STANDARD OPERATING PROCEDURES

I. STRUCTURE AND COMPOSITION

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2. Scope
3. Responsibilities
4. Constitution and functions
5. Confidentiality/Conflict of Interest Agreement
6. Training of Members and Staff
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8. Compensation of Members and Consultants

Supersedes 02
Version 03
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 18 October 2013
Approved By Dominador M. Chiong Jr., MD
Approval Date 30 October 2013
## I. STRUCTURE AND COMPOSITION

### DOCUMENT HISTORY

<table>
<thead>
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<th>Author</th>
<th>Version</th>
<th>Date</th>
<th>Describe the Main Change</th>
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<td>Dr. Tito C. Atienza</td>
<td>1</td>
<td>15 May 2012</td>
<td>1st draft</td>
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<td>Dr. Noemi Buensuceso</td>
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<td>Dr. Tito C. Atienza</td>
<td>2</td>
<td>10 Jan 2013</td>
<td>1. Change of appointing body of members to Chief of Professional Staff</td>
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<td>Dr. Noemi Buensuceso</td>
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<td>2. Details on payment of honorarium of IRB Members and Independent Consultants (8.1)</td>
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<td>Ms. Perly-Ann P. Benigno</td>
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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

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 the 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).
I. STRUCTURE AND COMPOSITION

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, 2012], 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, 2012. *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 publicise 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

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
1. STRUCTURE AND COMPOSITION

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

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.

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,2012], 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

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>
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<tbody>
<tr>
<td>Prepare <a href="#">VMMC-IRB Form 1-D,2012. Confidentiality Agreement and Conflict of Interest Disclosure</a></td>
<td>Secretariat Staff</td>
</tr>
<tr>
<td>Accomplish <a href="#">VMMC-IRB Form 1-D,2012. Confidentiality Agreement and Conflict of Interest Disclosure</a></td>
<td>Chair, Vice-Chair, Secretary, Members, Secretariat Staff</td>
</tr>
<tr>
<td>Store Documents</td>
<td>Secretariat Staff</td>
</tr>
</tbody>
</table>
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,2012. 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,2012. 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 Chancellor 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,2012. 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.
I. STRUCTURE AND COMPOSITION

6. TRAINING OF VMMC-IRB MEMBERS AND PERSONNEL WORKFLOW

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>RESPONSIBILITY</th>
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<tbody>
<tr>
<td>Set training requirements</td>
<td>Chair</td>
</tr>
<tr>
<td>Find available training, seminars, lectures, workshops</td>
<td>Members/Secretariat Staff</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>Attend training and keep the training record</td>
<td>Members/Secretariat Staff</td>
</tr>
<tr>
<td>Store training record in VMMC-IRB Membership Files under Training of VMMC-IRB Members</td>
<td>Secretariat Staff</td>
</tr>
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</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, 2012. 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

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<th>ACTIVITY</th>
<th>RESPONSIBILITY</th>
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<td>Invite Independent Consultants to the VMMC-IRB</td>
<td>VMMC-IRB Chair</td>
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<tr>
<td>Sign conforme and VMMC-IRB Form 1-D,2012: Confidentiality Agreement and Conflict of Interest Disclosure</td>
<td>Independent Consultant</td>
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<tr>
<td>Appoint the roster of Independent VMMC-IRB Chair Consultants</td>
<td>VMMC-IRB Chair</td>
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</tr>
<tr>
<td>Store roster of Independent Consultants in the Independent Consultants File</td>
<td>Secretariat Staff</td>
</tr>
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**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.

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,2012. Service Agreement for Independent Consultants
- VMMC-IRB Form 1-D,2012. Confidentiality Agreement and Conflict of Interest Disclosure
- VMMC-IRB Form 2-C,2012. Study Protocol Assessment Form
- VMMC-IRB Form 2-D,2012. Informed Consent Assessment Form
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7.1.4.2. Review assigned protocols that concern his/her specialty using the VMMC-IRB Form 2-C,2012. 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

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<th>ACTIVITY</th>
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<tr>
<td>Recommend Honorarium</td>
<td>VMMC-IRB Chair</td>
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<tr>
<td>Approved Honorarium</td>
<td>Chief Professional Staff (CPS)</td>
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<tr>
<td>Communicate Honorarium Information to Personnel and Independent Consultants</td>
<td>Secretariat Staff</td>
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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 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.

8.2. Approval of Honorarium

8.2.1. 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.