

 chh_irb@chonghua.com.ph	CHONG HUA HOSPITAL INSTITUTIONAL REVIEW BOARD	SOP/004/05 Effective date: 01 January 2017
	Title: 1.4 Confidentiality/Conflict of Interest Agreement	Page 1 of 13

ජනාතලජනාතලජනාතලජනා
Table of Contents
 ජනාතලජනාතලජනාතලජනා

No.	Content	Page No.
	Table of Contents	1
1.	Purpose	2
2.	Scope	2
3.	Responsibility	2
4.	Flowchart	3
5.	Detailed Instruction	4
5.1	Read the text carefully and thoroughly	4
5.2	Ask questions, if any	4
5.3	Sign with consent	4
5.4	Keep the Agreement in mind	4
6.	ANNEX	
	Annex 1:	
	Confidentiality/ Conflict of Interest Agreement Form (for Newly Appointed Members)	5
	Annex 2:	
	Confidentiality/ Conflict of Interest Agreement Form (for Guest Attendees to CHH IRB Meetings)	8
	Annex 3:	
	Confidentiality/ Conflict of Interest Agreement Form (for Non-Members Requesting copies of CHH IRB Documents)	9
	Annex 4:	
	Confidentiality/ Conflict of Interest Agreement Form (for Independent Consultant)	10
7.	References.....	13

 chh_irb@chonghua.com.ph	CHONG HUA HOSPITAL INSTITUTIONAL REVIEW BOARD	SOP/004/05 Effective date: 01 January 2017
	Title: 1.4 Confidentiality/Conflict of Interest Agreement	Page 2 of 13

1. Purpose

The purpose of this section is to provide a form of Confidentiality / Conflict of Interest Agreement and identify who should read, understand, accept, keep in mind, sign and date the form. The procedures provide details when and where to sign as well as how the signed document should be kept.

2. Scope

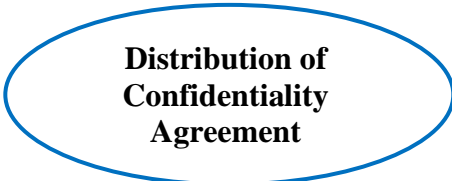



This SOP covers the Agreements on both Confidentiality and Conflict of Interest concerning information and procedures followed by the CHH IRB.

3. Responsibility

It is the responsibility of all newly-appointed CHH IRB members to read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form before beginning their ethical review tasks with Chong Hua Hospital to protect the rights of study participants.

 chh_irb@chonghua.com.ph	CHONG HUA HOSPITAL INSTITUTIONAL REVIEW BOARD	SOP/004/05 Effective date: 01 January 2017
	Title: 1.4 Confidentiality/Conflict of Interest Agreement	Page 3 of 13

4. Flowchart

No.	ACTIVITY	RESPONSIBLE PERSONNEL
I		CHH IRB members / guest attendees / observers
II		CHH IRB members / guest attendees / observers
III		CHH IRB members / guest attendees / observers
IV		CHH IRB members / guest attendees / observers

 chh_irb@chonghua.com.ph	CHONG HUA HOSPITAL INSTITUTIONAL REVIEW BOARD	SOP/004/05 Effective date: 01 January 2017
	Title: 1.4 Confidentiality/Conflict of Interest Agreement	Page 4 of 13

5. Detailed Instructions

5.1 Read the text carefully and thoroughly.

- Newly appointed members obtain two copies of the Agreement Form (ANNEX 1, Form HRP-IRB-004)
- Read through the text of the form very carefully.
- The members fill in their names and their office on the blanks.

5.2 Ask questions, if any.

- Direct questions to the Secretariat, if any part or sentences is not clear.
- Let the officer explain or clarify the contents of the document.

5.3 Sign with consent.


- Sign and date both copies at the document before a member of the Secretariat.
- Give the forms back to a staff secretary.
- The members keep a copy in their records.
- When a member is reappointed he/she needs to sign and date a new Confidentiality/Conflict of Interest Agreement.

5.4 Keep the Agreement in mind.

- The staff secretary keeps a copy of the signed Agreement as the Institute's records.
- Keep the copies in a Confidentiality/Conflict of Interest Agreement file.
- Store the file in a secure cabinet with limited key holders.

 chh_irb@chonghua.com.ph	CHONG HUA HOSPITAL INSTITUTIONAL REVIEW BOARD	SOP/004/05 Effective date: 01 January 2017
	Title: 1.4 Confidentiality/Conflict of Interest Agreement	Page 5 of 13

6. **ANNEX 1: Confidentiality/ Conflict of Interest Agreement Form (for Newly Appointed Members)**

	<p>崇華醫院 Chong Hua Hospital Fuente Osmeña, Cebu City Tel# +63(32) 255-8000; Fax# +63(32) 253-5639</p>	<p>ANNEX 1</p> <p>CONFIDENTIALITY/ CONFLICT OF INTEREST AGREEMENT FORM</p> <p>Form HRP-IRB-004</p>
<p>In recognition of the fact that I, _____ herein referred to as the "Undersigned", has been appointed as a member of the CHONG HUA HOSPITAL IRB has been asked to assess research studies involving human subjects in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines;</p> <p>Whereas, the appointment of the undersigned as a member of CHONG HUA HOSPITAL IRB is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest;</p> <p>Whereas, the fundamental duty of an IEC/IRB member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;</p> <p>Whereas, the CHONG HUA HOSPITAL IRB must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects;</p> <p>The undersigned, as a member of the CHONG HUA HOSPITAL IRB, is expected to meet the same high standards of ethical behavior to carry out its mandate.</p> <p>This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the CHONG HUA HOSPITAL IRB. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.</p> <p>As such, the Undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IRB.</p> <p>The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.</p>		
CONFIDENTIALITY/CONFLICT OF INTEREST AGREEMENT FORM Page 1 of 3		



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**CHONG HUA HOSPITAL
INSTITUTIONAL REVIEW BOARD**

Title:

**1.4 Confidentiality/Conflict of Interest
Agreement**

SOP/004/05

**Effective date:
01 January 2017**

Page 6 of 13

ANNEX 1



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**CONFIDENTIALITY/
CONFLICT OF INTEREST
AGREEMENT FORM**

Form HRP-IRB-004

Conflict of Interest

It is recognized that the potential for conflict of interest will always exist but has faith in the IEC/IRB and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

It is the policy of the **CHONG HUA HOSPITAL IRB** that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the **CHONG HUA HOSPITAL IRB**.

The Undersigned will immediately disclose to the Chairperson of the **CHONG HUA HOSPITAL IRB** any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that an IRB member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the EC member(s) in question. The Committee may elect to investigate the applicant's claim of the potential conflict.

When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the IEC/IRB review or approval except to provide information requested by the Committee.

Examples of conflict of interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment.



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INSTITUTIONAL REVIEW BOARD**

Title:

**1.4 Confidentiality/Conflict of Interest
Agreement**

SOP/004/05

**Effective date:
01 January 2017**

Page 7 of 13

ANNEX 1



**崇華醫院
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Fuente Osmeña, Cebu City
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**CONFIDENTIALITY/
CONFLICT OF INTEREST
AGREEMENT FORM**

Form HRP-IRB-004

Agreement on Confidentiality and Conflict of Interest

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the CHONG HUA HOSPITAL IRB. A copy will be given to you for your records.

In the course of my activities as a member of the CHH IRB, I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the Access to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee member.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me toward a quorum for voting.

I, _____ have read and accept the aforementioned terms and conditions as explained in this Agreement.

Undersigned Signature


Date

CHONG HUA HOSPITAL
MEDICAL DIRECTOR

Date


 chh_irb@chonghua.com.ph	CHONG HUA HOSPITAL INSTITUTIONAL REVIEW BOARD	SOP/004/05 Effective date: 01 January 2017
	Title: 1.4 Confidentiality/Conflict of Interest Agreement	Page 8 of 13

ANNEX 2: Confidentiality/ Conflict of Interest Agreement Form (for Guest Attendees to CHH IRB Meetings)

 <p>崇華醫院 Chong Hua Hospital Fuente Osmeña, Cebu City Tel# +63(32) 255-8010; Fax# +63(32) 253-5639</p>	<p>ANNEX 2</p> <p>CONFIDENTIALITY AGREEMENT FORM FOR GUEST ATTENDEES TO CHH IRB MEETINGS Form HRP-IRB-005</p>
<p>I, _____ understand that I am allowed to attend the CHH IRB meeting as a guest or an observer. In the course of the meeting of the CHH IRB, some confidential information may be disclosed or discussed. Upon signing this form, I agree to take reasonable measures to keep the information as Confidential.</p> <p style="text-align: center;">Indicate the details (date and number) of the CHH IRB Meeting attended:</p> <p>_____</p> <p>_____</p> <p>_____</p>	
_____ Signature of the Guest or Observer	_____ Date
_____ Chairperson of CHH IRB	_____ Date
<p style="font-size: small;">CONFIDENTIALITY AGREEMENT FORM FOR GUEST ATTENDEES TO CHH IRB MEETINGS</p> <p style="text-align: right; font-size: small;">Page 1 of 1</p>	


 chh_irb@chonghua.com.ph	CHONG HUA HOSPITAL INSTITUTIONAL REVIEW BOARD	SOP/004/05 Effective date: 01 January 2017
	Title: 1.4 Confidentiality/Conflict of Interest Agreement	Page 9 of 13

ANNEX 3: Confidentiality/ Conflict of Interest Agreement Form (for Non-Members Requesting copies of CHH IRB Documents)

	<p>崇華醫院 Chong Hua Hospital Fuente Osmeña, Cebu City Tel# +63(32) 255-8000; Fax# +63(32) 253-5639</p>	<p>ANNEX 3</p> <p>CONFIDENTIALITY AGREEMENT FORM FOR NON-MEMBERS REQUESTING COPIES OF CHH IRB DOCUMENTS</p> <p>Form HRP-IRB-006</p>
<p>I, _____ as a non-member of CHH IRB, understand that the copy (ies) given to me by the CHH IRB is (are) confidential. I shall use the information only for the indicated purpose as described to the CHH IRB and shall not duplicate, give or distribute these documents to any person(s) without permission from the CHH IRB. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.</p>		
<p>I have received copies of the following CHH IRB documents:</p>		
<p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>		
<p>_____ Signature of the recipient</p>	<p>_____ Date</p>	
<p>_____ Chairperson of CHH IRB</p>	<p>_____ Date</p>	
<small>CONFIDENTIALITY AGREEMENT FORM FOR NON-MEMBERS REQUESTING COPIES OF CHH IRB DOCUMENTS</small>		<small>Page 1 of 1</small>


 chh_irb@chonghua.com.ph	CHONG HUA HOSPITAL INSTITUTIONAL REVIEW BOARD	SOP/004/05 Effective date: 01 January 2017
	Title: 1.4 Confidentiality/Conflict of Interest Agreement	Page 10 of 13

ANNEX 4: Confidentiality/ Conflict of Interest Agreement Form (for Independent Consultant)

 <p>崇華醫院 Chong Hua Hospital Fuente Osmeña, Cebu City Tel# +63(32) 255-8000; Fax# +63(32) 253-6639</p>	<p>ANNEX 4</p> <p>CONFIDENTIALITY/ CONFLICT OF INTEREST AGREEMENT FORM</p> <p>Form HRP-IRB-033</p>
<p>In recognition of the fact that I, _____ herein referred to as the "Undersigned", has been appointed as an independent consultant of the CHONG HUA HOSPITAL IRB has been asked to assess research studies involving human subjects in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines;</p> <p>Whereas, the appointment of the undersigned as an independent consultant of CHONG HUA HOSPITAL IRB is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest;</p> <p>Whereas, the fundamental duty of an IEC/IRB member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;</p> <p>Whereas, the CHONG HUA HOSPITAL IRB must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects;</p> <p>The undersigned, as an independent consultant of the CHONG HUA HOSPITAL IRB, is expected to meet the same high standards of ethical behavior to carry out its mandate.</p> <p>This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as an independent consultant of the CHONG HUA HOSPITAL IRB. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.</p> <p>As such, the Undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IRB.</p> <p>The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.</p>	
CONFIDENTIALITY/CONFLICT OF INTEREST AGREEMENT FORM Page 1 of 3	

 chh_irb@chonghua.com.ph	CHONG HUA HOSPITAL INSTITUTIONAL REVIEW BOARD	SOP/004/05 Effective date: 01 January 2017
	Title: 1.4 Confidentiality/Conflict of Interest Agreement	Page 11 of 13

ANNEX 4



崇華醫院
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Fuente Osmeña, Cebu City
Tel# +63(32) 255-8000; Fax# +63(32) 253-5639

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CONFLICT OF INTEREST
AGREEMENT FORM**

Form HRP-IRB-033

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CONFIDENTIALITY/CONFLICT OF INTEREST AGREEMENT FORM

Page 2 of 3



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**CHONG HUA HOSPITAL
INSTITUTIONAL REVIEW BOARD**

Title:

**1.4 Confidentiality/Conflict of Interest
Agreement**

SOP/004/05

**Effective date:
01 January 2017**

Page 12 of 13

ANNEX 4



**崇華醫院
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Fuente Osmeña, Cebu City
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CONFLICT OF INTEREST
AGREEMENT FORM**

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Undersigned Signature

Date

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Date

 chh_irb@chonghua.com.ph	CHONG HUA HOSPITAL INSTITUTIONAL REVIEW BOARD	SOP/004/05 Effective date: 01 January 2017
	Title: 1.4 Confidentiality/Conflict of Interest Agreement	Page 13 of 13

7. References

- ❖ 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