


	CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL INSTITUTIONAL REVIEW BOARD	
Version 1	7.4 Managing Access to Confidential Files	Effective Date: January 02, 2019

Supersedes:	Previous SOPs
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Reviewed by:	 Dr. Manuel Emerson Donaldo
Reviewed Date:	December 14, 2018
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Date Approved	December 20, 2018
Date Effective:	January 2, 2019





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1. Policy Statement

Documents submitted to the CIM-CVGH IRB are considered confidential. Management of requests for access to confidential files helps protect the intellectual property rights of researchers and enhances the credibility and integrity of the IRB.

2. Objective of the Activity

This SOP provides instructions to the Secretariat related to the protection of confidentiality of all study files as well as documents of the IRB

3. Scope

This SOP begins with the classification of the IRB documents which are confidential, and ends with the logging of access of the documents concerned.

4. Responsibility

It is the responsibility of the IRB Secretariat under the supervision of the Member Secretary to ensure that confidentiality is maintained in the management of all study files and records.

5. Process Flow/Steps



ACTIVITY	RESPONSIBILITY
<i>Step 1: Classification of the IRB documents which are confidential</i>	<i>IRB secretariat</i>
<i>Step 2: Receipt and logging of request for access to confidential files</i>	<i>IRB Members, Chair, Member Secretary</i>
<i>Step 3: Approval of requests for access and retrieval of documents</i>	<i>IRB Chair</i>
<i>Step 4: Supervision of use of retrieved document</i>	<i>IRB Staff</i>
<i>Step 5: Return of document to the files</i>	<i>IRB Secretariat</i>
<i>Step 6: Logging of access</i>	<i>IRB Secretariat</i>

6. Description of Procedures

Step 1: Classification of the IRB documents which are confidential

Study files submitted to the CIM-CVGHIRB and related documents are considered confidential, such as:

- Study protocols and related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews) IRB documents (Minutes of the meeting or decisions), Correspondence (experts, auditors, study participants, etc.)

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Step 2: *Receipt and logging of request for access to confidential files*

Access to IRB confidential documents is subject to the following limitations:

- IRB members and staff with a signed Confidentiality Agreement and Conflict of Interest Disclosure can access confidential documents outside of regular protocol review access upon request.
- Non-members can access specific documents by submitting a written formal request. The Secretariat will provide a copy of the Agreement Form for Non-members requesting for copies of IRB Documents to be accomplished by the person making the request to be signed by the Chair.
- Regulatory authorities have full access to IRB documents provided it is within their mandate (e.g. FDA), and upon reasonable notice to make the files available signed by the recognized official of the regulatory authority (e.g. FDA Director).
- The request will be logged in the incoming/outgoing communications book.

Step 3: *Approval of requests for access and retrieval of documents*



- The request for document retrieval shall be discussed in the IRB meeting and shall be approved by the members.

Step 4: *Supervision of use of retrieved document* Recording of copies made of from confidential documents

- The Secretariat records the retrieval of IRB documents. The following data shall be recorded in the log of request (Annex 3).
 - Study File Code
 - Date borrowed
 - Number of borrower
 - Name and Signature of borrower upon retrieval
 - Signature of IRB Secretariat upon return
 - Document copied
 - Number of copies made
 - Number of copies received
- All requests for access are recorded by the Secretariat Staff in the log before copies of any documents are released.
- The Secretariat makes only the exact number of copies requested.
- Upon receipt of the copies, the person who requested the copies will sign the Log of Request Form

Step 5: *Return of document to the files*

- Access to CIM-CVGH IRB documents is generally room use only but any request to make copies can be accommodated only on a case to case basis.

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- The Secretariat records the retrieval of CIM-CVGH IRB documents.

7. Forms-



- Annex 1 – Confidentiality/ Conflict of Interest Agreement Form for Members
- Annex 2 - Confidentiality/ Conflict of Interest Agreement Form for Non Members
- Annex 3 - Log of Request for Copies of CIM-CVGH IRB’s Documents

8. History of SOP



Version No.	Date	Authors	Main Change
01	April 13, 2019	CIM-CVGH-IRB MEMBERS	First Draft
02			
03			



9. References:

- Philippine Health Research Ethics Board (PHREB) Workbook 2015
- World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
- National Ethical Guidelines for Health Research 2011 PNHRs
- <http://chonghua.com.ph/irb/SOP.html>



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ANNEX 1

 <h1 style="margin: 0;">CIM-CVGH</h1> <p style="margin: 0;">INSTITUTIONAL REVIEW BOARD 79 F. RAMOS ST., CEBU CITY Tel. 253-7413 Fax. (63-32) 253-9127</p>		<p style="text-align: center; color: blue; margin: 0;">ANNEX 1</p> <p style="text-align: center; color: blue; margin: 0;">CONFIDENTIALITY AGREEMENT FORM</p> <p style="text-align: center; color: blue; margin: 0;">FOR IRB MEMBERS REQUESTING FOR COPIES OF IRB DOCUMENTS</p>
<p>I, _____, as member of CIM – CVGH IRB, understand that the copy (ies) given to me by the CIM – CVGH IRB is (are) confidential. I shall use the information only for the indicated purpose as described to the CIM-CVGH IRB and shall not duplicate, give or distribute these documents to any person(s) without permission from the CIM-CVGH IRB. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.</p> <p style="text-align: center;">I have received copies of the following CIM-CVGH IRB documents</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>		
<p>_____</p> <p>Signature of the Recipient</p>	<p>_____</p> <p>Date</p>	
<p>_____</p> <p>CIM-CVGH IRB, Chair</p>	<p>_____</p> <p>Date</p>	


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ANNEX 2

 <h1 style="margin: 0;">CIM-CVGH</h1> <p style="margin: 0;">INSTITUTIONAL REVIEW BOARD 79 F. RAMOS ST., CEBU CITY Tel. 253-7413 Fax. (63-32) 253-9127</p>		<p style="color: blue; font-weight: bold;">ANNEX 2 CONFIDENTIALITY AGREEMENT FORM FOR NON-IRB MEMBERS REQUESTING FOR COPIES OF IRB DOCUMENTS</p>
<p>I, _____, as a non-member of CIM – CVGH IRB, understand that the copy (ies) given to me by the CIM – CVGH IRB is (are) confidential. I shall use the information only for the indicated purpose as described to the CIM-CVGH IRB and shall not duplicate, give or distribute these documents to any person(s) without permission from the CIM-CVGH IRB. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.</p> <p style="text-align: center;">I have received copies of the following CIM-CVGH IRB documents</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>		
<p>_____</p> <p>Signature of the Recipient</p>	<p>_____</p> <p>Date</p>	
<p>_____</p> <p>CIM-CVGH IRB, Chair</p>	<p>_____</p> <p>Date</p>	
<p>CONFIDENTIALITY AGREEMENT FORM FOR NON-MEMBERS REQUESTING COPIES OF CIM-CVGH IRB DOCUMENTS</p>		<p>Page 1 of 1</p>


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ANNEX 3



CIM-CVGH

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79 F. RAMOS ST., CEBU CITY
Tel. 253-7413 Fax. (63-32) 253-9127



ANNEX 3

LOG OF REQUEST

FOR COPIES OF CIM-CVGH DOCUMENTS

STUDY FILE CODE <small>(protocol # / file #)</small>	DATE BORROWED <small>(protocol # / file #)</small>	NAME AND SIGNATURE OF THE BORROWER <small>(upon retrieval)</small>	NAME AND SIGNATURE OF IRB SECRETARIAT <small>(upon return)</small>	DOCUMENT COPIED	NO. OF COPIES MADE	NO. OF COPIES RECEIVED

LOG OF REQUEST FOR COPIES OF CIM-CVGH IRB DOCUMENTS

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