
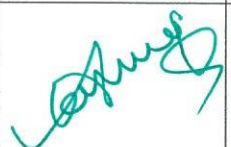



ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 2 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

STANDARD OPERATING PROCEDURES

ETHICS COMMITTEE, INSTITUTE OF NEPHROUROLOGY, BENGALURU

	NAME	DESIGNATION	SIGNATURE	DATE
PREPARED BY	Dr. Kowsalya.R	Professor of Biochemistry, Member Ethics Committee, INU, Bengaluru		13.11.2020
REVIEWED BY	Dr. Pradeep.M.S.	Prof. & HOD of Anaesthesiology, Member Secretary, Ethics Committee INU, Bengaluru.		13.11.2020
AUTHORISED BY	Dr. J.M. Jeetendra Kumar	Dean, ESIC-Medical College & PGIMSR, Chairperson of Ethics Committee		14.11.2020

डॉ जितेन्द्र कुमार जे एम / Dr. Jeetendra Kumar J.M.
डीन / DEAN
ई.एस.आई. सी, एम सी, पी जी आई एम एस आर और एम एच
ESIC MC PGIMSR & MH
राजाजीनगर, बेंगलुरु / Rajajinagar, Bengaluru-10


Dr. Pradeep M.S
Member Secretary
Institutional Ethical Committee
Institute of NephroUrology
Bengaluru-560002

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 2 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

CONTENTS

Sl. No.	Title	Page No.
1	Objective of SOP	4
2	General principles in biomedical research involving human subjects	4
3	Role of Institutional Ethics Committee (IEC)	6
4	Authority under which Institutional Ethics Committee (IEC) is constituted	7
5	Composition of IEC	7
6	Membership requirement and recruitment of members	8
7	Quorum requirement	9
8	Responsibilities of IEC members	10
9	Resignation/replacement/termination/disqualification procedure	10
10	IEC membership list	11
11	Conflict of interest	12
12	Terms of reference	12
13	Training	13
14	The work procedure of the IEC	13
15	Types of clinical research projects reviewed by the committee	18
16	List of documents reviewed for each clinical trial project	18
17	Serious adverse events	19
18	Vulnerable groups	22
19	Record keeping	22
20	Management of regulatory inspection	23
21	Conducting audits of investigative site	25
22	Expedited review	25
23	Plan of overseeing satellite centers	28

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY
Victoria Hospital Campus, Bengaluru, Karnataka 560002
STANDARD OPERATING PROCEDURE

SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 3 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

Appendices

Appendices	Title	Page Nos
Appendix-I	IEC Application Form	30-38
Appendix-II	IEC Appointment Letter	39
Appendix-III	IEC Acceptance Letter	40-41
Appendix-IV	IEC Confidentiality Agreement Form	42-44
Appendix-V	IEC Conflict of Interest Agreement Form	45-46
Appendix-VI	IEC Annual Calendar Template	47
Appendix-VII	IEC Approval Letter	48-50
Appendix -VIII	IEC Fee Details	51
Appendix-IX	IEC Audit Calendar	52
Appendix-X	Periodic Self -Assessment Format	53
Appendix-XI	Training Calendar	54

<p style="text-align: center;">ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE</p>			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 4 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

1. Objective of SOP:

The objective of this SOP is to contribute to the effective functioning of the Institutional Ethics Committee (IEC) for Relating to Clinical Trial or Bioavailability and Bioequivalence Study compliance to **New Drugs and Clinical Trials Rules, 2019** released by CDSCO office to meet quality and consistent ethical review mechanism for health and biomedical research is put in place for all proposals dealt by the committee as prescribed by the Ethical guidelines for biomedical research on human subjects of ICMR, ICH GCP, Indian GCP and applicable regulatory requirements.

2. General principles in biomedical research involving human subjects:

The committee will ensure a strict concordance with the statements of General principles on Research using Human Subjects in Biomedical Research as well as the Statement of Specific Principles on Research using Human subjects in specific areas of biomedical Research, as laid down by Indian Council of Medical Research (ICMR).

The general statement includes:

- The Purpose of the research should be directed towards the increase in knowledge about human beings
- Research is conducted under conditions that no one person/persons becomes a mere means for the betterment of other.
- Research is subjected to a regime of Evaluation at all stages on proposal, i.e. design, experimentation, statistical validity, declaration and use of results thereafter.

To ensure that the research protocols that are carried out at **INSTITUTE OF NEPHRO UROLOGY** are in accordance to the guidelines laid down by Indian Council of Medical Research (ICMR), Indian GCP, ICH GCP and New drug and clinical trials Rules 2019 the following criteria, but not limited to these only, must be met:

- Do not compromise the safety of the subject.
- Study procedures to be conducted under the supervision of medical persons with the required expertise

<p style="text-align: center;">ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE</p>			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 5 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

- Include solely patients who have given voluntary and informed, consent to participate in the clinical study.

Any research using the human beings as subjects of medical or scientific research or experimentation shall bear in mind the following principles.

- Principles of essentiality** whereby, the research entailing the use of human subjects is considered to be absolutely essential after a due consideration of all alternatives.
- Principles of voluntariness, informed consent and community agreement**
Whereby, research subjects are fully apprised of research subject and others.
- Principle of non-exploitation**, whereby, as a general rule, research subjects are remunerated for their involvement in the research or experiment; and, irrespective of the social and economic condition or status, or literacy or educational levels attained by the research subjects kept fully apprised of all the dangers arising in and out of the research.
- Principles of privacy and confidentiality** whereby, the identity and records of the human subjects of the research or experiment are as far as possible kept confidential.
- Principles of precaution and risk minimization** whereby, due care and caution is taken at all stages of the research and experiment.
- Principles of professional competence** whereby, the research is conducted at all times by competent and qualified persons who act with total integrity and impartiality. The team must be led by a competent Principal Investigator, whose credentials and previous experience in Clinical trials will be discussed by the IEC before the proposed trial is discussed further.
- Principles of accountability and transparency** whereby, the research or experiment will be conducted in a fair, honest, impartial and transparent manner

<p style="text-align: center;">ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE</p>			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 6 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

after a full disclosure is made by those associated with the research or experiment of each aspect of their interest in the research.

- viii. **Principles of the maximization of the public interest and of distributive justice** whereby, the research or experiment and its subsequent appreciative use are conducted and used to benefit all human kind.
- ix. **Principle of institutional arrangements** whereby, there shall be a duty on all persons connected with the research to ensure that all the procedures required to be complied with and all institutional arrangements required to be made in respect of the research and its subsequently use or application are duly made in a benefit and transparent manner.
- x. **Principle of public domain** whereby, the research and any further research, experimentation or evaluation in response to, and emanating from such research is brought into the public domain.
- xi. **Principle of totality of responsibility** whereby, the professional and moral responsibility, for the due observance of all the principles, guidelines or prescriptions laid down generally or in respect of the research or experiment in question, devolves on all those directly or indirectly connected with the research or experiment.
- xii. **Principle of compliance** whereby, there is a general and positive duty on all persons conducting, associated or connected with any research entailing the use of a human subject.

3. Role of Institutional Ethics Committee (IEC):

IEC will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of all actual and potential research participants. The goal of research, however important will never be permitted to override the health and well being of the research subjects. The

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY
Victoria Hospital Campus, Bengaluru, Karnataka 560002
STANDARD OPERATING PROCEDURE

SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 7 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

IEC will ensure that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non-maleficence and justice are taken care of in the planning, conduct and reporting of the proposed research. For this purpose, IEC will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefits and provision for appropriate compensations wherever required.

It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures. The committee will also examine compliance with all applicable regulatory requirements, applicable guidelines and laws.

4. Authority under which Institutional Ethics Committee (IEC) is constituted:

The Institutional Ethics Committee is constituted by the authority vested in the principal of INSTITUTE OF NEPHRO UROLOGY. The Institutional Ethics Committee has been constituted under the guidelines of New drug and Clinical trials 2019, ICMR, WHO Operating Guidelines for Ethical Review Committee that Review Biomedical Research, and ICH (International Conference on Harmonization) Good Clinical Practice (GCP).

Name: Ethics Committee: ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY

5. Composition of the IEC:

The Institutional Ethics Committee of the **INSTITUTE OF NEPHRO UROLOGY** is multidisciplinary and multi-sectorial in composition. Independence and competence are the two hallmarks of the IEC. The Chairperson of the Committee is from outside the Institution. This is to maintain the independence of the Committee. The Member Secretary is from the Institution and will be responsible for day to day activities of the IEC. Other members are amalgamation of medical / non-medical, scientific and non-scientific background, including lay public to reflect the differed viewpoints.

The composition may be as follows:-

1. Chairperson

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 8 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

2. Basic medical scientist(s)
3. Clinicians
4. Legal expert(s)
5. Social scientist(s) / representative(s) of non-governmental voluntary agency
6. Lay person(s) from the community
7. Member-Secretary

The IEC has adequate representation of age, gender, community etc. in the committee to safeguard the interest and welfare of all sections of the community/society. All the IEC members are aware of the local, social and cultural norms to facilitate the competent review of the proposals and also to protect the rights, safety and well being of the human subjects participating in the biomedical research.

If required, IEC may invite subject experts to offer their views, for example for drug trials a pharmacologist; preferably a clinical pharmacologist may be included. Similarly, based on the requirement of research area, for example HIV, genetic disorders etc. specific patient groups may also be represented in the committee.

All the members will be appointed by the Chairman of **INSTITUTE OF NEPHRO UROLOGY** with appropriate documentation of their appointment and acceptance. The appointment will be based on their competencies and integrity.

6. Membership requirement and recruitment of members:

- The members for IEC will be recruited by the Chairman or any of the Directors of **INSTITUTE OF NEPHRO UROLOGY** initially for a period of 3 years. A copy of letter of appointment and acceptance, member profile (CV), the confidentiality agreement & disclosure of conflict of interest agreement duly signed by all the members will be kept as IEC records.

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 9 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

- At the end of 3 years, as the case may be, the committee will be reconstituted, and 25% of the members will be replaced with a formal documentation of reconstitution and replacement.
- A member can be replaced in the event of death or long term non-availability (i.e. absence of a member in three consecutive IEC meetings) or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.
- A member can tender resignation from the committee with proper reasons to do so.
- All IEC members should maintain absolute confidentiality of all discussions during the meeting and must sign a confidentiality form.
- Prior to involvement in IEC meetings, all members must declare their conflict of interest. If prior to any meeting a member deems that he/she has a conflict of interest in a study to be discussed then he/she must immediately disclose the conflict of interest and must not participate in the deliberation of the IEC.
- All members must be trained prior to their involvement in IEC meetings.
- IEC members should be selected in their personal capabilities, based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the IEC's work.

7. Quorum requirement:

According to New Drugs and Clinical Trials Rules, 2019, minimum 5 members are required to compose a quorum. All decisions must be taken in meetings and not by circulation of project proposals. Minutes of Meeting along with the list of members present during the meeting must be maintained.

- i. Basic Medical Scientist

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 10 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

- ii. Clinician
- iii. Legal Expert
- iv. Social Scientist / Representative of NGO / Ethicist / Theologian
- v. Lay person from community

8. Responsibilities of IEC Members:

- i. Review the protocols
- ii. Attend the EC meetings (6 or more per year)
- iii. Opine on the new project provided
- iv. Monitoring of approved projects, with special reference to Adverse events/SAE
- v. Survey of execution of the projects, as and when required
- vi. Provide inputs to the Data Safety Monitoring Committee
- vii. Maintain confidentiality

9. Resignation / replacement /termination / disqualification procedure:

The members who have resigned may be replaced at the discretion of the appointing authority for the same. EC members who decide to resign must provide at least 30 calendar days notice prior to the next scheduled meeting. Appointment may be made in the consultation with Member Secretary and Chairperson.

A member may be relieved or terminated of his/her membership in case of:

- i. Long term non-availability (i.e. absence of a member in three consecutive IEC meetings)
- ii. For any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.
- iii. Inability to participate in the IEC meetings on any grounds
- iv. Relocation to another city or any such matter, from where member cannot participate in the IEC deliberations.

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY
Victoria Hospital Campus, Bengaluru, Karnataka 560002
STANDARD OPERATING PROCEDURE

SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 11 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

10. IEC membership list:

New member list			
Sl.No	Name of the members	Qualification	Position
1	Dr. Jeetendra J M Kumar	MBBS, MD Medicine	Chair Person
2	Dr. Pradeep.M.S.	MBBS, MD Anaesthesiology	Member Secretary
3	Dr. C.R. Jayanthi	MBBS, MD Pharmacology	Medical Scientist
4	Dr. A.J. Kamath	MBBS, MS General Surgery, M.Ch Urology	Clinician
5	Dr. Sharon Ruth	M.Phil, Clinical Psychology	Lay Person
6	Dr. Kowsalya.R.,	MBBS, MD (Bio-chemistry)	Clinician
7	Mrs. Akkamahadevi Hiremath	BA, LLB, PG Diploma in Human Resource.	Legal Expert
8	Mr.Manjunath Reddy L	BE Biotechnology PGDCR	Member
9	Mr. B.S. Srinivas	VedantaVidwat, Agama Vidwat	Lay Person

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY
Victoria Hospital Campus, Bengaluru, Karnataka 560002
STANDARD OPERATING PROCEDURE

SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 12 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

11. Conflict of interest:

All IEC, including the Chairperson, are subject to the Policy on Conflicts of Interest approved by the Chairman of INSTITUTE OF NEPHRO UROLOGY from time to time. In the event that a matter arises in which an Ethics Committee member is implicated, the Ethics Committee shall meet without the presence of the implicated Ethics Committee member.

12. Terms of reference:

The terms of references for IEC includes description on composition of IEC, terms of appointment of members with reference to the duration of the term, quorum requirement, the policy for removal, replacement, resignation procedure, frequency of meetings, and payment of processing fee to the IEC for review, honorarium / consultancy to the members / invited experts etc. as given in the SOP.

The SOPs will be revised periodically (i.e. within every two years) or based on the changing requirements. The term of appointment of members will extended for another term and a defined percentage of members (25%) will be changed every three years. It would be preferable to appoint persons trained in bioethics or persons conversant with ethical guidelines and laws of the country. Substitute member may be nominated if meetings have been continuously missed (i.e. three consecutive times) by a member due to illness or other unforeseen circumstances.

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 13 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

13. Training:

All IEC members are trained on ethical principles, good clinical practice and applicable regulations prior to involvement in IEC meetings. The IEC members will be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics by its own members or regular training organized by constituted body (ies), so that they become aware of their role and responsibilities. . Any change in the regulatory requirements will be brought to their attention. All IEC members must be aware of local, social and cultural norms as this is the most important social control mechanism. The training calendar gives us a record of all the training of the Ethics Committee Members.

14. The work procedure of the IEC is as follows:

- IEC SOP is to be written in Times New Roman font with font size 12. The Appendices may have smaller font size to adjust as per the page requirement or size. The SOP will be distributed in controlled form to all the members and other stakeholders. The SOP will be revised within every two years, but if the requirements change, it can be revised intermittently. The SOP version or date will be changed only if the SOP is revised. If the appendices are modified or changed intermittently the SOP need not to be revised. The new appendices may be enclosed along with the SOP to address change or modification in the enclosed appendices.

- **The chairperson will conduct all meetings of the IEC as per New drugs and Clinical trials, 2019 released by CDSCO**

The chair person fully capable of managing the IEC and the matters brought before it, with fairness and impartiality. The task of making the IEC a respected part of the institutional community will fall primarily on the shoulders of this individual. The IEC must be perceived to be fair and impartial immune from pressure of Institute of Nephro Urology administration.

The IEC Chairperson will respect the diverse backgrounds, perspectives, and

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 14 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

sources of expertise of all IEC members, especially the contributions of the non-scientists, and must have the ability to foster respect among the IEC members.

The Chairperson shall ensure active participation of all members (particularly non-affiliated, non-medical/ non- technical members) in all discussions and deliberations. The Chairperson shall ratify minutes of the previous meetings, handle complaints against researchers and EC members, conflict of interest issues and requests for use of EC data etc.

The Member Secretary will be a staff member of INSTITUTE OF NEPHRO UROLOGY and he is responsible for organizing the meetings, maintaining the records and communicating with all concerned.

He/she will prepare the minutes of the meetings and get it approved by Chairperson before communicating to the researchers.

- Ethics Committee will meet on once in the month.
- Applicant/Researcher must submit the proposal to the IEC in prescribed format along with the study protocol at least 3 (three) weeks in advance of the scheduled IEC meetings. The IEC member (or Designee) will acknowledge the receipt of the package by signing and dating the acknowledgment copy of the application letter. If available the member (or designee) will stamp the letter with IEC stamp.
- On receipt of proposal, the documents will be circulated to all the IEC members well in advance of the meeting, for detailed review. While reviewing the proposal following criteria should be considered:
 - Minimize risk to the participants
 - Risks must be reasonable in relation to the 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

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY
Victoria Hospital Campus, Bengaluru, Karnataka 560002
STANDARD OPERATING PROCEDURE

SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 15 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

- There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data where appropriate
- Appropriate safeguards are included to protect vulnerable participants
- During each meeting limited number of protocols will be discussed (i.e. as decided and communicated by Ethics Committee) keeping in view that all parameters required for competent review are discussed and consensus drawn
- Quorum of 5 members, as given in the SOP, is required to conduct the IEC meeting. If a member is unable to attend a meeting, his/her opinion on the project MUST be submitted in writing to the Chairperson of the committee, before the date of the meeting for a decision. The members, who are unable to attend a meeting, will not be allowed to vote. But their feedback or suggestions on the proposal may be discussed during the meeting to maintain the multi-sectorial and competent review of the proposal.
- For expedited review the IEC will meet earlier as is required. Requirement of quorum is similar to that explained above.
- The final decision of the IEC will be in from of any one of the categories given below:
 - a. Approval
 - b. Disapproval
 - c. Modification before Approval
 - d. Discontinuation of previously approved project
- The IEC decisions will be communicated in writing under the signature of the IEC Member Secretary.

In case of a positive decision a statement of the responsibilities of the applicant will be communicated. The IEC expects that, the researchers keep the committee informed of, but not limiting to the following:

- All cases of protocol amendments should be submitted for IEC review and approval before implementation

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY
Victoria Hospital Campus, Bengaluru, Karnataka 560002
STANDARD OPERATING PROCEDURE

SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 16 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

- All cases of amendments to the Informed Consent Form and Patient Information Sheet must be submitted to IEC for review and approval before implementation.
 - All cases of amendments to recruitment material
 - Serious and unexpected adverse events related to the conduct of the study
 - Protocol deviation, if any should be informed with adequate justification
 - Any new information that may affect the risk/benefit ratio of the study
 - Annual progress report (the clock for the same starts from the date of receipt of IEC approval for the study)
 - Final report to be submitted at the end of the study
 - Premature termination of the study should be notified with reasons along with summary of the data obtained so far
 - Site close out to be notified along with the final status report including the details of subjects, IP and documentation
 - All administrative changes, which has study implications must be notified to IEC
- In case of a conditional decision i.e. where ethics clearance is subject to condition i.e. Modification of study documents or requirement of additional documents, the IEC will communicate to the researcher or Investigator the stipulated requirement, including suggestions for revision and the procedure for re-reviewing the application. Any time limit imposed for reply will also be stated.
 - In case of negative decision a clear statement of the reason(s) for the negative decision will be communicated to the researcher or Investigator including whether it may be submitted as new proposal with appropriate changes. The right to appeal and procedure for re-review (if any) will also be communicated.
 - With regard to approval of amendments: should an amendment to a study-related document be administrative in nature and does not involve any change which may jeopardize the subject or the study, then it may be approved by EC in an

<p style="text-align: center;">ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE</p>			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 17 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

expedited manner or as an amendment. But the decision to consider the amendment as minor or major lies fully with the IEC. If an amendment is considered major it will be approved during a full meeting involving the full quorum as stated in the New Drugs and Clinical Trials Rules, 2019.

- Reported Indian SAE's will be discussed during the IEC meetings to decide on the quantum of compensation and causality of the event.
- An IEC may decide to reverse its positive decision on a study if it receives information that may adversely affect the risk/benefit ration
- The discontinuation of a trial may be ordered if the IEC finds that the goals of the trial have already been achieved midway or unequivocal results are obtained.
- IEC allows investigators to present and defend the proposals during the IEC meetings. The Investigator may also be called to present if a clarification is sought on certain issues in the applications
- IEC may seek help from the outside experts (form within or outside **INSTITUTE OF NEPHRO UROLOGY**) if required. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities; patient groups or special interest groups e.g. Cancer patients, HIV/AIDS positive persons or ethnic minorities. They are required to give their specialized views but do not take part in the decision making process which will be made by members of the IEC
- Minutes of meetings will be documented and maintained for every meeting conducted by IEC
- IEC decision will be communicated within four (4) weeks of the submission for protocols requiring review by the IEC members.
- IEC decision to be completed within four (4) to five (5) weeks from submission for expedited protocols or amendments.
- All proposals are to be submitted in the prescribed IEC application form

<p style="text-align: center;">ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE</p>			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 18 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

- Thirteen hard copies of the proposal along with a soft copy need to be submitted to IEC for competent review. Prescribed fee should be remitted along with the application
- The date of IEC meetings will be communicated to researchers or investigators in form of an annual calendar. If there is any change in the schedule it will be communicated well in advance.

15. Types of clinical research projects reviewed by the committee:

- Observational studies
- Record reviews and historical studies
- Surveys, Questionnaires and Interviews
- Epidemiological studies
- Prospective studies either with or without any intervention
- Company sponsored drug trials
- Studies evaluating new devices and implants
- Patch test

16. List of documents reviewed for each clinical trial project:

1. IEC application form
2. Protocol or protocol amendments
3. Investigator brochure or amendments
4. English language informed consent form, translations and its back translations
5. Translation and back translation certificates
6. Any recruitment or retention material or any other advertisement. Their translations and back translations along with certificates, if applicable
7. Insurance policy
8. Updated CVs of the Investigators along with medical registration certificates
9. GCP training certificates of the Investigators

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY
Victoria Hospital Campus, Bengaluru, Karnataka 560002
STANDARD OPERATING PROCEDURE

SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 19 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

10. Undertaking from investigators
11. Copy of Clinical Trial Agreement (CTA)
12. DCGI clearance/approval, if applicable. If approval is awaited mention in application letter and submit the DCGI submission letter
13. CTRI registration number
14. IEC approvals from other investigative site(s), if applicable
15. Other relevant regulatory approvals, if applicable
16. Financial Disclosure Form (FDF) form all investigators
17. Case Report Form (CRFs), subject diary, questionnaires, follow-up cards etc. If translations and back translations to be used then those along with certificates also need to be submitted.
18. Source templates provided by Sponsor. If it is site specific template printed on letter head it must only be notified to IEC for review. Site specific template does not require IEC approval.
19. Any Other relevant documents required for the study

17. Serious adverse events:

Serious adverse events (SAE) will be reviewed in IEC meetings. Opinions from specialists in the particular area, who don't have any conflict of interest, may be taken, if required. In cases of significant SAEs, Principal Investigator of the study will be asked to justify the continuation of the study.

Any SAE, including laboratory test abnormalities, clinical trial related injury or death, regardless of causal relationship, will immediately be reported to the Institutional Ethics Committee Chairman, Sponsor and RA (DCGI) within **24 hours**.

Reporting of fatal SAEs

Investigator to report fatal SAE within **24 hours** of becoming aware [New Drugs and Clinical Trials Rules, 2019] to

- Sponsor/Contract Research Organization (CRO),

<p style="text-align: center;">ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE</p>			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 20 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

- Chairperson of Ethics Committee
- Drugs Controller General of India (DCGI)
- Chairman of INSTITUTE OF NEPHRO

UROLOGY

Investigator to submit the analyzed report (causality assessment) within **14 (fourteen) days** of becoming aware of the event to [as per New Drugs and Clinical Trials Rules, 2019].

- Sponsor/CRO (if applicable)
- Chairman of Ethics Committee
- Head of Institute
- DCGI
- Chairman of Expert Committee

In case of serious adverse event of death occurring to the clinical trial subject, the IEC shall forward it's report on the serious adverse event of death, after due analysis along with its opinion on the financial compensation, if any, to be paid by the Sponsor or his representative, whosoever had permission from the Licensing Authority as defined under rule 21(b) for conducting the clinical trial, to the:

- Licensing Authority (DCGI)

The report need to be submitted within 30 (thirty) days of the occurrence of the SAE. The Ethics Committee will foresee that subjects receive the benefits as decided by the LA/Expert Committee.

Reporting of Non-fatal SAEs

Investigator to report non-fatal SAE within **24 hours** of becoming aware [as per New Drugs and Clinical Trials Rules, 2019] to

- Sponsor/CRO
- Chairman of Ethics Committee
- DCGI

<p align="center">ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE</p>			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 21 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

- Chairperson of INSTITUTE OF NEPHRO UROLOGY.

Investigator/Sponsor to submit the analyzed report (causality assessment) within 14 (fourteen) days of becoming aware of the event to [as per New Drugs and Clinical Trials Rules, 2019]:

- Chairman of Ethics Committee,
- Head of Institute
- DCGI

In case of serious adverse event other than death occurring to the clinical trial subject, the IEC shall forward it's report on the serious adverse event of death, after due analysis along with its opinion on the financial compensation, if any, to be paid by the Sponsor or his representative, whosoever had permission from the Licensing Authority as defined under rule 21(b) for conducting the clinical trial, to:

- Licensing Authority (DCGI)

The report needs to be submitted within 30 (thirty) days of the occurrence of the SAE. The Ethics Committee will foresee that subjects receive the benefits as decided by the LA.

<p style="text-align: center;">ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE</p>			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 22 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

18. Vulnerable groups:

Effort may be made to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed.

- Research on genetics should not lead to racial inequalities;
- Persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them;
- Rights and welfare of mentally challenged and mentally differently able persons who are incapable of giving informed consent or those with behavioral disorders must be protected.
- Appropriate proxy consent from the legal guardian should be taken after the person is well informed about the study, need for participation, risks and benefits involved and the privacy and confidentiality procedures. The entire consent process should be properly documented.
- Adequate justification is required for the involvement of participants such as prisoners, students, subordinates, employees, Children, service personnel etc. who have reduced autonomy as research participants, since the consent provided may be under duress or various other compelling reasons.

19. Record keeping:

All documentation and communication of an Ethics Committee are to be dated, filed and preserved according to the standard operating procedures. It is the responsibility of IEC staff to ensure that all study files are prepared, maintained, and kept securely for a period of not less than five years (both in soft and hard copy) from the date of study completion or termination. . Approved protocols are assigned unique identifier that ensures confidentiality and facilitates retrieval at any time. Strict confidentiality must be maintained during access and retrieval procedures. Records should be maintained for the following namely:

- The constitution and composition of the IEC
- The curriculum vitae of all IEC members
- Standard operating procedures followed by the IEC

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 23 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

- National and international guidelines
- Copies of the protocol, data collection formats, CRFs, investigational brochures etc. submitted for review
- All correspondence with IEC members and investigators regarding application, decision and follow up
- Agenda of all IEC meetings
- Minutes of all IEC meetings with signature of the Chairperson
- Copies of decisions communicated to the applicants
- Record of all notification issued for premature termination of a study with a summary of the reasons
- Final report of the study including microfilms, CDs.

All closed study files will be separately archived. After completion of archival period the closed files will be shredded and disposed off. A log book of disposed documents will be maintained.

20. Management of regulatory inspection:

The regulatory inspection of the IEC can be conducted with or without prior notification by the regulatory agency. Foreseeing the regulatory inspection the IEC will take all the measures required to ensure that the trials are conducted strictly in accordance with the clinical trial regulations and guidelines.

Ethics committee shall remain open for inspection by the inspectors or officials of the Central Drugs Standard Control Organization (CDSCO). The IEC shall allow inspectors or officials of the CDSCO to enter its premises to inspect any record, data, or document related to clinical trials approved by the IEC and shall provide adequate replies to

<p style="text-align: center;">ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE</p>			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 24 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

queries/observations (if any) raised by such inspectors or officials of the CDSCO in relation to the conduct of the clinical trial.

Preparation for the Regulatory Inspection:

- i. IEC will be registered under the Licensing Authority. The renewal of registration will be done three months prior to the expiry of registration. For this IEC will keep a track of the registration approval date.
- ii. IEC will be constituted as per the ICMR Guidelines & New Drugs and Clinical Trials Rules, 2019
- iii. IEC will ensure that the right, safety and well being of the subjects participating in the biomedical research is always protected
- iv. IEC will review all study protocols considering the following criteria:
 - Minimize risk to the participant
 - 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 provisions 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
 - Appropriate safeguard are included to protect vulnerable population
- v. IEC will maintain all appropriate records to substantiate proper functioning of the Ethics Committee deliverables.
- vi. If the Inspection is conducted with prior notice, all the members of the IEC will be made aware of the Inspection.

<p style="text-align: center;">ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE</p>			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 25 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

During Inspection:

- During the Inspection the delegated personnel from IEC will be present to face the Inspection.
- He/she will provide the inspectors with requested records/documents.
- If any questions are raised by the Inspectors, the delegated personnel will answer all the questions to the point and with facts/evidence.

After Inspection:

- On receipt of the query letter, if applicable, the IEC will ensure that all queries are addressed within the stipulated timelines.
- If required, the corrective actions will be implemented.

21. Conducting audits of the investigative sites:

It is the responsibility of the IEC members to perform on-site inspection of selected studies of relevant projects it has approved to ensure the rights and safety of the research participants. The members or Secretariat in consultation with the Chairperson may initiate an on-site evaluation of a study site for cause or for a routine audit. A complete report of the findings is sent to the Chairperson within 14 days of the audit and presented during the Full Board Meeting. The IEC recommendations are communicated to the PI within 14 days of the meeting.

Frequency of the auditing of any protocol approved by the IEC is decided on the interim study reports submitted to the IEC.

22. Expedited review

The proposals presenting no more than minimal risk to research participants may be subjected to expedited review. The Member-Secretary and the Chairperson of the IEC or designated member of the committee may do expedited review only if the protocol involves:

- Minor deviations from originally approved research during the period of approval (usually of one year duration)

<p style="text-align: center;">ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE</p>			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 26 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

- Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis
- Research activities that involve only procedures listed in one or more of the following categories:

Clinical studies of drugs and medical devices only when -

- Research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population
or
- Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.
- Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.
- When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and the same participants should not be included in the clinical trial that may be initiated later based on the findings of the pilot study

a) Research on interventions in emergency situation

When proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, physicians may use new intervention as investigational drug (IND) / devices/ vaccine to provide emergency medical care to their patients in life threatening conditions. Research in such instance of medical care could be allowed in patients –

- I. When consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible.

However, information about the intervention should be given to

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY
Victoria Hospital Campus, Bengaluru, Karnataka 560002
STANDARD OPERATING PROCEDURE

SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 27 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

- II. the relative/ legal guardian when available later;
- III. When the intervention has undergone testing for safety prior to its use in emergency situations and sponsor has obtained prior approval of DCGI;
- IV. Only if the local IEC reviews the protocol since institutional responsibility is of paramount importance in such instances.
- V. If Data Safety Monitoring Board (DSMB) is constituted to review the data;

b) Research on disaster management

A disaster is the sudden occurrence of a calamitous event at any time resulting in substantial material damage, affecting persons, society, community or state(s). It may be periodic, caused by both nature and humans and creates an imbalance between the capacity and resources of the society and the needs of the survivors or the people whose lives are threatened, over a given period of time. It may also be unethical sometimes not to do research in such circumstances. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore, the following points need to be considered when reviewing such research:

- I. Research planned to be conducted after a disaster should be essential culturally sensitive and specific in nature with possible application in future disaster situations.
- II. Disaster-affected community participation before and during the research is essential and its representative or advocate must be identified.
- III. Extra care must be taken to protect the privacy and confidentiality of participants and communities.
- IV. Protection must be ensured so that only minimal additional risk is imposed.

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 28 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

- V. The research undertaken should provide direct or indirect benefits to the participants, the disaster-affected community or future disaster- affected population and a prior agreement should be reached on this, whenever possible, between the community and the researcher.
- VI. All international collaborative research in the disaster-affected area should be done with a local partner on equal partnership basis.
- VII. Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.

23. Plan of overseeing satellite centers

INSTITUTE OF NEPHRO UROLOGY Ethics Committee will oversee all existing/upcoming satellite centers of INSTITUTE OF NEPHRO UROLOGY in Bangalore.

Applicants willing to conduct study in any of the satellite centers must submit the proposal 4 (four) weeks in advance of the scheduled IEC meetings at INSTITUTE OF NEPHRO UROLOGY Bangalore, India.

The IEC Member Secretary or coordinator will acknowledge the receipt of the package. The acknowledged copy will be signed, dated and stamped.

All IEC notifications must be sent to INSTITUTE OF NEPHRO UROLOGY Ethics Committee, Victoria Hospital Campus, Bengaluru, Karnataka 560002, India (soft copy & hard copy).

Soft copy of acknowledgement letter will be sent within 2 hours and hard copy will be sent within 48 hours of receiving of the letter to the satellite centre.

IEC will arrange meetings through video conferencing in each meeting or as required to stay abreast with the study status.

IEC will conduct inspection half yearly to each satellite centre where the study is going

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 29 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

on. The IEC will review all study documents in the presence of PI & conduct a meeting with PI & study team.

Serious adverse events:

Serious adverse events (SAE) will be reviewed by Ethics Committee, INSTITUTE OF NEPHRO UROLOGY on an expedited meeting.

Investigators need to report fatal and non-fatal SAE within 24 hours of becoming aware [as per New Drugs and Clinical Trials Rules, 2019] to

- Chairperson of Ethics Committee
- Sponsor/Contract Research Organization (CRO)
- Drugs Controller General of India (DCGI)
- Chairman of INSTITUTE OF NEPHRO UROLOGY.

Record Keeping:

All communications and documents of IEC with satellite centers will be dated, filed and archived according to the standard operating procedures of Ethics Committee, INSTITUTE OF NEPHRO UROLOGY under supervision of designated IEC staff.

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY
Victoria Hospital Campus, Bengaluru, Karnataka 560002
STANDARD OPERATING PROCEDURE

SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 30 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

Appendix-I

IEC APPLICATION FORM

Instruction: Submit 12 copies of the research documents along with the application form and the covering letter. One soft copy also needs to be submitted in a pen drive.

No research project shall be/can be started unless ethics clearance/approval is obtained.

This form must not be used for submitting amendments. The amendments can be submitted along with the covering letter. A sample format is included below, applicants need to use this as a guideline for their submission.

1. Protocol Title:			
Protocol No.:		Total Study Participants:	

2. Study Type: Tick the applicable:				
Survey	<input type="checkbox"/>	Retrospective	<input type="checkbox"/>	Prospective
Social	<input type="checkbox"/>	Behavioral Research	<input type="checkbox"/>	Community Based
Observational	<input type="checkbox"/>	Epidemiology	<input type="checkbox"/>	Interventional
Clinical Trial	<input type="checkbox"/>	Genetic Study	<input type="checkbox"/>	Other: _____

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY
Victoria Hospital Campus, Bengaluru, Karnataka 560002
STANDARD OPERATING PROCEDURE

SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 31 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

3. Phase of Clinical Trial:

Phase I	<input type="checkbox"/>	Phase II	<input type="checkbox"/>	Phase III	<input type="checkbox"/>	Phase IV	<input type="checkbox"/>
---------	--------------------------	----------	--------------------------	-----------	--------------------------	----------	--------------------------

4. Study Investigators Details:

Name of Investigators/Co-Investigator	Designation

Note: If more investigators give details under the extra comment section.

5. Study Objectives:

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY
Victoria Hospital Campus, Bengaluru, Karnataka 560002
STANDARD OPERATING PROCEDURE

SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 32 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

5. Study Objectives:

--

6. Justification for the Conduct of this Study:

--

7. Methodology:

Inclusion Criteria	
Exclusion Criteria	
Control(s)	
Study Design	

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY
Victoria Hospital Campus, Bengaluru, Karnataka 560002
STANDARD OPERATING PROCEDURE

SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 33 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

7. Methodology:

Dosage of Drug	
Duration of Treatment	
Investigations Specifically related to Project	
Permission to use copyrighted Questionnaire/Performa	
Other	

8. Regulatory Permission:

Permission from DCGI	Required	<input type="checkbox"/>	Not Required
	Received	<input type="checkbox"/>	Applied when

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY
Victoria Hospital Campus, Bengaluru, Karnataka 560002
STANDARD OPERATING PROCEDURE

SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 34 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

9. Safety:

Safety measures for proposed interventions

Results of relevant laboratory tests

Results of studies in humans

10. Plans to Withdraw Standard Therapy During the Conduct of Research:

Yes ☐ No ☐

Remarks:

11. Provision of Coverage for Medical Risk(s) During the Study Period:

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY
Victoria Hospital Campus, Bengaluru, Karnataka 560002
STANDARD OPERATING PROCEDURE

SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 35 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

--

12. How you will maintain confidentiality of subject?

--

13. Total Budget (approx in Rs). Who will bear the cost of investigation/implants drugs/contracts?

--

14. Participant Information Sheet and Informed Consent Form			
English	<input type="checkbox"/> Yes <input type="checkbox"/> No	Version/Date	
Translated	<input type="checkbox"/> Yes <input type="checkbox"/> No	Languages	
Back Translated	<input type="checkbox"/> Yes <input type="checkbox"/> No		

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY
Victoria Hospital Campus, Bengaluru, Karnataka 560002
STANDARD OPERATING PROCEDURE

SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 36 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

15. Conflict of Interest for any other Investigator(s), If yes please explain in brief:

Sl. No.	Name of Investigator	Brief Description
1.		
2.		
3.		
4.		
5.		

16. Whether any work on this project has started or not?

☐ (Check if Yes)

(Please enclose a separate certificate to this effect)

17. Attached Documents:

Sl. No.	Document	Yes	No
1.	Covering letter		
2.	Approval letter from the head of the department/institution		
3.	Protocol of the proposed research		
4.	Ethical issue in the study and plans to address these issues		
5.	Investigator brochure		
6.	Informed consent form (English)		
7.	Informed consent form local/regional languages		
8.	Back translations of Informed consent forms		
9.	Translation and back translation certificates		

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY
Victoria Hospital Campus, Bengaluru, Karnataka 560002
STANDARD OPERATING PROCEDURE

SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 37 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

17. Attached Documents:

Sl. No.	Document	Yes	No
10.	Recruitment and retention material		
11.	Case report forms, subject diary, questionnaires, follow-up cards etc.		
12.	Where applicable translations of subject diary, questionnaires and follow-up cards		
13.	Where applicable back translations of translated subject diary, questionnaire and follow-up cards		
14.	Translation and back translation certificates of subject diaries, questionnaire and follow-up cards		
15.	Curriculum vitae of all the investigators with relevant publication in last five years		
16.	Medical registration certificate of all the investigators		
17.	GCP training certificates of all the investigators		
18.	Investigator undertaking		
19.	Form FDA 1572 if applicable		
20.	Financial disclosure form from all the investigators		
21.	Regulatory clearance documents		
22.	Source of funding and financial requirement for the project		
23.	Other financial issues including those related to insurance		
24.	Any standard operating procedure to be followed, if applicable		
25.	Other site EC approvals, if applicable;		
26.	Statement of conflict of interest, if any		
27.	Any other information relevant to the study		

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY
Victoria Hospital Campus, Bengaluru, Karnataka 560002
STANDARD OPERATING PROCEDURE

SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 38 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

17. Attached Documents:

Sl. No.	Document	Yes	No
28.	CTRI number/document		
29	List of other documents submitted: a: _____ b: _____ c: _____ d: _____ e: _____		

18. CTRI Registration Details

☐ (Check if Done)

Provide the details below: _____

Investigator Name			
Signature		Date	

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 39 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

Appendix-II

IEC APPOINTMENT LETTER

Date:

From

Member Secretary
Victoria Hospital
Campus, Bengaluru,
Karnataka 560002

To

Dear Sir/Madam,

Subject: Request to be the Honorable Member of Ethics Committee INSTITUTE OF NEPHRO UROLOGY.

This is to inform you that we are forming an Ethics Committee at INSTITUTE OF NEPHRO UROLOGY as per New Drugs and Clinical Trials Rules, 2019 and ICMR guidelines.

The Ethics Committee would be responsible for approving (on ethical grounds) any research/clinical-non clinical trials being undertaken at **INSTITUTE OF NEPHRO UROLOGY** and we request you to be the Honorary Member of the Ethics Committee.

I sincerely hope you will accept our request.

Kindly send a written word of acceptance.

Thanking you,

Sincerely.

Dr M S Pradeep

Member Secretary

<p align="center">ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE</p>			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 40 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

Appendix-III

IEC ACCEPTANCE LETTER

Date: From,

To,

The Chairman
INSTITUTE OF
NEPHRO
UROLOGY

Subject: Consent to be a member of Ethics Committee INSTITUTE OF NEPHRO UROLOGY Ref.: *****

Dear Sir,

In response to your letter stated above, I give my consent to become a member of IEC of **INSTITUTE OF NEPHRO UROLOGY**. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues.

I shall be willing for my name, profession and affiliation to be published.

I shall not keep any literature or study related document with me after the discussion and final review.

I shall maintain all the research project related information confidential and shall not reveal the same to anyone other than project related personnel.

I herewith enclose my CV.

Thanking you,

Yours sincerely,

Signature: _____

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY
Victoria Hospital Campus, Bengaluru, Karnataka 560002
STANDARD OPERATING PROCEDURE

SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 41 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

Name of the Member: _____

Date:

Address: _____

Telephone No: (Off)

(Res.)

email:

Mobile No.

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 42 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

Appendix-IV

IEC CONFIDENTIALITY AGREEMENT FORM

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 human subjects 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 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

<p align="center">ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE</p>			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 43 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

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 the conditions set forth above. The original (signed and dated Agreement) will be kept on file in 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.

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY
Victoria Hospital Campus, Bengaluru, Karnataka 560002
STANDARD OPERATING PROCEDURE

SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 44 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

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

Signature

Date

Chairman Signature

Date

Member Secretary Signature

Date

<p style="text-align: center;">ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE</p>			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 45 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

Appendix-V

IEC CONFLICT OF INTEREST FORM

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 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 IEC 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 should not participate in the IEC meeting or voting procedure.

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.

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY
Victoria Hospital Campus, Bengaluru, Karnataka 560002
STANDARD OPERATING PROCEDURE

SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 46 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

- 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 of the member)
have read and accept the aforementioned terms and conditions as explained in this Agreement.

Signature

Date

Chairperson Signature

Date

Member Secretary Signature

Date

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY
Victoria Hospital Campus, Bengaluru, Karnataka 560002
STANDARD OPERATING PROCEDURE

SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 47 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

Appendix-VI

IEC MEETING CALENDAR

(Year: 20__ to 20__)

Sl. No.	Month of the Year	Date of Meeting

Name of Member Secretary

Signature

Date

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 48 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

Appendix-VII

IEC MEETING CALENDAR

**ETHICS COMMITTEE APPROVAL LETTER TEMPLATE (TO BE PRINTED
ON EC LETTER HEAD, IF EC LETTERHEAD NOT AVAILABLE, SEAL
CONSISTING OF EC ADDRESS REQUIRED ON THE LAST PAGE)**

Date: dd/mmm/yyyy

Reference no.: <Delete if NA>

To

<Name of the Principal Investigator>

<Name of the Institution>

<Address of the Institution>

Protocol Title: <Please mention the Protocol Title Here>

Protocol No.: <Please mention the Protocol Number/Version/Date Here>

Subject: Approval for the conduct of the above referenced study

Dear Dr. <Name of the PI>

With reference to your Submission letter dated <dd/mmm/yyyy>, the INSTITUTE OF NEPHRO UROLOGY Ethics Committee has reviewed and discussed your application for conduct of clinical trial on <dd/mmm/yyyy>.

Sl. No	Document	Document (Version/Date)
1.		
2.		

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 49 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

3.		
4.		

The following members were present at the meeting held on **<date, time & place>**.

Sl. no.	Name of the Member	Designation and Qualification	Representation as per New Drugs and Clinical Trials Rules, 2019	Gender	Affiliation with the Institution
	<Name of the Member>	<Designation> & <Qualification>	< Basic Medical Scientist/ clinician/ Legal Expert/representative of non-governmental voluntary agency / philosopher / ethicist / theologian/ Lay Person>	<M/F>	<Y/N>

This is to confirm that only members who are independent of the Investigator and the Sponsor of the trial have voted/ provided opinion on the trial.

We approve the documents and the conduct of the trial in the presented form.

The INSTITUTE OF NEPHRO UROLOGY Ethics Committee must be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and requests to be provided a copy of the final report.

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY Victoria Hospital Campus, Bengaluru, Karnataka 560002 STANDARD OPERATING PROCEDURE			
SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 50 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

The INSTITUTE OF NEPHRO UROLOGY Ethics Committee follows procedures that are in compliance with the requirements of ICH (international Conference on Harmonization) guidance related to GCP (Good Clinical Practice) and applicable Indian regulations.

Yours Sincerely,

_____ (name of the Member Secretary)

Member Secretary

INSTITUTE OF NEPHRO UROLOGY

Victoria Hospital Campus, Bengaluru, Karnataka 560002

(Seal consisting of the address of the EC required)

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY
Victoria Hospital Campus, Bengaluru, Karnataka 560002
STANDARD OPERATING PROCEDURE

SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 51 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

Appendix-VIII
IEC Fee Details

Sl. No.	EC Services	Amount (INR)
1.	Initial review and recommendations of clinical trials	60000 (Indian)
2.	Repeat review (Protocol amendment) and recommendations of clinical trials	25000
3	post marketing surveillance studies and Phase IV	40000
3.	Expedited Review Projects	75000

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY
Victoria Hospital Campus, Bengaluru, Karnataka 560002
STANDARD OPERATING PROCEDURE

SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 52 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

Appendix-IX

AUDIT CALENDAR:

Name of the study:				
Name of Investigator :				
AUDIT CALENDAR: :				
DATE	MONTH	YEAR	TIME	CONCERNED PERSON
Signature of Investigator:				
Signature of Member Secretary:				
Signature of CRC:				

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY
Victoria Hospital Campus, Bengaluru, Karnataka 560002
STANDARD OPERATING PROCEDURE

SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 53 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

Appendix - X

**ETHICS COMMITTEE INSTITUTE OF NEPHRO UROLOGY.
PERIODIC SELF ASSESSMENT FORMAT**

GRADING CRITERION: 5=Excellent, 4= Very Good, 3=Good, 2=Satisfactory, 1=Needs Improvement
MEETING FOR THE MONTH OF: ../../....

PARAMETERS:	WORK EFFICIENCY	PERIODIC MEETINGS	AUDIT OF STUDIES	RULES AND REGULATIONS
Names of EC Members				

ETHICS COMMITTEE, INSTITUTE OF NEPHRO UROLOGY
Victoria Hospital Campus, Bengaluru, Karnataka 560002
STANDARD OPERATING PROCEDURE

SUBJECT	SOP		
SOP No.: EC/SOP/001	Version No.: 2.0	Supersedes Document: 1.0 Date: 12 November 2020	Page 54 of 54
Issue Date: 14/November/2020	Effective Date: 16/November/2020	Next Revision on: 13/November/2021	

Appendix XI

Training Calendar

	TRAINING RECORD : DAY/MONTH/YEAR	
	TOPIC -ICH-GCP & BASIC EC GUIDELINES:	
Name	Designation	Signature