justified by the anticipated benefits.</td>
</tr>
<tr>
<td>Risk factors</td>
<td>Variables or conditions that increase the risk or chances of disease or infection; determinants of disease development. See also risk.</td>
</tr>
<tr>
<td>Scientific review</td>
<td>Also called technical review, is the evaluation of the research protocol to ascertain scientific soundness and appropriateness of the objectives and design of the proposed study and the qualifications of the researcher. See also technical review.</td>
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</table>
| Serious adverse event | The adverse event is SERIOUS and should be reported when patient outcome is:  
  *Death* - if the death is suspected as being direct outcome of the adverse event  
  *Life-Threatening* - if the patient was at substantial risk of dying at the time of the adverse event or it is suspected that the use or continued use of the product would result in the patient’s death  
  *Examples*: Pacemaker failure; gastrointestinal hemorrhage; bone marrow suppression; infusion pump failure which permits uncontrolled free flow resulting in excessive drug dosing  
  *Hospitalization (initial or prolonged)* - if admission to the hospital or prolongation of a hospital stay results because of the adverse event  
  *Examples*: Anaphylaxis; pseudomembranous colitis; or bleeding causing or prolonging hospitalization  
  *Disability* - if the adverse event resulted in a significant, persistent, or permanent change, impairment, damage or disruption in the patient’s body function/structure, physical activities or quality of life  
  *Examples*: Cerebrovascular accident due to drug-induced hypercoagulability; toxicity; peripheral neuropathy  
  *Congenital Anomaly* – if there are suspicions that exposure to a medical product prior to conception or during pregnancy resulted in an adverse outcome on the child  
  *Examples*: Vaginal cancer in female offspring from diethylstilbestrol during pregnancy; malformation in the offspring caused by thalidomide  
  *Requires Intervention to prevent permanent impairment or damage* – Report if you suspect that the use of a medical product may result in a condition which requires medical or surgical intervention to preclude permanent impairment or damage to a patient  
  *Examples*: Acetaminophen overdose-induced hepatotoxicity requiring treatment with acetylcysteine to prevent permanent damage; burns from radiation equipment requiring drug therapy; breakage of a screw requiring replacement of hardware to prevent the malfunction of a fractured long bone
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<tr>
<th>Glossary Term</th>
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<td>Side effect</td>
<td>Undesired effect of a treatment which is either immediate or long-term.</td>
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<tr>
<td>Sponsor</td>
<td>An individual, a company, an institution or an organization which take responsibility for the initiation, management and/or financing of a clinical trial</td>
</tr>
<tr>
<td>Standard of care of treatment</td>
<td>Healthcare intervention or regimen that is generally accepted by health practitioners and experts as beneficial to an individual needing such care. Standard treatment is the treatment that is currently thought to be effective in medical practice.</td>
</tr>
<tr>
<td>Suspected unexpected serious adverse reaction (SUSAR)</td>
<td>A serious adverse reaction in research participants who were given a drug, that may or may not be dose related, but are not expected or anticipated since these reactions are not consistent with the current information about the medicinal product in question. This may occur during clinical trials or clinical care.</td>
</tr>
<tr>
<td>Standard Operating Procedure (SOP)</td>
<td>Detailed, written instructions, in a certain format, describing all activities and actions undertaken by an organization to achieve uniformity of the performance of a specific function. The aim of the SOPs and their accompanying checklist and forms is to simplify the organization and documentation of operation, while maintaining high standards of Good Clinical Practice.</td>
</tr>
<tr>
<td>Technical review</td>
<td>The process of examining, assessing or evaluating a research protocol by technical experts, seasoned researchers, statisticians and other relevant specialist or authority to ensure the scientific soundness and appropriateness of the objective and design of the study and the qualifications of the investigator(s). See scientific review.</td>
</tr>
<tr>
<td>Termination of the research</td>
<td>Ending or discontinuing a research study before its scheduled completion when the safety or benefit of the study participants is doubtful or at risk.</td>
</tr>
<tr>
<td>Trial-related expenses</td>
<td>Expenses incurred by the study participants related to their participation in a research study such as transportation, meals, loss of income.</td>
</tr>
<tr>
<td>Undue influence</td>
<td>An inappropriate power, pressure or control or domination which may be mental, moral or physical that deprives a person of freedom of judgment, choice and thus, substitutes another’s choice or desire in place of its own.</td>
</tr>
<tr>
<td>Unexpected adverse event</td>
<td>An adverse reaction that has not been anticipated, nor previously experienced, or observed, and is not consistent with the informed consent, information sheets or applicable product information in the investigator’s protocol or brochure, product information in the investigator’s protocol or brochure, product or package insert or summary of product characteristic. See also adverse event and serious adverse event.</td>
</tr>
<tr>
<td>Voluntary</td>
<td>Free of coercion, duress, or undue inducement; used in the research context to refer to a subject’s decision to participate (or to continue to participate) in a research activity.</td>
</tr>
<tr>
<td>Vulnerability</td>
<td>A substantial incapacity to protect one’s own interest owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member a hierarchical group.</td>
</tr>
<tr>
<td>Vulnerable subjects/participants/groups</td>
<td>Individuals or groups of individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. These are also classes of individuals who have characteristics that lessen their capacity to protect their own interests or promote their own welfare; These are “persons whose situation or characteristics may make them unable to provide free and informed consent to participate in research. This group includes children, institutionalized persons, those who have cognitive impairments, and those in a position of inferiority”</td>
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<tr>
<td>Withdraw</td>
<td>Decision of the subject or respondent or patient to continue participating</td>
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REFERENCES


5. Declaration of Helsinki


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