

**Title: Confidentiality / Conflict of Interest Agreements**

**SOP Code: SOP 03/V1 dated 18<sup>th</sup> February 2017**

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**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, 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 Institutional Ethics Committee (IEC)

**3. Responsibility**

- It is responsibility of each IEC member reviewing research project or attending IEC 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 IEC member at the beginning of the tenure of his/her membership
- It is the responsibility of each and every newly-appointed member of IEC to read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form before beginning ethical and/or scientific review tasks and prior to his/her attending IEC meetings held to review research studies to protect the rights of study participants.
- It is the responsibility of the guest/observers intending to attend an IEC meeting to read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form prior to attending an IEC meeting and/or before ethical review tasks with the Institutional 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 IEC and/or attending a meeting of IEC.
- The Secretariat will ensure that the Confidentiality / Conflict of Interest Agreement Forms are duly signed and dated by the IEC members, Guests or observers for IEC meetings or Independent Consultants prior to attending an IEC meeting, accessing IEC documents or undertaking review processes (as applicable) and notify to the IEC Chairperson. The Secretariat will file signed Confidentiality/ Conflict of Interest Agreement forms in the files entitled 'Confidentiality /Conflict of Interest Agreement Forms'

**4. Flow chart**

No.	Activity	Responsibility
1.	Provide appropriate forms to IEC member, Guest attendees, Observers, Independent	IEC Secretariat

	Consultant	
2	Read the text carefully and thoroughly	IEC members / guest attendees / observers / Independent Consultant
3	Ask questions, if any	IEC members / guest attendees / observers / Independent Consultant
4	Sign and indicate consent	IEC members / guest attendees / observers / Independent Consultant
5	Keep the Agreement in mind.	IEC members / guest attendees / observers / Independent Consultant
6	File the signed forms	IEC secretariat

## **5. Detailed instructions**

### ***5.1 Read the text carefully and thoroughly.***

- The appropriate Confidentiality and / or Conflict of Interest Agreement Form will be provided to the IEC member, Guest attendee, Observer and Independent Consultant
- Every member at beginning of the tenure and before he/she commences to review research projects submitted to IEC and before he/she starts to function as an IEC members and before he/she starts attending IEC meeting will read the Confidentiality /Conflict of Interest Agreement Form - AX 01/SOP 03/V1 and AX 02/SOP 03/V1, carefully and thoroughly.
- Every observer or guest for IEC meeting: before initiating ethical review and / or before commencement of the meeting will read the Confidentiality / Conflict of Interest Agreement Form AX 03/SOP 03/V1 carefully and thoroughly
- Every Independent Consultant before initiating ethical review and / or before commencement of IEC meeting will read the Confidentiality / Conflict of Interest Agreement Form -AX 04/SOP 03/V1 carefully and thoroughly
- IEC member, Guest attendee, observer, Independent Consultant will fill up the details such as name, designation and official address.

### ***5.2 Ask questions, if any.***

- If any of the IEC members/Guests /observers for IEC meetings/Independent Consultants have any doubts, need clarifications or if any part or sentences is not clear, they will seek clarifications or additional information from the Secretariat. The Member Secretary will provide explanations, additional information and / or 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, before the beginning of their tenure, Guests /observers for IEC meetings, Independent Consultants will sign and date the document before a member of the Secretariat.
- They will give the signed form back to the Secretariat
- The Secretariat will obtain the signature of the IEC Chairperson on the Confidentiality /Conflict of Interest Agreement Form.
- The secretariat will provide IEC member, Guests or observers for IEC meetings, Independent Consultants a photocopy 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 original copies of the signed Agreements at the Institutional Ethics Committee office in the files entitled 'Confidentiality/Conflict of Interest Agreement file for members, guests, observers, Independent Consultants (IC)'
- 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 Institutional Ethics Committee meetings/Independent Consultants must implement the clauses of the signed Confidentiality Agreement Form as in AX 01/SOP 03/V1 , AX 03/SOP 03/V1 and AX 04/SOP 03/V1 respectively.

## 6. Glossary

<b>Confidentiality</b>	The nonoccurrence of unauthorized disclosure of information
<b>Confidentiality Agreement</b>	Sometimes called Secrecy or Non-disclosure agreement 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. 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.
<b>Conflict of Interest</b>	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>There are three key elements in this definition: financial interest, official duties, and professional interest.</p> <p>A conflict of interest occurs when:</p> <ul style="list-style-type: none"><li>• An individual's private interest differs from his or her professional obligations to the institute.</li><li>• Professional actions or decisions occur that an independent observer might reasonably question.</li><li>• A conflict depends upon situation and not on the character or actions of the individual.</li><li>• Potential conflicts of interest must be disclosed and managed as per policy.</li></ul>
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## **7. References**

- [1] World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000 (Geneva 2000 [www.who.int/tdr/publications/publications/](http://www.who.int/tdr/publications/publications/) last accessed 31<sup>st</sup> August 2013).
- [2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- <http://www.ich.org/LOB/media/MEDIA482.pdf> (last accessed 31<sup>st</sup> August 2013).

## **8. Annexure**

Annexure 1	<i>AX 01/SOP 03/V1</i>	Confidentiality Agreement Form for IEC members
Annexure 2	<i>AX 02/SOP 03/V1</i>	Conflict of Interest Agreement Form for IEC Members
Annexure 3	<i>AX 03/SOP 03/V1</i>	Confidentiality Agreement for Guest/Observer Attendees to IEC Meetings
Annexure 4	<i>AX 04/SOP 03/V1</i>	Confidentiality Agreement for Independent Consultants

### **Annexure 1**

*AX 01/SOP 03/V1*

#### **Confidentiality 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", have been appointed as a member of the IEC and have been asked to assess research studies involving research participants in order to ensure that they are conducted in a humane and ethical

manner, adhering to the highest standards of care as per the national, and local regulations and institutional policies and guidelines and international and national guidelines;

Whereas, the appointment of the undersigned as a member of the IEC is based on individual merits and not as an advocate or representative of a home province, territory or community nor as a 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 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 research participants;

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 and 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.

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.

**Agreement on Confidentiality**

*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 destroy all Confidential Information (including any minutes or notes I have made as part of my duties) to the Chairperson upon termination of my functions as a Committee member.

I, \_\_\_\_\_ (name of the member) have read and accept the aforementioned terms and conditions as explained in this Agreement.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Chairperson's Signature

\_\_\_\_\_  
Date

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

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

**Annexure 2**

*AX 02/SOP 03/V1*

**Conflict of Interest Agreement Form for IEC Members**

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 research participants.

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 decision making 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.

#### **Agreement on 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.*

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me for discussion or decision making in respect of such proposal.

I, \_\_\_\_\_ (name) have read and accept the aforementioned terms and conditions as explained in this Agreement.

\_\_\_\_\_  
**Signature**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Chairperson's Signature**

\_\_\_\_\_  
**Date**

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

\_\_\_\_\_  
**Signature**

\_\_\_\_\_  
**Date**



**Annexure 3**

*AX 03/SOP 03/V1*

**Confidentiality Agreement Form**

**For Guest / Observer Attendees to IEC Meetings**

I, \_\_\_\_\_ (name), understand that I am being allowed to attend the Institutional Ethics Committee meeting scheduled on \_\_\_\_\_ at \_\_\_\_\_ am/ pm as a Guest. The meeting will be conducted in the \_\_\_\_\_, Institute of NephroUrology, Bengaluru-560002. In the course of the meeting of the Institutional 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.

_____ <b>Signature of the Guest</b>	_____ <b>Date</b>
_____ <b>Chairperson of IEC</b>	_____ <b>Date</b>

I, \_\_\_\_\_ (name) acknowledge that I have received a copy of this Agreement signed by the IEC -Chairperson and me.

\_\_\_\_\_  
**Signature of the Guest**

\_\_\_\_\_  
**Date**

**Annexure 4**

*AX 04/SOP 03/V1*

**Confidentiality Agreement Form for Independent Consultants**

**/ Independent Monitors**

I, \_\_\_\_\_ (Name and Designation) as a non-member of Institutional Ethics Committee (IEC) understand that the copy / copies given to me by the IEC is/are confidential. I shall use the information only for the indicated purpose as described by the IEC and shall not duplicate, give or distribute these documents to any

person(s) without prior permission from the IEC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

_____ <b>Signature of the recipient</b>	_____ <b>Date</b>
_____ <b>Chairperson of IEC</b>	_____ <b>Date</b>

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

\_\_\_\_\_  
**Signature**

\_\_\_\_\_  
**Date**

### **Annexure 5**

*AX 05/SOP 03/V1*

#### **Confidentiality Agreement Form for Institutional Funding Societies**

I, \_\_\_\_\_  
\_\_\_\_\_  
(Name and Designation) as a member/  
staff of Funding Society (Research Society) understand that the copy / copies given to me by the IEC is/are confidential. I shall use the information only for the indicated purpose as described by the IEC and shall not duplicate, give or distribute these documents to any person(s) without prior permission from the IEC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

_____ <b>Signature of the member/ staff of Funding Society</b>	_____ <b>Date</b>
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<hr/> <b>Chairperson of IEC</b>	<hr/> <b>Date</b>
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I, \_\_\_\_\_ (name) acknowledge that I have received a copy of this Agreement signed by the Chairperson of the IEC and me.

\_\_\_\_\_  
**Signature**

\_\_\_\_\_  
**Date**