



Independent Ethics Committee (IEC)
Regd. No. 1433/1999 G.B.B.S.D

1. Purpose

The purpose of this Standard Operating Procedure(SOP) 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 Independent Ethics Committee (IEC)

3. Responsibility

- It is responsibility of each Independent Ethics Committee member reviewing research project or attending the Independent Ethics Committee meeting to read, understand, accept and sign the agreement contained in the confidentiality/ Conflict of Interest Form. The form should be read, understood, accepted and signed by each Independent Ethics Committee member at the beginning of the tenure of his/her membership
- It is the responsibility of each and every newly-appointed Independent Ethics Committee member to read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form with the Independent Ethics Committee before beginning ethical and/or scientific review tasks and prior to his/her attending the meetings of Independent Ethics Committee held to review research studies to protect the rights of study participants.
- It is the responsibility of the guest/observers attending the Independent Ethics Committee meeting to read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form at the beginning of the Independent Ethics Committee meeting and/or before ethical review tasks with the Independent Ethics Committee are commenced.
- It is the responsibility of the Independent Consultant (IC) to read, understand, accept and sign the agreement contained in the Confidentiality/Conflict of Interest form before beginning their ethical review tasks with the Independent Ethics Committee and/or attending a meeting of Independent Ethics Committee.



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- The Secretariat will ensure that the Confidentiality /Conflict of Interest Agreement Forms are duly signed and dated by the IEC members, Guests /observers for IEC meetings/Independent Consultants and notify to the IEC Chairperson. These documents will be filed in the files entitled ‘Confidentiality /Conflict of Interest Agreement Forms’

4. Flow chart

<u>No.</u>	<u>Activity</u>	<u>Responsibility</u>
1	Read the text carefully and thoroughly	Independent Ethics Committee members / guest attendees / observers / Independent Consultant
2	Ask questions, if any	Independent Ethics Committee members / guest attendees / observers / Independent Consultant
3	Sign to indicate consent	Independent Ethics Committee members / guest attendees / observers / Independent Consultant
4	Keep the Agreement in mind.	Independent Ethics Committee members / guest attendees / observers / Independent Consultant

5. Detailed instructions

5.1 Read the text carefully and thoroughly.

- Every member at beginning of the tenure, before initiating ethical review for Independent Ethics Committee and before commencement of the meeting of Independent Ethics Committee held for review of research projects will read the Confidentiality /Conflict of Interest Agreement Form *AF/01/01-SOP03/01*, carefully and thoroughly
- Every observer/ guest for Independent Ethics Committee meeting: before initiating ethical review and before commencement of the meeting will read the Confidentiality /Conflict of Interest Agreement Form *AF/02/01-SOP03/01* carefully and thoroughly
- Every Independent Consultant before initiating ethical review and before commencement of Independent Ethics Committee meeting (whenever



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applicable) will read the Confidentiality /Conflict of Interest Agreement Form *AF/03/01-SOP03/01* carefully and thoroughly

- All the IEC members at the beginning of the tenure, Guests /observers for Independent Ethics Committee meetings/Independent Consultants will be provided with two copies of Confidentiality /Conflict of Interest Agreement Form by the Secretariat.
- Subsequently to their reading through the text of the form very carefully they will fill in their names, designation and their official address.

5.2 Ask questions, if any.

- If any of the IEC members/Guests /observers for Independent Ethics Committee meetings/Independent Consultants have any doubts, need clarifications or if any part or sentences are not clear in the Confidentiality /Conflict of Interest Agreement Forms *AF/01/01-SOP03/01*, *AF/02/01-SOP03/01*, *AF/03/01-SOP03/01* respectively, they can direct questions to the Secretariat. The Member Secretary will provide explanations/clarifications. If any further explanations are needed they can be provided by the Chairperson/ Legal expert/other IEC members.

5.3 Sign to indicate consent.

- The newly appointed IEC member/Independent Ethics Committee members before the beginning of their tenure, Guests /observers for Independent Ethics Committee meetings/Independent Consultants will sign and date both the copies of the document before a member of the Secretariat.
- They will give the forms back to the Secretariat to obtain sign and date of the IEC Chairperson. The Secretariat will obtain the signature of the IEC Chairperson on both the copies of the Confidentiality /Conflict of Interest Agreement Form.
- The members/Guests /observers for Independent Ethics Committee meetings/Independent Consultants will receive one copy of the Confidentiality /Conflict of Interest Agreement Form for their records (duly signed and dated by them and IEC Chairperson) and acknowledge the receipt of agreement by their signature.
- The Secretariat keeps the second copy of the signed Agreement at the Independent Ethics Committee office in the files entitled 'Confidentiality/Conflict of Interest Agreement file for members, guests, observers, Independent Consultants (IC)'



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- The Secretariat will store the file in a secure cabinet with limited key holders.

5.4 Keep the Agreement in mind.

- The IEC members/Guests /observers for Independent Ethics Committee meetings/Independent Consultants must adhere to the highest standards of ethical conduct and must ensure that the cardinal principles of ethics i.e. autonomy of the individual, beneficence, nonmaleficence and justice are followed while reviewing the project.
- The IEC members/Guests /observers for Independent Ethics Committee meetings/Independent Consultants must implement the clauses of the signed Confidentiality Agreement Form as in *AF/01/01-SOP03/01*, *AF/02/01-SOP03/01* and *AF/03/01-SOP03/01* respectively.

6. Glossary

Confidentiality	The nonoccurrence of unauthorized disclosure of information
Confidentiality Agreement	<p>Sometimes called Secrecy or Non-disclosure agreement</p> <p>An agreement designed to protect trade secrets, information and expertise from being misused by those who have learned about them.</p> <p>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 will handle the confidential information.</p> <p>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.</p>
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.



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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, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000 (Geneva 2000 www.who.int/tdr/publications/publications/- last accessed 24 March 2008).
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP)1996-<http://www.ich.org/LOB/media/MEDIA482.pdf> (last accessed 24 March 2008).

8. Annexure

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| ANNEX 1 | AF/01/01-SOP03/01 Confidentiality/Conflict of Interest Agreement Form for IEC members |
| ANNEX 2 | AF/02/01-SOP03/01 Confidentiality Agreement for Guest/Observer Attendees to IEC Meetings |
| ANNEX 3 | AF/03/01-SOP03/01 Confidentiality Agreement for Independent Consultants |



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Annex 1
AF/01/01-SOP03/01

Confidentiality / Conflict of Interest Agreement Form for IEC Members

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 IEC Mumbai has been asked to assess research studies involving human subjects in order to ensure that they are conducted in a human 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 IEC Mumbai 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 an IEC 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 IEC Mumbai 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;

The undersigned, as a member of the IEC, 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 duties as a member of the IEC. 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 IEC.



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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.

Conflict of Interest

It is recognized that the potential for conflict of interest will always exist but has faith in the IEC 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 IEC 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 IEC.

The Undersigned will immediately disclose to the Chairperson of the IEC 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 or voting in respect of such proposals.

If an applicant submitting a protocol believes that an IEC 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 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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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 IEC. A copy will be given to you for your records.

In the course of my activities as a member of the IEC, I may be provided with confidential information and documentation (which we will refer to as the Confidential Information; subject to applicable legislation, including the Access to "Confidential Information"). I agree to take reasonable measures to protect the 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.

I acknowledge that I have received a copy of this Agreement signed by the Independent Ethics Committee Chairperson and me.

Undersigned Signature

Date

Independent Ethics Committee

Date

Undersigned Signature

Date



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Annex 2
AF/02/01-SOP03/01

Confidentiality Agreement Form
for Guest / Observer Attendees to IEC, Mumbai Meetings

I, _____, understand that I am allowed to attend the Independent Ethics Committee meeting scheduled on _____ at _____ am/ pm as a Guest. The meeting will be conducted in the Seminar Room, Dept. of Clinical Pharmacology, TN Medical College and BYL Nair Ch. Hospital. In the course of the meeting of the Independent Ethics Committee some confidential information may be disclosed or discussed. Upon signing this form, I ensure to take reasonable measures to keep the information as confidential.

Signature of the Guest

Date

Chairperson of IEC

Date

I, _____ (Enter name) acknowledge that I have received a copy of this Agreement signed by Independent Ethics Committee Chairperson and me.

Undersigned Signature

Date



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Annex 3
AF/03/01-SOP03/01

Confidentiality Agreement Form for Independent Consultants

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

Signature of the recipient

Date

Chairperson of IEC

Date

I, _____ (Enter name) acknowledge that I have received a copy of this Agreement signed by Chairperson IEC and me.

Undersigned Signature

Date