Independent
Ethics Committee
(Clinical Research) India

Standard Operating Procedures

(SOP -06/01)

For

Initial Review of Submitted Protocol

Independent Ethics Committee (Clinical Research) India

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Independent Ethics Committee (IEC) members review an initially submitted protocol for approval using the Assessment Form for initial review. The Assessment Form (*AF/01/01-SOP06/01*) is designed to standardize the review process and to facilitate reporting, recommendations and comments given to each individual protocol.

2. Scope

This SOP applies to the review and assessment of all protocols submitted for initial review and approval from the IEC. The specific points in the guidelines attached to the Assessment Form for initial review must be adequately addressed in the protocol itself and/or protocol-related documents under review. Relevant points made during discussion and deliberation about a specific protocol should be recorded in the minutes of the meeting. The decision reached by the IEC and the reasons for its decision is recorded on the IEC Decision Form (*AF/02/01-SOP06/01*).

3. Responsibility

It is the responsibility of all the IEC members to fill the Assessment form along with decision and comments they might have after reviewing each study protocol. The IEC Secretariat is responsible for recording and filing the decision, relevant points and deliberation about a specific protocol, including the reasons for that decision. The Chairperson must sign and date to approve the decision in the IEC Decision Form (*AF/02/01-SOP06/01*).

4. Flow chart

No.	Activity	Responsibility
1	Summarize the protocol in an Assessment Form and distribute the protocol package	IEC/ Secretariat
2	Receive the distributed protocol Package	IEC members
3	Verify the contents of the package	IEC members
4	Review the Protocol	IEC members
5	Examine the qualification of investigators and of study sites.	IEC members

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No.	Activity	Responsibility
6	Review study participation	IEC members
7	Examine community involvement and impact	IEC members
8	Make a decision	IEC members
9	Gather the assessment reports	IEC/Secretariat
10	At the IEC meeting record the IEC Decision	IEC/Secretariat
11	Final communication of the IEC Decision taken on the project to the Principal Investigator	Secretariat
12	Storage of documents	Secretariat

5. Detailed instructions

5.1 Summarize the protocol in an Assessment Form and distribute the protocol package.

5.1.1 General Protocol Information

The Secretariat will fill in the following details in the Study Assessment Form for Initial review *AF/01/01-SOP06/01* prior to circulation

- Title of the protocol
- Protocol number and date (as per IEC office records)
- Principal Investigators, contact number, site address
- Funding agency & contact number
- Study types
- Duration of the study
- Review status – Regular / Expedited
- Reviewer's name
- Objective and brief description of the Study

The Secretariat will attach this Assessment Form for Initial Review (*AF/01/01-SOP06/*01) along with the Project Submission Application Form *AF/01/01-SOP05/01* and Document Checklist *AF/02/01-SOP05/01* with the protocol and related documents and courier to the respective Independent Ethics Committee member. The IEC Secretariat will telephonically inform the members of the packet and also reconfirm the receipt of the packet by the IEC members telephonically. In case of non-receipt of the project packet by an IEC member, it will be verified with the courier services and if

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necessary the project packet will be re-couriered to the IEC member.

1.0 Receive the distributed protocol Package

The IEC member will receive the protocol package with the Project Application Form (*AF/01/01-SOP05/ 01*), Checklist of all documents (*AF/ 02/01-SOP05/01*), and Study Assessment Form for Initial Review (*AF/01/01-SOP06/01).*

5.3 Verify the contents of the package

- The Independent Ethics Committee member will verify all the contents and *AF/01/01-SOP05/01*, AF*/02/01-SOP05/01, AF/01/01-SOP06/01* documents.
- The Independent Ethics Committee member will confirm the due date for the review and check the meeting date to see if it is convenient to attend the meeting.
- The Independent Ethics Committee member will notify the IEC Secretariat if there are documents missing in accordance to *AF/02/01-SOP05/01* or the specified date of the IEC meeting cannot be met.

1.0 Review the protocol

- The Independent Ethics Committee member will check the Project Application Form (*AF/01/01-SOP05/01)* for completeness of the information and signatures of the Principal Investigator.
- The protocol will be reviewed by each member as per guidelines to review a study protocol described in *AF/01/01-SOP06/01*. The Study Assessment Form for Initial review (*AF/01/01-SOP06/01)* will be completed by each reviewer and submitted to Secretariat at the time of meeting or before the meeting. The completed Assessment Form is the official record of the provisional decision reached by the Independent Ethics Committee member for the specific protocol.
- The Independent Ethics Committee member will consider the following criteria when performing the review of the study protocol:
  - minimize risks to participants;
  - risks must be reasonable in relation to anticipated benefits;
  - participants are selected equitably;
  - informed consent is adequate, easy to understand and properly documented;
  - the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants, where appropriate;
  - there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data, where appropriate; and
  - Appropriate safeguards are included to protect vulnerable participants.
- Make comments where appropriate.

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5.5 Examine the qualification of investigators and of study sites.

- The IEC members must consider whether the qualifications and training background of the participating investigators relate to the study by reviewing their CVs.
- The IEC members must examine disclosure or declaration of potential conflicts of interest
- The IEC members must confirm whether the facilities and infrastructure at study sites can accommodate the study by reviewing the site profile.

5.6 Review study participation.

The IEC member will examine for the presence of the following points while reviewing the patient information sheet/Informed Consent Form as per guidelines to review Informed Consent Document/Patient Information Sheet in *AF/01/01-SOP06/01*

- Voluntary, non-coercive recruitment/participation / withdrawal
- Procedures for obtaining informed consent
- Contents of the patient information sheet - title, objective, study design and procedures
- Contents and language of the informed consent document
- Translation of the informed consent document in the local languages
- Language used – plain and easy to understand by general public
- Contact persons with address and phone numbers for questions about subject's rights and study or injury
- Privacy and confidentiality
- Risks and discomforts – physical / mental / social
- Alternative treatments
- Benefits – to participants and to others
- Compensation for participation / for injury– reasonable /unreasonable
- Involvement of vulnerable participants
- Provisions for medical/psychosocial support
- Treatment for study related injuries
- Use of biological materials
- Check for provision for signatures with dates of participant, person conducting informed consent discussion, investigator and witness

5.7 Examine community involvement and impact.

The IEC members will also consider the following points in the protocol, Informed Consent Form/ Patient Information Sheet

- Community consultation

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- Involvement of local researchers and institutions in the protocol design, analysis and publication of the results
- Contribution to development of local capacity for research and treatment
- Benefit to local communities
- Availability of study results

5.8 Make a decision.

- Each IEC member on complete review of protocol and related documents will write any comments, suggestions and reason for disapproval
- The IEC member will record the provisional decision by marking in the desired block on any of the following: "*Approved, Approved with recommendation, or Disapproved."*
- The IEC member will check the completeness and correctness of the Assessment Form (*AF/01/01-SOP06/01)* and sign and date the Assessment Report.
- The IEC member will give or send the complete forms to the IEC Secretariat.

5.9 Gather the assessment reports.

- The IEC Secretariat will collect the Assessment Forms (*AF/01/01-SOP06/01)* and the review result from each reviewer and organize the forms in order.
- The Secretariat will summarize the comments, suggestions, and opinions of each study for each IEC member and present in the meeting.

5.10 At the IEC meeting record the IEC decision

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- The Secretary will read the comments, suggestions of the IEC members in the meeting during the review and approval process of that specific project. The IEC members can re-discuss and clarify the comments and suggestions and each member will take a decision for the project as: "*Approved, Approved with recommendation or Disapproved"* which will be recorded by the Secretary in the IEC Decision Form *AF/02/01-SOP06/01*.
- If the IEC decision is '*Approved*', it implies the approval of the study as it is presented with no modifications and the study can be initiated.
- If the IEC decision is '*Approved with recommendation'*, it implies that
  - Requires modifications to items noted at the convened meeting and project be re-submitted to be followed-up by the Chairperson, after receipt of the requested modifications.
  - Expedited review to be performed by at least 2 members designated by the Chairperson.
  - Full Board Committee review of the documents.
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- The final decision on the project as: *"Approved, Approved with recommendation"* will be reached by consensus.
- Even if any one of the IEC members raises an objection, the objections are noted in the minutes and conveyed to the Principal Investigator as query letter and justification is requested. If any member/ members of the committee is /are participating in the research project under discussion, they will opt out from all deliberations on the project. This will be recorded in the minutes of the meeting. The investigator/sub-investigator may be called in to provide clarifications on the study protocol that he/she has submitted for review to the IEC.
- If the study is approved, the Committee determines the frequency of Continuing Review from each investigator.
- The Secretariat will list participating members in the meeting and summarize the guidance, advice and decision reached by the IEC members.
- The Secretariat will obtain the sign of the Chairperson of the IEC on the IEC Decision Form *AF/02/01-SOP06/01*.
- With the study protocol, the Assessment Form from all members and IEC Decision Form will be filed in the project file by the Administrative Officer.
- The Administrative Officer will return the file and the protocol to the appropriate shelves.

5.11 Final communication of the IEC decision taken on the project to the Principal Investigator

- The Secretariat sends an approval letter as *AF/03/01-SOP06/01* to the principal investigator when the IEC decision is approved.
- The letter contains, at a minimum, a listing of each document approved, the date set by the Committee for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the course of the study.
- The approval and expiration date is written on the approval letter along with the list of IEC members approving the project.
- The approval letter is signed by the IEC Chairperson and sent to the Principal Investigator within 10 working days.
- If the Committee reaches a consensus to disapprove the study, the Secretariat immediately notifies the investigator in writing about the decision and the reason for not approving the study. A notifying letter to the investigator should state the following:
  - "If you wish to appeal to this decision, please contact the IEC and submit your appeal in writing, addressed to the IEC Chairperson with justification as to why the appeal should be granted"
- If the Committee requires modifications to any of the documents, the Secretariat sends a written request of the specific changes in the form of query letter to the investigator asking him or her to make the necessary changes and resubmit the documents to the IEC. The Principal Investigator has to respond to this query

letter within 90 working days of the receipt of the query letter. If the Principal Investigator fails to reply within 90 working days the project is declared closed for IEC records.

- The Secretariat will verify the correctness of the wordings and spelling in all the letters and process all the above tasks within 10 days after the meeting.

5.12 Storage of Documents

- The Secretariat will keep a copy of the Approval letter/Query letter/Disapproval letter in the project file along with all the reviewed documents.
- The Administrative Officer will store the file on an appropriate shelf in the designated cabinet.

6. Glossary

Study Assessment Form	An official record that documents the protocol review process.
Document	Document may be of any forms, e.g., paper, electronic mail (e-mail), faxes, audio or video tape, etc.
Pre-clinical study	Animal and *in vitro* studies provide information on possible toxicities and mechanisms of action, and starting doses for Clinical studies.
Vulnerable subjects	A vulnerable category of subjects includes children, prisoners, pregnant women, handicapped or mentally disabled persons, refugees, displaced persons and economically or educationally disadvantaged persons, who are likely to be vulnerable to coercion or undue influence.
Initial Review	The first time review of that protocol made by two or three individual reviewers (IEC members or non-members) in advance of the full Committee meeting, and comments of the reviewers will be reported to the full Committee meeting.
Phase I studies	Initial introduction of an investigational new drug (IND) into Clinicals, studies designed to determine the metabolism and pharmacological actions of drugs in Clinicals, and studies designed to assess the side effects associated with increasing doses.
Phase II study	A Study of drug metabolism, structure-activity relationships, and mechanism of action in Clinicals, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes.
Phase III study	A Study expands controlled and uncontrolled trials performed after preliminary evidence suggesting effectiveness of the drug has been obtained. They are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to

provide an adequate basis for physician labeling.

Phase IV study	A study that seeks to expand an approved medication's use into a new population, new indication, or new dose.

7. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 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).
2. Cavazos N., Forster D., and Bowen A.J., Ethical Concerns in Placebo-controlled studies: An Analytical Approach, Drug Information Journal 36(2) 2002: pgs 249-259, via WIRB documents

8. Annexure

ANNEX 1	AF/01/01-SOP06/01	Study Assessment Form for Initial Review
ANNEX 2	AF/02/01-SOP06/01	IEC Decision Form
ANNEX 3	AF/03/01-SOP06/01	Approval letter

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Annex 1
AF /01/01-SOP06/01

Study Assessment Form for Initial Review

Protocol Number : (as per IEC records)		Date of receipt at IEC office (D/M/Y):	
Protocol Title :			
Principal Investigators: If multiple sites list the names of Principal Investigator sites follows			
Name of the Principal Investigator	Site address	Contact number	
Total No. of Participants the site:		No. of Study site:	
Sponsor:		Contact No.	
CRO:		Contact No.	
Duration of the Study:		Status:	F New F Revised F Amended
Reviewer's name :		Contact No.	
Type of the Study :	F Intervention F Epidemiology F Observation F Document based F Individual based F Genetic F Social Survey F Others, specify…….		
Review Status:	F Regular F Expedited		
Description of the Study in brief: Mark whatever applied to the study. F Randomized F Stratified Randomized F Open-labeled F Double blinded F Placebo controlled F Treatment controlled F Cross-over F Parallel F Interim Analysis F Use of Tissue samples F Use of Blood samples F Use of genetic materials F Multicenter study F Screening F Descriptive Brief the study design Study Objectives:			

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Review the protocol and related documents as per the guidelines attached with Annex 1.

Comments:

Assessment Report

Provisional Decision: F Approved F Approved with Recommendation

Signature of IEC member reviewing the project:	F Disapproved Date:

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Guidelines for reviewing a study protocol

Reviewers should think about and try to find answers to the following questions:

1. **How will the knowledge, result or outcome of the study contribute to Clinical well-being?**
   - **Knowledge from the basic research may possibly benefit.**
   - **A new choice of method, drug or device that benefits the subject during the study and others in the future.**
   - **Provide safety data or more competitive choices.**

2. **Does the study design will be able to give answers to the objectives? Whether**
   - **the endpoints are appropriately selected.**
   - **the participating duration of a study participant is adequate to allow sufficient change in the endpoints.**
   - **the control arm is appropriately selected for best comparison.**
   - **the placebo is justified.**
   - **the number of study participants in non-treatment (or placebo) arm is minimized.**
   - **unbiased assignment (e.g. randomization, etc.) is in practice.**
   - **Inclusion and exclusion criteria are carefully selected to eliminate confounding factors as much as possible.**
   - **the sample group size appropriate with the given statistical assumptions.**
   - **predictable risks are minimized.**
   - **the tests and procedures that are more than minimal risk are cautiously used.**
   - **subject deception is avoid.**
   - **instruction and counseling for study participants are included (if needed) when deception is integral to the study design.**
   - **the study participants are adequately assessed and provided follow-up care, if needed.**

3. **Who will be the participants in the study? Whether**
   - **the described population is appropriate for the study.**
   - **predictable vulnerabilities are considered.**
   - **it is completely necessary to conduct the study in a vulnerable population. If not, is there any other way to get the study answers?**
   - **there will be secondary participants.**

4. **Do the inclusion and exclusion criteria**
   - **selectively include participants most likely to serve the objective of the study?**
   - **equitably include participants?**
   - **properly exclude participants who can predictably confound the results?**

- **properly exclude participants who may predictably be at increased risk in the study due to coexisting conditions or circumstances?**

5. **Does the study design have adequate built-in safeguards for risks?**
   - **Appropriate screening of potential participants?**
   - **Use of a stepwise dose escalation with analysis of the results before proceeding?**
   - **Does the frequency of visits and biological samplings reasonably monitor the expected effects?**
   - **Are there defined stopping (discontinuation) /withdrawal criteria for participants with worsening condition?**
   - **Is there minimized use of medication withdrawal and placebo whenever possible?**
   - **Will rescue medications and procedures be allowed when appropriate?**
   - **Is there a defined safety committee to perform interim assessments, when appropriate?**
   - **Is appropriate follow-up designed into the study? For instance, gene transfer research may require following the participants for years or for their entire lifetime after they receive the gene transfer agent.**
6. **Is pre-clinical and/or early clinical studies sufficiently performed before this study?**
   - **The animal study and *in vitro* testing results?**
   - **Previous clinical results, if done?**
   - **Whether the proposed study is appropriately built on the pre-clinical and/or early clinical results.**
     - **the selected dose based on adequate prior results?**
     - **monitoring tests designed to detect expected possible risks and side effects?**
7. **Does the study and the informed consent process include issues of special concern, such as:**
   - **waiver or alteration of consent?**
   - **Delayed consent (e.g., emergency treatment, etc.)?**
   - **Deception?**
   - **Sensitive information of participants that may require a confidentiality statement?**

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Guidelines to review Informed Consent Document/Patient Information Sheet

The actual process of informed consent should:

- **Give the participants significant information about the study.**
- **Make sure the participants have enough time to carefully read and consider all options.**
- **Answer all questions of the participants before making decision to participate.**
- **Explain risks or concerns to the participants.**
- **Make sure that all information is understood and satisfied by the participants.**
- **Make sure the participants understand the study and the consent process.**
- **Obtain voluntary informed consent to participate.**
- **Make sure the participants can freely consent without coercion, pressure or other undue influences.**
- **Consent should be informally verified on a continuing basis.**
- **Continue to inform the participants throughout the study.**
- **Continue to re-affirm the consent to participate throughout the study.**

Procedures or methods used in the informed consent process if recruitment of study participants include:

- **A consent form**
- **Brochures, Pamphlets or other reading materials (i.e., letters to participants, phone pre-screening questionnaires, phone hold messages)**
- **Internet information**
- **Instruction sheets**
- **Audio-visual presentations**
- **Charts, diagrams or posters**
- **Discussions**
- **Consultation with others**

Techniques to improve the readability of consent forms:

- **Use short sentences and paragraphs**
- **Limit to one thought or topic in a sentence, avoid run-on sentence**
- **Use simple words, less syllables in a word.**
- **Use common words; remove technical jargon and medical terms.**
- **Try to use correct basic grammar and form.**
- **Use "gene transfer" instead of "gene therapy" (less implied effectiveness).**
- **Use "agent" instead of "drug" or "medicine" (less implied effectiveness).**
- **Try to avoid the use of "treatment", "therapy" or "therapeutic" in studies involving gene transfer (because these words imply effectiveness)**

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Guidelines to Placebo Justification

Background conditions, such as benefits of standard treatment, risk of using placebo, risk management and disclosure should be considered. The followings are some guides to ease Board decision.

III. Benefits of standard treatment

4) Is there a standard treatment?

5) Is the standard treatment widely accepted?

6) Has efficacy of the treatment been consistently proven?

7) Are all newly diagnosed patients with this condition put in standard treatment (versus observed or other)?

8) Does the treatment act on the basic mechanism of the disease (vs. symptoms)?

9) Are most (≥85%) of the patients with this condition responsive to standard treatment alternatives (vs. resistant or refractory)?

If the answers of (1) to (6) are "yes", placebo is not recommended.
If any one or more answers are "no", placebo may be possible.

10) Are the side effects of the standard treatment severe?

11) Does standard treatment have many uncomfortable side effects?

12) Does standard treatment have contraindications that prevent some subjects from being treated?

13) Is there substantial (≤25%) placebo response in this disease or symptom?

If the answer of* (7) *to* (10) *are "no", placebo is not recommended.
If any one or more answers are "yes", placebo may be possible.

II. Risks of placebo

2) Is the risk of using placebo instead of treatment life threatening?

If yes, placebo is not acceptable.

3) Is the use of placebo instead of treatment likely to lead to permanent damage?

If yes, placebo is not acceptable.

4) Is the risk of using placebo instead of treatment likely to cause irreversible disease progression?

If yes, placebo is not acceptable.

5) **Can the use of placebo instead of treatment lead to an acute emergency?**

6) **Is the risk of using placebo instead of treatment the persistence of distressing symptoms?**

7) **Is the risk of using placebo instead of treatment severe physical discomfort or pain?**

If the answer of* (4) *to* (6) *are "yes", placebo is not acceptable unless risk management is adequate.

VIII. Risk management

2) **Is there benefit in the overall management of the subject?**

- ***Yes, consider placebo***
- ***No, placebo not recommended.***

3) **Will the discontinuation of previous treatment put the participant in danger of acute relapse when transferred to placebo?**

- ***No, consider placebo***
- ***Yes, placebo not recommended.***

4) **Are subjects at high risk for the use of placebo excluded?**

- ***Yes, consider placebo***
- ***No, placebo not recommended.***

5) **Is the duration of the study the minimum necessary in relation to the action of the drug?**

- ***Yes, consider placebo***
- ***No, placebo not recommended.***

6) **Are there clearly defined stopping rules to withdraw the subject in case he/she does not improve?**

- ***Yes, consider placebo***
- ***No, placebo not recommended.***

7) **Is risk monitoring adequate to identify progression of the disease before the subject experience severe consequences?**

- ***Not applicable.***
- ***Yes, consider placebo***
- ***No, placebo not recommended.***

8) **Are there clearly defined stopping rules to withdraw the subject before the advent of severe disease progression?**

- ***Yes, consider placebo***
- ***No, placebo not recommended.***

9) If the risk of placebo is an acute emergency, are rescue medication and emergency treatment available?

- ***Not applicable.***
- ***Yes, consider placebo***
- ***No, placebo not recommended.***

10) If the risk of placebo is the persistence of distressing symptoms, is concurrent medication to control them allowed?

- ***Not applicable.***
- ***Yes, consider placebo.***
- ***No, placebo not recommended.***

11) If the risk of placebo is severely physical discomfort or pain, is there rescue medication?

- ***Not applicable.***
- ***Yes, consider placebo.***
- ***No, placebo not recommended.***

IX. Risk disclosure in the consent form

3) Are the risks of getting placebo instead of active treatment fully disclosed?

- ***Yes, consider placebo.***

4) Are the risks of the test drug disclosed?

- ***Yes, consider placebo.***

5) Are the advantages of alternative treatments explained?

- ***Yes, consider placebo.***

<u>Conclusions</u>:

1. The use of placebo is ethically acceptable because:

- **Subjects are not exposed to severe or permanent harm by the use of placebo.**
- **Subjects under placebo will benefit from the overall treatment of the disease.**
- **Risks of the use of placebo are minimized.**
- **Risks are adequately disclosed in the consent form.**

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Annex 2
AF/02/01-SOP06/01

IEC Decision Form

Date of IEC meeting: ……
Protocol number: ……

Protocol Title:	
Principal Investigators:	Site:
Documents under review in the meeting:	
Final Decision at the meeting:	F Approved F Approved with Recommendation F Disapproved

No.	IEC Members present at the meeting (Name)	Decision			
		AP	AR	DA	EAV

Note: *AP - Approved; AR – Approved with recommendation;*
DA – Disapproved; EAV-Earlier approval valid
Resubmitted protocol to be subjected to: expedited review/full board view

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Approved with recommendations is subjected to:

- Reviewed by Chairperson only in Full Board/Expedited meeting
- Reviewed by any 2 IEC members in Full Board/Expedited meeting

0. Name of IEC member: _____ Sign: _____

0. Name of IEC member: _____ Sign: _____

- Reviewed in Full Board IEC meeting

Signature:

……
Chairperson

Date:…….

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Annex 3
AF/03/01-SOP06/01

INDEPENDENT ETHICS COMMITTEE
PROJECT APPROVAL LETTER

Address of Ethics Committee		
Principal Investigator		
Clinical trial protocol title :-		
The Independent Ethics Committee has reviewed the following documents submitted for the above – mentioned clinical study.		
Name of document	RV	AP
1. 2 3 4		

RV denotes Reviewed ; AP denotes Approved

MEMBERS PRESENT AT MEETING HELD ON --- --TO REVIEW PROJECT

Name of member	**Position on Ethics Committee**	**Status (P/ABS)**	**Qualification / Profession / Occupation**

ABS denotes Abstainees P denotes Present

The approval is valid from **---- till -----** and the renewal of this clinical project is subject to review of "Annual Study Report" submitted to this Ethics Committee by the Investigator.

The research proponents are hereby informed that the Independent Ethics Committee (IEC) will require the following:

1. All adverse events that are either serious or unexpected to be reported within 7 working days to the IEC.
2. The progress report to be submitted to the IEC at least annually.
3. Upon completion of the study, a final study status report needs to be submitted to the IEC.

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A maximum of----patients will be enrolled at this trial site.

DECISION

Opinion of the Independent Ethics Committee for Research on Clinical Subjects (IEC)
_____√__ Approval **_____Provisional approval** **_____Disapproval** **Date of approval : 00/00/200__** **Dr. R. D. Lele** **Chairperson**