

Annexure 3

Conflict of Interest:

Definition: _____

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, and 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.

Conflict of Interest Agreement Form for Institutional Ethics Committee Members

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

The Undersigned will immediately disclose to the Chairperson of the Institutional Ethics Committee 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 Institutional Ethics Committee 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 Ethics Committee 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 Institutional Ethics Committee review or approval except to provide information requested by the Committee.

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

Sr. No.	Element for Review	Check (X)
1	Review qualifications of all investigators participating in the proposed research study	
2	Essentiality and Objective of the study	
3	Scientific design and conduct of the study	
4	Approval of appropriate scientific review committees	
5	Study Protocol including Amendments	
6	Investigator Brochure	
7	Regulatory status of the New Drug in India and developed countries	

8	DCGI Approval	
9	Investigator Undertaking	
10	Conflict of Interests	
11	Examination of predictable risks/harms	
12	Risk Management Strategy	
13	Examination of potential benefits	
14	Procedure for selection of subjects in methodology including inclusion exclusion, withdrawal criteria and other issues like advertisement details	
15	Proposed methods for patient accrual including advertisement etc. proposed to be used for the purpose	
16	Voluntary Participation	
17	Patient information sheet and informed consent form in vernacular (local) language	
18	Informed Consent Process	
19	Protection of privacy and confidentiality	
20	Involvement of the community, wherever necessary	
21	Whom to contact in case of an emergency	
22	Management of research related injuries, adverse events	
23	Compensation in case of trial related injury	
24	Justification for placebo in control arm, if any	
25	Alternative treatment options	
26	Availability of products after the study, if applicable	
27	Insurance Policy	
28	Investigator's Agreement	
29	Plans for data analysis and reporting	
30	Adherence to all regulatory requirements and applicable guidelines	
31	Competence of investigators, research and supporting staff	
32	Facilities and infrastructure of study sites	
33	Criteria for withdrawal of patients, suspending or terminating the study	
34	Ensure compliance with the norms of ICH-GCP guidelines, Indian GCP	

- 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 Institutional Ethics Committee. 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