

CHAPTER 2.2

CONFIDENTIALITY/CONFLICT OF INTEREST AGREEMENT

SOP NUMBER: SOP/004/01



**Institutional Review Board
(IRB)**

Khesar Gyalpo University of Medical Sciences of Bhutan

www.kgumsb.edu.bt

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Author: SOP Team

Approved by: Chairperson, IRB

Name: **Dr. Karma Tenzin**

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1. PURPOSE

The purpose of this section shall be to provide a form of Confidentiality/ Conflict of Interest Agreement and identify who shall 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 shall be kept.

2. SCOPE

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

3. RESPONSIBILITY

All newly-appointed IRB members shall be responsible to read, understand, accept and sign the agreement contained in the Confidentiality/ Conflict of Interest form before beginning their ethical review tasks with the KGUMSB to protect the rights of human study participants.

4. FLOW CHART

No.	Activity	Responsibility
1	Read the text carefully and thoroughly ↓	IRB members / guest attendees / observers
2	Ask questions, if any ↓	IRB members / guest attendees / observers
3	Sign to indicate consent ↓	IRB members / guest attendees / observers
4	Keep the Agreement in mind. ↓	IRB members / guest attendees / observers
5	Archive the signed forms	IRB Secretariat

5. DETAILED INSTRUCTIONS

5.1. Read the text carefully and thoroughly.

- 5.1.1. Newly appointed members obtain two copies of the Agreement Form *AF/01-004/01*.
- 5.1.2. Read through the text of the form very carefully.
- 5.1.3. The members fill in their names and their office on the blanks.

5.2. Ask questions, if any.

- 5.2.1. Direct questions to the Secretariat/Chairperson, if any part or sentences is not clear.
- 5.2.2. The Secretariat/Chairperson shall explain or clarify the contents of the document.

5.3. Sign with consent.

- 5.3.1. Sign and date both copies of the document in presence of a member of the Secretariat.
- 5.3.2. The members keep a copy as their records.

5.4. Keep the Agreement in mind.

- 5.4.1. The individual who sign the Confidentiality/ Conflict of Interest Agreement shall remember and comply with the requirements listed in the agreement.

5.5. Archive the signed forms of Confidentiality/Conflict of Interest Agreement.

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

6. GLOSSARY

Confidentiality	The non-occurrence of unauthorized disclosure of information:
Confidentiality Agreement	<p><i>Sometimes called Secrecy or Nondisclosure agreements:</i> An agreement designed to protect trade secrets, information 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.</p> <p>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.</p> <p>An important point that must be covered in any confidentiality agreement is the standard by which the parties shall handle the confidential information. The agreement shall establish a time period during which disclosures shall be made and the period during which confidentiality of the information is to be maintained.</p>
Conflict of Interest	<p>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.</p> <p>There are three key elements in this definition: financial interest; official duties; professional interest.</p> <p>A conflict of interest occurs when:</p> <ul style="list-style-type: none"> • 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 shall be disclosed and managed as per policy.

7. REFERENCES

- 7.1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
- 7.2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 2016.

8. ANNEX

ANNEX 1	AF/01-004/01	Confidentiality/ Conflict of Interest Agreement Form
ANNEX 2	AF/02-004/01	Confidentiality Agreement form for Guest/ Observer Attendees to IRB Meetings
ANNEX 3	AF/03-004/01	Confidentiality Agreement for Non-members Requesting Copy(S) of IRB Documents

Confidentiality / Conflict of Interest Agreement Form

In recognition of the fact, that I.....*member's name, and his/her affiliation*.....herein referred to as the "Undersigned", has been appointed as a member of the 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;

Whereas, the appointment of the undersigned as a member of the *IRB* is based on individual merits and not as an advocate or representative of a particular district / community nor as the delegate of any organization or private interest;

Whereas, the fundamental duty of an 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;

Whereas, the IRB shall 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;

The undersigned, as a member of the IRB, is expected to meet the same high standards of ethical behaviour to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the 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 KGUMSB's policies, including Ministry of Health's policies and any contractual obligations they may have to third parties.

Any breach to this agreement shall be dealt as per the existing laws of the country.

Conflict of Interest

It is recognized that the potential for conflict of interest shall 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 subjects.

It is the policy of the 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 during the meeting.

The Undersigned shall immediately disclose to the Chairperson of the 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 shall be in writing and addressed to the Chairperson. The request shall contain evidence that substantiates the claim that a conflict exists with the IRB 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 shall notify the Chairperson and may not participate in the 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.

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) shall be kept on file in the custody of the IRB. A copy shall be given to you for your records.

In the course of my activities as a member of the IRB, I may be provided with confidential information and documentation (which we shall 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
_____ President, KGUMSB	_____ Date

(Please affix legal stamp)

Confidentiality Agreement Form for Guest Attendees to IRB Meetings

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

Chairperson of IRB

Date

(Please affix legal stamp)

Confidentiality Agreement Form for Non-members Requesting Copies of IRB's Documents

I,....., as a non-member of IRB, understand that the copy(s) 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

Member Secretary

Date

(Please affix legal stamp)