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	2.2. Confidentiality/Conflict of Interest Agreement	

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1. Purpose

The purpose of this section is to describe potential conflict of interest (COI) and Confidentiality for IRB member, alternate members; staffs and other non-members who have access to protocols and other relevant documents. It provides a form for Confidentiality / Conflict of Interest Agreement and identify who should read, understand, accept, keep in mind, sign and date. 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 IRB members, alternate members; staffs and other non-members.

3. Responsibility

IRB members, alternate members; staffs and other non-members are responsible for disclosing any COI and maintain confidentiality of documents for ensuring the requirements of this SOP. It is the responsibility of all newly-appointed IRB members and alternate members as well as new staff of SERO to read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form before beginning their ethical review tasks with the institute to protect the rights of study participants.

4. Flow chart

No.	Activity	Responsibility
1	Read the text carefully and thoroughly ↓	IRB members /alternate members/ guest attendees / observers/staffs/other non-members
2	Ask questions, if any ↓	IRB members /alternate members/ guest attendees / observers/staffs/other non-members
3	Sign to indicate consent ↓	IRB members /alternate members/ guest attendees / observers/staffs/other non-members

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4 Keep the Agreement in mind.

IRB members /alternate members/ guest attendees / observers/staffs/other non-members

5. Detailed instructions

5.1. Read the text carefully and thoroughly

- IRB members /alternate members (EPHI-IRB AF 01-004/02.0) Director General and Deputy Director General (EPHI-IRB AF 02-004/02.0), guest attendees (EPHI-IRB AF 03-004/02.0), non-members requesting IRB documents (EPHI-IRB AF 04-004/02.0), SERO non-member staff (EPHI-IRB AF 05-004/02.0) and consultants (EPHI-IRB AF 06-004/02.0) obtain two copies of their respective agreement form,
- Read through the text of the form very carefully;
- The members fill in their names and their directorate 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 Compliance Officer to sign and date
- The members keep a copy as their records

5.4. Keep the Agreement in mind

- The Compliance Office 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

6. Glossary

Confidentiality The nonoccurrence of unauthorized disclosure of information:

Confidentiality Agreement Sometimes called Secrecy or Nondisclosure agreements
An agreement designed to protect trade secrets, information

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and expertise from being misused by those who have learned about them. The type of information that can be included under the umbrella of confidential information is virtually unlimited.

Most confidentiality agreements exclude certain types of information from the definition of confidential information. It is very important that the recipient include these exceptions in the confidentiality agreement.

An important point that must be covered in any confidentiality agreement is the standard by which the parties will handle the confidential information.

The agreement must establish a time period during which disclosures will be made and the period during which confidentiality of the information is to be maintained.

Conflict of Interest

A situation in which a person, such as a public official, an employee, or a professional, has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties.

There are three key elements in this definition: financial interest; official duties; professional interest.

A conflict of interest occurs when:

- An individual's private interest differs from his or her professional obligations to the institute.
- Professional actions or decisions occur that an independent observer might reasonably question.
- A conflict depends upon situation and not on the character or actions of the individual.
- Potential conflicts of interest must be disclosed and managed as per policy.

7. References

1. World Health Organization, Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participant, 2011.
2. International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use Guidance for Good Clinical Practice (ICH GCP) E6(R2), 2016.

8. Annex

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Annex 1: Confidentiality Agreement Form for EPHI-IRB Members and Alternate Members
 (EPHI-IRB AF 01-004/02.0)

8.1 Maintaining Confidentiality/Conflict of Interest Agreement

8.1.1 Confidentiality agreement

EPHI-IRB could request its members or alternate members to assess research proposals in order to ensure that they are conducted according to relevant national and local regulations; institutional policies and guidelines; International declarations and guidelines.

Whereas, the appointment of the undersigned member or alternate member of EPHI-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;

Whereas, the fundamental duty of a member or alternate member of EPHI-IRB is to independently review both scientific and ethical aspects of research protocols, make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, EPHI-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 study participants;

The undersigned is expected to meet the same high standards of ethical behavior to carry out its mandate.

This agreement thus encompasses any information deemed confidential or proprietary provided to the undersigned in conjunction with the member or alternate member of EPHI-IRB. Any written information provided to the undersigned that is of a confidential, proprietary, or privileged nature shall be identified accordingly.

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.

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.

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8.1.2 Conflict of Interest

It is recognized that the potential for conflict of interest will always exist but has faith in the IRB and its chairperson to manage the conflict issues so that the ultimate outcome is the protection of human study participants and protection of intellectual right.

It is the policy of EPHI-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 IRB.

The undersigned will immediately disclose to the chairperson of EPHI-IRB on any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the board or secretariat office, and to abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol claim that a member or alternate member of EPHI-IRB has actual or potential conflict of interest, the investigator may request that the member be excluded from the review and determination 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 IRB member or alternate member in question. The IRB may elect, as appropriate, to investigate the applicant's claim of the potential conflict for its decision.

When a member or alternate member of EPHI-IRB has a conflict of interest, he/she should notify the chairperson and may not participate in the IRB review or decision except to provide information requested by the board.

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

- A member or alternate member of EPHI-IRB 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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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 EPHI-IRB. A copy will be given to you for your records.

In the course of my activities to assess and/or determine on research proposals, I will make sure that research is conducted in humane and ethical manner and adhere to relevant national and local regulations; institutional policies and guidelines; and International declarations and guidelines.

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 and other law of the land not to disclose the confidential information to any person; not to use the confidential information for any purpose outside the board’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 board duties) to the chairperson upon termination of my functions as a board member or alternate member.

Whenever I have conflict of interest on a particular protocol/project, I shall immediately inform the chairperson not to count me toward a quorum for voting.

I,, have read and accepted the aforementioned terms and conditions as explained in this agreement.

 Signature of Member/Alternate member

 Date

NAME AND SIGNATURE OF EPHI-IRB CHAIRPERSON

 Date

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Annex 2: Agreement on Confidentiality and Conflict of Interest Form for Director
General/Deputy Director Generals/Directorate Directors
(EPHI-IRB AF 02-004/02.0)

I,....., as a Director General/Deputy Director General/Directorate Director will come across different protocols and related documents. I understand that the documents given to me by the IRB is (are) confidential. I shall use the information only for the indicated purpose as described to the IRB and shall not duplicate, give or distribute these documents or release information that emanate from the documents to any person(s) without permission from the IRB. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as confidential.

I am also aware of the policy of EPHI-IRB regarding conflict of interest and that no reviewer may participate in the review, comment or participate in decision making of any activity in which he/she has actual/potential conflict of interest except to provide information as requested by the IRB. Accordingly, I will declare, if I have any, my actual or potential conflict of interest (COI) in relation to the proposal entitled “_____,” in which I am assigned to review by EPHI-IRB or its secretariat office, describing the reason for the COI is_____.

Name and Signature of Official

Date

**NAME AND SIGNATURE OF EPHI-IRB
CHAIRPERSON**

Date

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Annex 3: Confidentiality Agreement Form for Guest Attendees to IRB Meetings
 (EPHI-IRB AF 03-004/02.0)

I,....., understand that I am allowed to attend the IRB meeting as a guest or an observer. In the course of the meeting of the 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.

Indicate the details (date and number) of the IRB Meeting attended:

.....

 Signature of the Guest or Observer

 Date

 NAME AND SIGNATURE OF EPHI-IRB CHAIRPERSON

 Date

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Annex 4: Confidentiality Agreement Form for Non EPHI-IRB members/Alternate members
 Requesting Copies of IRB’s Documents
 (EPHI-IRB AF 04-004/02.0)

I,....., as a non-member of IRB, understand that the copy (ies) given to me by the IRB is (are) confidential. I shall use the information only for the indicated purpose as described to the IRB and shall not duplicate, give or distribute these documents to any person(s) without permission from the IRB. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

I have received copies of the following IRB documents:

.....

.....

.....

.....

 Signature of the Recipient

 Date

**NAME AND SIGNATURE OF EPHI-IRB
 CHAIRPERSON**

 Date

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Annex 5: Confidentiality Agreement Form for SERO Non EPHI-IRB members/Alternate member staff on documents (EPHI-IRB AF 05-004/02.0)

I,....., staff of SERO, understand that the documents related to tasks of EPHI-IRB that I am accessing are confidential. I shall use the information only for the purpose that I am assigned for and shall not duplicate, give or distribute these documents or provide any related information to any person(s) without permission from chairperson of EPHI-IRB. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the documents and information as confidential.

 Signature of SERO Staff

 Date

**NAME AND SIGNATURE OF EPHI-IRB
 CHAIRPERSON**

 Date

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Annex 6: Agreement on Confidentiality and Conflict of Interest Form for Consultants
(EPHI-IRB AF 06-004/02.0)

I,....., as a reviewer of protocol and related documents is aware of the policy of EPHI-IRB regarding conflict of interest and that no reviewer may participate in the review, comment or participate in decision making of any activity in which he/she has actual/potential conflict of interest except to provide information as requested by the IRB. Accordingly, I will declare, if I have any, my actual or potential conflict of interest (COI) in relation to the proposal entitled “_____,” in which I am assigned to review by the EPHI-IRB or its secretariat office, describing the reason for the COI is_____.

I will accordingly refrain from the review process and/or discussion at the IRB meeting, and also will not take part in ongoing and periodic review and monitoring of the study.

Given that I don't have any conflict of interest, I also understand that the copy (ies) provided to me by the IRB is (are) confidential. I shall use the information only for the indicated purpose as described to the IRB and shall not duplicate, give or distribute these documents or release information that emanate from the documents to any person(s) without permission from the IRB. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

I have received copies of the following IRB documents:

.....

 Signature of Reviewer

 Date

 NAME AND SIGNATURE OF EPHI-IRB
 CHAIRPERSON

 Date