STANDARD OPERATING PROCEDURES FOR

"Institutional Ethics Committee"

Spine Research Foundation

44/1A Ramdhan Mitra Lane
Kolkata 700004

	Name	Designation	Signature	Date
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Reviewed by	Dr Indrajit Roy	Chairperson		15.01.2025
Approved By	Dr Saumyajit Basu	Head of the Institution		15.01.2025

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1. Introduction:

Established in Kolkata, the major metropolis of eastern India, Spine Research Foundation is a non-profit organization, made up of eminent physicians and surgeons with the primary focus on research in spine surgery and bringing spine surgery within the reach of economically challenged patients. This organisation has been instrumental in financially supporting patients who cannot afford difficult and expensive spine surgeries although in desperate need of such operations. More than 100 patients (and counting) have been supported by the foundation during these years.

The goal of Spine Research Foundation is to establish a platform for helping economically challenged patients (financially and/or otherwise) who cannot afford spinal surgeries, especially when the estimated cost of the surgery is high and the surgery is complicated and is of long duration. Foundation aims to educate common people about the treatment and prevention options of spine ailments like scoliosis and kyphosis. Foundation also conducts courses, seminars and workshops to spread the knowledge and awareness of spine surgery among doctors or specialists.

The **Institutional Ethics Committee (IEC)** is an essential body dedicated to ensuring the ethical integrity of biomedical research involving human subjects. It serves as a guiding force for researchers, offering critical insights into the ethical principles required for conducting studies involving human participants.

In addition to addressing ethical concerns, the IEC evaluates research proposals to determine their scientific relevance, feasibility, and potential risks associated with research projects. This dual mandate ensures that research projects contribute to scientific advancement while prioritizing the rights, safety, and well-being of participants. The operations of the IEC are governed by meticulously designed **Standard Operating Procedures (SOPs)**, developed in accordance with the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, which set the foundation for ethical practices in biomedical research.

These guidelines empower the IEC to maintain a transparent, equitable, and rigorous review process. By ensuring adherence to these national standards, the IEC fosters trust among stakeholders and upholds the highest ethical and scientific standards in research.

2. Objectives:

The Institutional Ethics Committee (IEC) is dedicated to ensuring the ethical integrity and scientific rigor of biomedical research and clinical trials. Its primary objectives include upholding the dignity, rights, safety, and well-being of human participants, while also evaluating the scientific relevance, feasibility, and potential risks of research proposals. The IEC seeks to minimize risks and prioritize participant welfare by maintaining a structured, transparent, and consistent review process in alignment with the ICMR National Ethical Guidelines. By providing guidance on ethical issues and promoting awareness of regulatory standards, the IEC fosters ethical research practices and ensures adherence to best practices through regularly updated Standard Operating Procedures (SOPs). It also monitors ongoing research to ensure compliance with approved protocols and addresses emerging ethical concerns. Committed to balancing scientific innovation with ethical responsibility, the IEC

plays a critical role in advancing research that is meaningful, accountable, and fair while safeguarding the rights, confidentiality, and safety of participants. Through these efforts, the IEC supports groundbreaking medical advancements within a framework of ethical excellence.

3.Authority under which Ethics Committee is constituted

SRF-IEC is an Institutional standing ethics committee which functions independently. The Director in consultation with the other senior members (specify their designation), SRF will appoint the Chairperson and all the committee members, based on their qualifications, competence and experience in reviewing and evaluating the scientific and ethical aspects of biomedical research proposals. The tenure/ period of IEC members will be for 3 years or till further orders. The Director will send the invitation letter to the members and willing members will send a confirmation of their acceptance by signing the letter and providing all the documents required for membership.

4. Roles and Responsibilities of IEC Members

Chair and Co-Chair

The Chairperson and Vice Chairperson play a pivotal role in ensuring the efficient and independent functioning of the Ethics Committee (EC). Their responsibilities include conducting EC meetings and fostering active participation from all members, particularly those who are non-affiliated, non-medical, or non-technical, during discussions and deliberations. This inclusivity ensures diverse perspectives are considered in the decision-making process. Additionally, they are responsible for ratifying the minutes of previous meetings to maintain continuity and accountability in the committee's activities.

Member Secretary

The Member Secretary is responsible for establishing effective procedures to manage the EC's operations, including receiving, preparing, circulating, and archiving research proposals and committee records. They ensure the smooth functioning of the EC by scheduling meetings, preparing agendas, ensuring quorum, and documenting minutes of meetings. Additionally, the Member Secretary organizes training sessions for EC members to keep them updated on ethical and regulatory requirements and prepares for audits and inspections by ensuring compliance with established protocols and guidelines.

Basic Medical Science Doctor

The Basic Medical Science Doctor is tasked with reviewing research proposals with a focus on scientific validity and ethical compliance. They ensure the ongoing review of serious adverse events (SAEs), protocol deviations, and progress or completion reports. By conducting thorough benefit-risk assessments, they play a key role in maintaining the safety and integrity of the research.

Clinicians

Clinicians are responsible for the scientific review of research protocols, including analyzing the intervention, benefit-risk balance, research design, methodology, sample size, study site, and statistical analysis. They conduct ongoing reviews of SAEs, protocol deviations or violations, and progress or completion reports. Clinicians also assess the medical care, facilities, and qualifications

of the principal investigator to ensure the study's feasibility and adequacy in providing medical care, management, and compensation when required.

Social Scientist/Philosopher/Ethicist/Theologian

Social scientists, philosophers, ethicists, or theologians bring an ethical and societal perspective to the EC's deliberations. They review proposals and informed consent documents (ICDs) to assess their impact within socio-cultural, religious, or philosophical contexts. These members serve as representatives of the community, ensuring the inclusion of patient and societal concerns in the ethical evaluation of research proposals.

Layperson

Laypersons provide an essential perspective by reviewing proposals for ethical considerations from a participant's viewpoint. They evaluate informed consent documents (ICDs) and their translations to ensure clarity and cultural appropriateness. By assessing the benefits and risks from the participant's perspective, they highlight societal and ethical concerns, ensuring that the research remains participant-focused and ethically sound.

Legal Expert

Legal experts contribute by conducting ethical reviews of proposals and key documents, such as informed consent documents (ICDs), Memoranda of Understanding (MoUs), and Clinical Trial Agreements (CTAs). They interpret and inform EC members about relevant regulations and any new legal updates, ensuring that the research complies with the current legal and regulatory framework.

5.Application and Approval Process

Application Submission:

- The applicant submits the application via email to the Member Secretary.
- The application includes all necessary documents, such as consent and assent forms, along with the research protocol.

Initial Verification:

- The Member Secretary receives the application and verifies the documents.
- This includes ensuring that all required forms (consent, assent, etc.) are correctly filled out and signed.
- The Member Secretary ensures that the application meets the basic criteria for review.

Forwarding to Chairperson and Vice Chairperson:

- Once the documents are verified, the Member Secretary forwards the application to the Chairperson and Vice Chairperson for further processing.
- They review the application for completeness and compliance with guidelines.

Notification to Applicant:

- The applicant is notified of the timeline for the review and approval process.

- This may include estimated timelines for when they will hear feedback or approval status.

Assignment of Reviewers:

- The Chairperson or Vice Chairperson assigns two reviewers to evaluate the application.
- The reviewers are chosen based on their expertise in the relevant field or subject of the application.

Forwarding to Reviewers:

- The Member Secretary forwards the application along with the necessary documents to the assigned reviewers.
- The reviewers begin their evaluation of the research protocol and any other relevant information provided.

Reviewer Feedback:

- The reviewers provide their feedback, which may include:
    - Requests for additional information or clarifications from the applicant.
    - Recommendations for changes or revisions to the research protocol or other elements of the application.
    - An initial status recommendation (approve, approve with modifications, or reject).

Applicant Response:

- The applicant responds to the reviewers' feedback by submitting the requested information or revising the research protocol accordingly.
- The applicant may need to address additional questions or concerns raised by the reviewers.

Final Review Meeting:

- The Chairperson or Vice Chairperson conducts the final review during a scheduled meeting with the reviewers and the Member Secretary.
- They review the feedback provided, the applicant’s responses, and finalize the approval decision.
- This meeting may also include discussions about any last-minute adjustments needed.

Approval and Notification:

- Once the application is approved, the Member Secretary issues the official approval letter to the applicant.
- The applicant is formally notified that their application has been approved and any additional instructions or next steps are provided.

Completion:

- The process is complete, and the applicant is ready to proceed with the approved research, adhering to any conditions set by the reviewing committee.

FORMS

Application form: Full review/Expedited/Exempt

I. BASIC INFORMATION

1. Name of the applicant*: _____
2. Position/Designation*:_____
    - Research Scholar
    - Faculty
    - Research Staff
3. Other affiliation, if any*_____
4. Name of the Principal Investigator*:_____
5. Name of the collaborators, if any*:
    - Yes
    - No

Name	Designation	Affiliation	Department and Institution	Contact Information

6. Name of the thesis advisor*:_____
7. Department*:_____
8. Tile of the study*: _____
9. Explain why your application should be considered under the **Full Review/Expedited/Exempt** category of ethics review*:

_____

_____

10. Duration of the study*:

Start Date	
End Date	

II. PROTOCOL SUMMARY

1. Mention the primary objective, research questions, hypothesis and broad information area of your research. *

2. How will your research contribute to the existing field of research?*

3. What type of research design will you use (e.g., observational, survey, secondary data analysis)?

4. Is there any specific limitation that your research design/ methodology entails?*

   - No
   - Yes

5. Describe briefly the profile of the study population that will be included in this study.*

6. What is the planned sample size, and how was it determined?*

7. How does this study plan to engage the community, and what broader social impacts are anticipated from its findings, if any?*

    - The study does not include a plan for community engagement or broader social impact.
    - Yes, the study includes a plan for community engagement or broader social impact

8. What data will be collected from the study participants?*

9. Mention the methodology that is selected for this study. Provide a rationale for selecting the methodology selected for this study.*

10. What potential risks or limitations exist within your study's methodology, and what strategies will you employ to mitigate these risks?*

11. Please identify any ethical concerns (if any) associated with your study, particularly regarding participant's privacy, informed consent, or potential conflicts of interest.*

12. What will be the location of the study?*

13. What is the expected timeline for the study, including data collection and analysis?

A. Start Date_____

B. End Date_____

III. PARTICIPANTS & INFORMED CONSENT

1.How will you recruit the study participants for your research? *

2.Does your study involve minors?*

- NA
- Below 8 year
- Between 9-18 years

3. What will be the process for documenting consent from the minor participants?*

(Write NA if not applicable)

4. Will you provide any monetary compensation to your study participants?*

5. Will the study participants receive any direct or indirect benefits? *

6. Are there any participant recruitment fees/ incentives for the study provided to the PI / Institution?If yes,

- Monetary
- Non-monetary

- NA

7.Describe the consent-taking process.*

8. Provide a rationale for not taking written consent from your study participants.*

9. Will you take a fresh consent from the participants after data collection/before and concluding your research findings?*

10. Does your study involve deception?*

- YES
- NO

11.Please describe the methodological rationale for the necessity of deception in this study.

12.Explain the debriefing process

13. Are you going to take consent from the study participants after revealing the true nature of the study?

14. What measures are in place to safeguard the autonomy and rights of vulnerable participants throughout the study?

15. Do you plan to implement any specific measures to protect vulnerable individuals from undue influence or exploitation?

16.Are there any specific cultural considerations related to health, illness, or treatment that the research team should be aware of and address in the design of the study?

17. Are there any community-based organizations or advocates involved in the study, and how will their feedback be integrated?

18. What strategies will you use to ensure that the study benefits the vulnerable population and does not lead to any unintended harm or exploitation?

19.Are there any long-term care or support services being offered to vulnerable participants following the completion of the study, especially if the study involves interventions or treatments?

20.What provisions are in place to ensure that vulnerable participants have access to any benefits (e.g., treatment, healthcare services) that result from the study?

IV.RISK(S) ASSESSMENT

1.Are there any anticipated physical/social/psychological discomforts/ risks to participants? *

2 Are there any unanticipated physical/social/psychological discomforts/ risks to participants?Are reporting procedures and management strategies described in the stu3.In case of data collection by personnel other than yourself, please explain their functions and how their efforts will be recognized/rewarded?*

4.What are your strategies to address mitigating risks related to data breaches, especially concerning the handling of sensitive information ?*

5. How will you handle sensitive data in accordance with ethical guidelines, and what steps will you take to address any breaches in data safety?*

V. DATA SAFETY

1. How will you collect data, and what methods will you use to ensure its accuracy and reliability?*
2. Will audio or visual elements be included during the data collection process?*
3. How will you store the collected data?*
4. What security measures are in place to protect this data ?*
5. Who will access to the data, and how will you restrict access to authorized personnel only?*
6. Will any personally identifiable information (PII) be collected? If so, how will you anonymize or de-identify the data to protect participant identities?*

7. Will the data be shared with other researchers or organizations? If yes, what measures will you take to ensure that shared data remains secure?*

8. How long will you retain the data after the study is completed, and what is your plan for securely disposing of the data post research?*

9. Will research team members receive training on data protection and confidentiality protocols?*

10. How will you ensure compliance with relevant laws and regulations regarding data protection?*

11. How will you ensure data safety throughout the study, and what steps will you take if safety concerns arise?*

12. How do you plan to handle potential conflicts between scientific objectives and ethical considerations, especially in terms of participant autonomy and data integrity?*

13. What do you plan to do with the collected data post research?*

VI. DISSEMINATION

1. Who is the intended audience for the disseminated data?*

3. In what formats will the data be disseminated?*

- Reports
- Presentations
- journal articles
- online databases

4. When do you plan to share the findings and data with the public or stakeholders?*

5. How will you ensure participant confidentiality when disseminating the data?*

6. How will authorship and contributions be determined in any resulting publications or presentations?*

7. Will participants be informed about how their data will be used and shared? If so, how will this information be communicated?*

VII. CHECKLIST

With this application, I am submitting*:

List of Supplementary Documents	NA	YES	NO	ENCLOSURE	EC REMARKS
Cover Letter		•		•	
Research Synopsis approved by the committee		•		•	
Brief CV of all Investigators		•		•	
Consent form		•		•	
Participant Information Sheet		•		•	
Performa/ Case report/ interview guides/Questionnaire		•		•	
Copy of content used to recruit study participants (email content/posters/ social media posts)		•		•	
Agreement between collaborating partners		•		•	
Approval letter from other participating institutes/organizations/universities		•		•	
Copy of contract or agreement signed with the sponsor or donor agency		•		•	

Research findings of pilot survey/preliminary study		•		•	
Approval letter for pilot study/preliminary study		•		•	

VIII. FUNDING & CONFLICT OF INTEREST

1. Have you received any personal compensation (e.g., consulting fees, honoraria, gifts) from the sponsor of this research or any related entity? If yes, specify the type and amount.*

2. Do you hold any advisory or leadership positions (e.g., board member, executive roles) with the sponsor or any organization that could benefit from this research?If yes, describe the role and the organization.*

3. Are you involved in any external collaborations with organizations that have a vested interest in the outcomes of this study? If yes, explain the nature of the collaboration.*

4. Do you or your team members hold any patents or intellectual property rights that may benefit from the results of this research? If yes, list the patents and how they relate to the study.*

5. Are there any pending patent applications that could be influenced by the findings of this research?If yes, please describe.*

6. What is the source of funding for this research? If yes, outline the type and source of support.*

7. Are you or your team members currently employed or consulting with an organization that has a stake in the research outcomes? If yes, state the organization and the nature of your involvement.*

8. Is there any other financial, professional, or personal conflict of interest that may compromise or be perceived to compromise the integrity of the research? If yes, provide a brief explanation.*

9. Have you disclosed all potential conflicts of interest in accordance with the institution's policies? If not, provide reasons for non-disclosure.*

10. Are there any management plans in place to mitigate potential conflicts of interest in this research? If yes, outline the key aspects of the plan.*

IX. DECLARATION

I/We confirm that:

- the information provided in this application is accurate and complete.
- responses and supplementary documents submitted for review and approval are approved by all investigators/collaborators associated with this research study,

- this study complies with ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants and guidelines of the Ethics Committee at Spine Foundation,

- this study will be conducted in compliance with the Drugs and Cosmetics Act of 1940, its Rules of 1945 (as amended), GCP guidelines, and other relevant regulations and guidelines,

- this study will adhere to all policies and guidelines of the institute, as well as those of the affiliated or collaborating institutions where the research will be conducted,

- you have completed the ethics training conducted by your institute,

- personnel participating in this study are qualified, appropriately trained, and will adhere to the provisions of the EC-approved protocol,

- an undertaking of what will be done with the leftover samples is provided, if applicable,

- submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports (if required), and a final report and also participate in any audit of the study if needed,

- . maintain accurate and complete records of all aspects of the study,

- protect the privacy of participants and assure confidentiality of data and biological samples,

- the investigators, researchers, and/or their close relatives have no conflicts of interest, whether financial or non-financial, with the sponsor(s) or the study's outcome.

Name of the PI:

Signature:

Date:

Name of the Co-PI

Signature:

Application for Proposed Amendment

Protocol Number:

Title of study:

List of Principal Investigators and Collaborators:

Name	Role in the Project	Designation	Affiliation

Date of EC approval:

Start Date of the Study:

Proposed Amendment (Specify the section for which you are proposing amendment):

Provide a rationale for the proposed amendment:

Risk Assessment:

Do you plan to take fresh consent from the study participants?

YES

*If yes, then share a copy of revised consent from with this application

Type of review requested for amendment:

Same as the approved application

Exempt

Expedited

Full Review

Declaration by the PI:

I hereby declare that all protocols related to my research remain unchanged. Any modifications to any aspect of my research project will be communicated to the ethics committee before proceeding further with the research.

Name of the PI:

Signature:

Date:

Informed Assent Form Template for Children/Minors

1. Name of the Principal Investigator/s:_____
2. Name of the collaborators and their affiliation:
   _____
3. _____
   ___
4. Title of the
   Project:_____
5. Name of the Host Institution/
   Organization:_____
6. Name of the Funding
   Agency:_____

PART I : Information Sheet

My name is ____ and I work on researching and testing vaccines to find out which ones are most effective in preventing ….. before it can make someone sick(improvise according to the relevance of the study). We want to see if this treatment/ medicine/method can help stop children from getting sick, and we believe this study could give us important answers.

I'm here to provide you with information and invite you to be part of this research study. You can choose whether or not you want to participate. We've already discussed this research with your parent(s)/guardian, and they understand that we're also asking for your permission. If you decide to take part in the study, your parent(s)/guardian must also give their consent. However, if you don't want to participate, that's perfectly alright, even if your parent(s) have agreed.

You are welcome to talk about this study with your parents, friends, or anyone else you trust. You don't need to make your decision right away, and you can take your time to discuss it before deciding.

If there's anything you don't understand or if you want me to explain something in more detail because you're curious or concerned, please feel free to ask. You can ask me to stop and explain at any time.

1. Brief introduction about your research:

_____

_____

2.Objective of the Study :_____

_____

_____

3. Participants Selection (a brief description about selection criteria)

_____

_____

4.Voluntary Participation:

_____

_____

5.Procedure and Protocol:

- Description of the process:
- Measures and precautions:
- Medical assistance and care that will be provided to the participants:
- Duration of the Study

  _____
  _____
  _____

6. Benefits:

7.Privacy and Confidentiality:

8. Ethics Approval:

Contact Information: If you have any queries or concerns, please reach out to_____

PART 2: Certificate of Assent

I have read this information (or it has been read to me). My questions have been answered, and I understand that I can ask more questions later if I need to.

I agree to participate in the research.

Print name of child _____

Signature of child: _____

Date:_____

day/month/year

OR

I do not wish to participate in the research, and I have not signed the assent below.

_____ (by child/minor)

If the participant (minor) cannot read or write/hesitant to sign:

I confirm that I have witnessed the accurate reading of the consent form to the participant, and the participant has had the opportunity to ask questions. I affirm that the participant has freely given their consent.

Witness's Name (Print): _____
Thumbprint of Participant: _____
Witness's Signature: _____
Date: _____
(Day/Month/Year)

Or

- YES
- NO

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the child understands that the following will be done:

1.

2.

3.

I confirm that the child was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that

the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this assent form has been provided to the participant.

Print Name of Researcher/person taking the assent_____

Signature of Researcher /person taking the assent _____

Date _____

Day/month/year

Copy provided to the participant _____(initialed by researcher/assistant)

Parent/Guardian has signed an informed consent ___Yes ___No _____(initialed by researcher/assistant)

INFORMED CONSENT FORM TEMPLATE

1. Name of the Principal Investigator/s:_____
2. Name of the collaborators and their affiliation: _____

_____

3. Title of the Project:_____
4. Name of the Host Institution/ Organization:_____
5. Name of the Funding Agency:_____

_____

PART I : Information Sheet

Brief I 6. Brief Introduction about your research:_____

_____

7. Objective of the Study:_____

_____

8. Participants Selection (a brief description about selection criteria):

_____

_____

9.Voluntary Participation:

_____

_____

10.Procedure and Protocol:

- Description of the process:
- Measures and precautions:

- Medical assistance and care that will be provided to the participants:
- Duration of the Study:

_____

11. Benefits:

12.Privacy and Confidentiality:

13.Ethics Approval:

Contact Information: If you have any queries or concerns, please reach out to_____

PART II: Certificate of Consent

I have read the information provided above, or it has been read to me. I have had the opportunity to ask questions regarding the information, and all my questions have been answered to my satisfaction. I voluntarily consent to participate in this research.

Participant's Name (Print): _____
Participant's Signature: _____
Date: _____
(Day/Month/Year)

If the participant cannot read or write/hesitant to sign:

I confirm that I have witnessed the accurate reading of the consent form to the participant, and the participant has had the opportunity to ask questions. I affirm that the participant has freely given their consent.

Witness's Name (Print): _____
Thumbprint of Participant: _____
Witness's Signature: _____
Date: _____
(Day/Month/Year)

Or

- YES
- NO

PART III. Statement by the Researcher or Person Obtaining Consent

I confirm that I have read the information sheet to the participant and, to the best of my ability, ensured that the participant understands what will be involved in this research.

Signature:_____ Name:_____

Affiliation/Designation: _____

PART IV: Informed Consent Form for Storage and Future Use of Unused Samples

1. **Information Sheet**

We are seeking your permission to store any unused samples (such as blood, tissue, sperm, or sputum) from your participation in this study for potential future use, either in our own research or in research conducted by others. Currently, you have only given permission for your sample to be used in the present study, and we would like to know if you agree to its future use.

We understand that some people may not want their samples used for certain types of research that they might not agree with, such as studies on birth control or reproductive technology. We will explain the possibilities of future research in simple terms. If genetic research is one of the options, we will clearly explain what this entails and what it might mean for you. You have the right to tell us if there is any type of research you do not want your sample to be used for, or if you do not want your sample used at all.

At this point, we are able to trace which blood, tissue, sperm, or sputum sample belongs to you. However, you will need to decide whether you want us to keep the sample but remove all identifying information, or whether you are comfortable with us knowing whose sample it is. We will explain the risks and benefits of both options. If the sample remains linked to you, we are obligated to inform you of any findings that may have immediate clinical relevance for your health.

Please note that your sample will never be sold for profit. Additionally, any research using your sample will be subject to ethical approval by a review board.

2.Right to Refuse and Withdraw

You are under no obligation to allow your samples to be kept or used for future research, and you can set any restrictions you wish on their use. Your decision will have no impact on your participation in the current study. You

also have the right to withdraw your permission at any time, without any consequences. If you choose to withdraw, you can contact [Name, Position, Contact Information] at [Institution Name] for further assistance.

3. Confidentiality

We will take all necessary measures to protect your confidentiality. However, please note there may be certain limitations. We will explain how your personal information and samples will be kept confidential throughout the study.

Certificate of Consent

Consent for Sample Storage and Disposal

If any of the [TYPE OF SAMPLE, e.g., blood, tissue] I have provided for this research project remains unused or leftover after the project is completed, I would like to indicate my preferences for its disposal or storage by selecting one option from each of the following:

- I wish for my [TYPE OF SAMPLE] sample to be destroyed immediately.
- I want my [TYPE OF SAMPLE] sample to be destroyed after ____ years.
- I give permission for my [TYPE OF SAMPLE] sample to be stored indefinitely.

If the sample is to be stored, please indicate your preferences below:

Participant's Acknowledgement

I confirm that I have read this information sheet, or it has been read to me, and I have had the opportunity to ask any questions regarding the storage and use of my samples. My questions have been answered to my satisfaction, and I voluntarily consent to the storage of my sample(s) in the manner and for the purpose specified above.

Participant's Information:

Print Name of Participant: _____
Signature of Participant: _____
Date: _____
(Day/Month/Year)

For Participants who cannot sign/read or write:

If the participant is illiterate, a literate witness must sign. Ideally, the witness should be chosen by the participant and should not be affiliated with the research team. The participant should also provide a thumbprint.

I have witnessed the accurate reading of this consent form to the participant. The participant had the opportunity to ask questions, and I confirm that they have given their consent freely and voluntarily.

Print Name of Witness: _____
Signature of Witness: _____
Thumbprint of Participant: _____
Date: _____

Statement by the Researcher/Person Taking Consent:

I confirm that I have accurately read the information sheet to the potential participant. I have ensured that the participant understands the following details regarding the storage of their sample(s):

1. [Explanation of Sample Storage]
2. [Explanation of Potential Use]
3. [Explanation of Future Research Possibilities]

The participant was given the opportunity to ask questions about the nature and manner of storage, and I have answered all of their questions to the best of my ability. I confirm that the participant has given their consent freely and voluntarily, without coercion.

A copy of this informed consent form has been provided to the participant.

- YES
- NO

Researcher's Information:

Print Name of Researcher/Person Taking the Consent: _____
Signature of Researcher/Person Taking the Consent: _____
Date: _____

RESEARCH CLOSURE APPLICATION

Protocol Number:

Title of study:

List of Principal Investigators and Collaborators:

Name	Role in the Project	Designation	Affiliation

Date of EC approval:

Start date of the study:

Date of completion:

Review category under which the study was approved:

Proposed amendment if any:

Date of EC approval:

Sample size of the population approved by the EC:

Actual sample size of the population recruited:

Number of participants discontinued/withdrawn their participation, if any:

Provide the reasons for withdrawal of participants:

Describe briefly how the study findings will be disseminated.

Describe the ethical issues (if any) encountered in the study.

Was there any violation of ethical guidelines or deviation during the study?

- No
- Yes_____

Do you plan to archive/ store the collected data post research?

- No
- Yes

If yes, then mention:

1. Time period
2. Who will have access to the data?
3. Will you store the anonymized data or anonymized data?
4. Please outline your plans for securely storing hard copies of documents such as the consent form, assent form, and survey questionnaires
5. How will you ensure data safety of the archival records?

Do you plan to conduct a post study follow up with your study participants?

- Yes_____
- No

Is there a plan to share any post-study benefits with the participants?

- Yes_____
- No

Provide a summary of the results along with the conclusion.

Was there any serious adverse event during the research?

- Yes_____
- No

If yes, how did you address the SAE?

Signature of the PI:

Signature of the Collaborators:

Signature of thesis advisor:

Standard Operating Procedure (SOP) for Membership Requirements for Ethics Committee (EC)

1. PURPOSE

To establish clear membership requirements for an Ethics Committee (EC) in accordance with the Indian Council of Medical Research (ICMR) Guidelines 2017, ensuring compliance with ethical standards in research involving human participants.

2. SCOPE

This document applies to all individuals or institutions forming an Ethics Committee for biomedical and health research involving human participants. It ensures adherence to ICMR 2017 guidelines and covers the membership composition, qualifications, roles, and responsibilities.

3. RESPONSIBILITY

The responsibility for appointing and managing the EC membership lies with the institution's leadership, such as the head of the organization, in compliance with the ICMR guidelines. Members of the EC are responsible for performing their duties impartially and maintaining the highest ethical standards.

4. DETAILED INSTRUCTIONS

4.1 Composition of the Ethics Committee

The EC must consist of a multidisciplinary and multi-sectoral team. Membership requirements are as follows:

- **Chairperson:** A distinguished individual from outside the institution with no affiliation to ensure impartiality.
- **Member Secretary:** A qualified individual responsible for coordinating the committee's activities.
- **Medical/Scientific Members:** At least two individuals with expertise in biomedical research or medical sciences.
- **Legal Expert:** An individual with knowledge of legal aspects, particularly in the domain of biomedical research.
- **Social Scientist/Philosopher/Ethicist:** To represent societal and ethical concerns.
- **Layperson:** A member from the community who is not associated with medical or scientific disciplines to represent the viewpoint of the general public.
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4.2 Membership Qualifications

Chairperson

- A senior professional with extensive experience in research or academia.
- Preferably external to the institution to maintain independence.
- Knowledge of ethical guidelines, such as the ICMR Guidelines 2017 and the Declaration of Helsinki.
- Experience in leading or participating in ethics committees is desirable.

Member Secretary

- A postgraduate degree in medicine, public health, or life sciences.
- Administrative skills and prior experience in clinical research or ethical review processes.

- Responsible for coordinating EC activities and maintaining documentation.

Basic Medical Scientist

- A medical or biomedical scientist with a postgraduate qualification (e.g., MD, MSc, PhD).
- Experience in laboratory or basic research related to spinal disorders or other biomedical fields.
- Must be capable of assessing scientific validity and methodological rigor in research proposals.

Clinician

- A qualified medical practitioner (MBBS with MD/MS or DNB) specializing in orthopedics, neurology, neurosurgery, or related disciplines.
- Practical experience in treating spine-related conditions.
- Familiarity with clinical trial methodologies and the ethical concerns in human research.

Legal Expert

- A law graduate (LLB or higher) with expertise in medical and healthcare law.
- Knowledge of national and international regulations governing biomedical research.
- Responsible for providing guidance on legal and regulatory compliance, including participant rights and confidentiality.

Social Scientist/Philosopher

- An academic or professional with a degree in sociology, anthropology, philosophy, or public health.
- Experience in research or community-based projects.
- Capable of addressing the social and cultural implications of proposed research studies.

Lay Person

- A literate individual with no affiliation to the institution or professional qualifications in biomedical research.
- Represents community perspectives and ensures the protection of participants' rights and well-being.
- Members must have relevant qualifications and experience based on their designated roles.
- Members should have formal training or orientation in research ethics.

4.3 Tenure and Renewal

- Membership tenure should typically range from 2-3 years, with a provision for renewal based on performance.
- Terms must be staggered to ensure continuity.

4.4 Conflict of Interest

- Members must declare any conflict of interest and recuse themselves from deliberations where applicable.

4.5 Resignation and Replacement

- Members may resign by providing written notice to the Chairperson. Vacancies should be filled promptly to maintain the committee's function.

5. FLOW CHART

Flow Chart of Membership Appointment and Approval Process:

1. **Identify Required Roles** → 2. **Shortlist Candidates Based on Expertise and Diversity** → 3. **Review Candidate Qualifications** → 4. **Provide Ethics Training** → 5. **Institutional Approval of Membership** → 6. **Notify Members and Begin Tenure**

6. ANNEXURES (FORMS)

Annexure 1: Membership Application Form

- Personal Details: Name, Contact Information, Affiliation
- Role Applying For: Chairperson/Member Secretary/Medical Expert, etc.
- Educational Qualifications
- Relevant Experience
- Declaration of Conflict of Interest

Annexure 2: Membership Renewal Form

- Member Details
- Previous Contributions to the EC
- Training or Workshops Attended
- Declaration of Continued Interest

Annexure 3: Conflict of Interest Declaration Form

- Member's Name
- Nature of Conflict
- Signature

7. REFERENCE

- **Indian Council of Medical Research (ICMR) National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017)**.
- Institutional Policies on Research Ethics.

Standard Operating Procedures (SOP) for Ethics Committee Review of Research Involving Vulnerable Populations

1. Purpose

To ensure the protection of the rights, safety, and well-being of vulnerable populations involved in research and to comply with the ethical principles outlined in the ICMR Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017).

2. Scope

This SOP applies to all research proposals involving vulnerable populations submitted to the Ethics Committee for review.

3. Definitions

- **Vulnerable populations**: Groups that may have limited autonomy or capacity to provide informed consent or who are at higher risk of harm or exploitation. Examples include:
    - Children
    - Pregnant women and fetuses
    - Individuals with mental illness or cognitive impairment
    - Socio-economically or educationally disadvantaged groups
    - Prisoners
    - Refugees or disaster-affected populations
    - Elderly individuals or those with chronic illnesses

4. Responsibilities of the Ethics Committee

1. Ensure that research involving vulnerable populations complies with the ethical principles outlined in the ICMR 2017 guidelines.
2. Safeguard the autonomy, privacy, and welfare of these populations.
3. Evaluate the scientific and ethical justification for involving vulnerable populations in the research.
4. Assess and ensure that adequate safeguards are in place to minimize risks.

5. SOP Steps

5.1 Initial Screening of Protocols

- Verify whether the research involves vulnerable populations.
- Confirm the inclusion and exclusion criteria to justify the necessity of involving the vulnerable group.

5.2 Review Process

1. **Scientific Justification**:
    - Assess the necessity of including vulnerable populations in the study.
    - Ensure that the research is relevant and has the potential to provide direct or societal benefits to the group.
2. **Risk-Benefit Analysis**:
    - Evaluate the risks involved and ensure that they are minimized.
    - Confirm that potential benefits to participants or society outweigh the risks.
3. **Informed Consent**:
    - Ensure that informed consent processes are tailored to the population's needs.
    - Verify that consent documents are in simple, understandable language.
    - Require consent from legally authorized representatives (LARs) when participants lack the capacity to consent.
    - For children, ensure that:
        - Parental or guardian consent is obtained.
        - Assent is obtained from children who are capable of understanding.
4. **Community Involvement**:
    - Where applicable, involve community representatives to enhance trust and cultural appropriateness.

5.3 Ethics Committee Composition

- Ensure that the Ethics Committee includes:
    - A member with expertise in the rights and welfare of vulnerable populations.
    - External experts or advocates, if required, for additional insights.

5.4 Additional Protections for Vulnerable Populations

- Minimize risks by:
    - Using non-invasive procedures whenever possible.

- Avoiding coercion or undue inducement.

- Require independent advocates for vulnerable groups to ensure their interests are prioritized.
- Implement more frequent monitoring and reporting for studies involving higher risks.

5.5 Decision-Making

- Provide conditional approval, requiring researchers to address any gaps or concerns before the study commences.
- Approve the protocol only if the Ethics Committee is satisfied with the safeguards in place.

5.6 Monitoring and Audits

- Conduct periodic monitoring of the study to ensure adherence to ethical standards.
- Require progress reports and safety updates from researchers at regular intervals.

6. Special Considerations for Specific Groups

1. **Pregnant Women and Fetuses**:
    - Research should pose no risk to the fetus unless it offers potential direct benefits.
    - Ensure appropriate counseling and consent processes.
2. **Children**:
    - Obtain parental or guardian consent.
    - Seek assent from children aged 7 years or older who can understand the research.
3. **Mentally Ill or Cognitively Impaired Individuals**:
    - Obtain consent from legally authorized representatives.
    - Ensure that the research poses minimal risk or is of therapeutic intent.
4. **Socio-economically Disadvantaged Groups**:
    - Avoid coercion or undue inducements.
    - Ensure that participation is voluntary and fully informed.
5. **Prisoners and Institutionalized Individuals**:
    - Ensure no exploitation and verify that participation is genuinely voluntary.

7. Documentation

- Maintain detailed records of:
    - Research protocols.
    - Consent documents.
    - Ethics Committee decisions, meeting minutes, and communications with researchers.
- Document reasons for approvals, rejections, or required modifications.

8. Training and Capacity Building

- Conduct regular training for Ethics Committee members on:
    - Ethical principles related to vulnerable populations.
    - Handling informed consent processes.
    - Monitoring and oversight of sensitive studies.

9. References

1. ICMR Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017).
2. Relevant national and international ethical guidelines and regulations.

10. Annexures

- **Annexure 1**: Template for Protocol Submission Checklist
- **Annexure 2**: Template for Informed Consent Documents
- **Annexure 3**: Monitoring Checklist for Studies Involving Vulnerable Population

This SOP ensures that research involving vulnerable populations adheres to the highest ethical standards, prioritizing their rights, dignity, and welfare.

Standard Operating Procedure (SOP) for Monitoring and Preventing Conflict of Interest (COI)

1. Purpose

To establish a clear and systematic procedure for identifying, disclosing, and managing conflicts of interest (COI) among Ethics Committee members to maintain the integrity of the ethical review process, in compliance with the ICMR Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017).

2. Scope

This SOP applies to all members of the Ethics Committee, including regular, ad-hoc, and external experts.

3. Responsibility

The Ethics Committee Chairperson and Member Secretary are responsible for ensuring adherence to this SOP. All Ethics Committee members are required to comply with the procedures outlined herein.

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4. Procedures

4.1 Declaration of Conflict of Interest

1. **Annual Declaration**:
    - All Ethics Committee members must complete and submit a COI Declaration Form (Annexure 1) at the beginning of their tenure and update it annually.
    - Any updates to potential conflicts must be reported immediately to the Member Secretary.
2. **Meeting-Specific Declaration**:
    - At the start of each meeting, the Chairperson will request members to disclose any COI related to the research protocols being reviewed.
    - Members must verbally declare any conflicts during the meeting.

4.2 Identification and Review of COI

1. The Member Secretary will review all disclosed conflicts before the meeting.
2. If a COI is identified, the Chairperson will:
    - Confirm the nature of the conflict with the member.
    - Ensure the conflict is recorded in the meeting minutes.

4.3 Management of Conflict of Interest

1. **Recusal**:
    - Members with a COI must recuse themselves from discussions and decision-making on the affected protocol.
    - The member may remain present to provide clarifications if required but cannot participate in voting or decision-making.
2. **Replacement**:
    - In case of a recusal, an alternate member may be invited to participate in the discussion to maintain quorum.
3. **Documentation**:
    - All COI disclosures, recusals, and actions taken must be documented in the meeting minutes and COI disclosure log (Annexure 2).

4.4 Monitoring and Compliance

1. The Member Secretary will:
    - Maintain a COI disclosure log for all members.
    - Conduct annual audits of COI declarations and meeting records to ensure compliance.
2. Regular training on COI will be included in the Ethics Committee's periodic training programs to enhance awareness and compliance.

4.5 Addressing Non-Compliance

1. Failure to disclose a COI or intentional misrepresentation will result in the following actions:
    - **First Instance**: Issuance of a formal warning.
    - **Repeated Violations**: Suspension or removal from the Ethics Committee, as determined by the Chairperson and institutional authorities.
2. The Member Secretary will report non-compliance cases to the Chairperson for appropriate action.

5. References

- ICMR Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017).
- International Conference on Harmonisation – Good Clinical Practice (ICH-GCP) Guidelines.
- Declaration of Helsinki.

Standard Operating Procedure (SOP)
Conditions of Appointment / Resignation/Removal/Replacement and Quorum Requirements
Institutional Ethics Committee for Biomedical Research

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1. Purpose

This SOP defines the conditions of appointment and quorum requirements for the Institutional Ethics Committee (IEC) for Biomedical Research, ensuring compliance with the ICMR Ethical Guidelines 2017. It aims to facilitate the efficient functioning of the IEC while safeguarding the rights, safety, and well-being of research participants.

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2. Scope

This SOP applies to the appointment, tenure, responsibilities, and quorum requirements for the members of the IEC involved in the ethical review of biomedical research projects.

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3. Conditions of Appointment

3.1 Composition of the IEC

The IEC must be multidisciplinary and multi-sectoral, comprising a minimum of 7 and a maximum of 15 members, including:

1) **Chairperson**: External to the institution.
2) **Member Secretary**: Coordinates the committee's activities.
3) **Basic Medical Scientist**: Expert in biomedical sciences.
4) **Clinician**: A qualified medical professional.
5) **Legal Expert**: Specialist in medical or healthcare law.
6) **Social Scientist/Philosopher**: Representative of societal perspectives.
7) **Lay Person**: Represents community interests and participant perspectives.

3.2 Eligibility Criteria

- Members must have the qualifications, expertise, and experience relevant to their designated role.
- Members should be willing to dedicate the necessary time and effort to IEC responsibilities.
- Members must declare any conflicts of interest and abstain from discussions or decisions where such conflicts exist.

3.3 Terms of Appointment

1) **Tenure**: Members will be appointed for a term of **3-5 years**, renewable based on performance and willingness.

2) **Renewal**: Renewal of membership will be based on institutional requirements and the member's contribution.

3) **Resignation**: Members may resign by providing written notice to the Chairperson.
4) **Termination**: Membership may be terminated for reasons such as prolonged absence, non-performance, or ethical violations.
5) **Replacement**: Vacant positions will be filled by appointing qualified individuals as per the composition requirements.

3.4 Appointment Letter

All members will receive an official appointment letter from the institution, specifying:

- Role and responsibilities
- Terms of appointment
- Code of conduct

Confidentiality agreement

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4. Quorum Requirements

4.1 Definition of Quorum

The quorum is the minimum number of IEC members required to convene a meeting and make valid decisions.

4.2 Minimum Quorum Requirements

For the IEC to conduct reviews and take decisions, a minimum of **5 members** must be present, including:Chairperson or Member Secretary

1) A Clinician
2) A Legal Expert
3) A Lay Person
4) At least one other member (e.g., Basic Medical Scientist or Social Scientist).

4.3 Conditions for Quorum

1. The quorum must be maintained throughout the meeting.
2. No decision shall be made in the absence of a quorum.
3. Alternate members may be invited to ensure quorum, provided they meet the eligibility criteria and have undergone adequate training.

4.4 Decision-Making Process

- Decisions shall be made by consensus. If consensus is not possible, decisions will be made by a majority vote.
- In case of a tie, the Chairperson will have the casting vote.
- Dissenting opinions must be recorded in the meeting minutes.
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5. Responsibilities of IEC Members

- Attend meetings regularly and contribute to discussions and decision-making processes.
- Review research proposals thoroughly before meetings.
- Ensure that research complies with ethical guidelines and safeguards participant rights.
- Maintain confidentiality of all discussions and decisions.
- Disclose conflicts of interest and abstain from related deliberations.

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6. Training Requirements

All IEC members must undergo initial and periodic training in research ethics, including:

ICMR Ethical Guidelines 2017

Good Clinical Practice (GCP)

National and international regulatory frameworks

Training sessions must be documented and updated regularly.

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7. Documentation and Record Keeping

The following records must be maintained by the IEC:

- Member CVs and appointment letters
- Confidentiality and conflict of interest agreements
- Meeting agendas and minutes
- Attendance records
- Decisions and correspondence with researchers

All records must be archived for a minimum of **5 years** post-completion of the respective research project.

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8. Review and Amendments

This SOP will be reviewed periodically and updated as needed to ensure compliance with evolving ethical and regulatory standards.

Standard Operating Procedure (SOP) for Institutional Ethics Committee (IEC) Training and Operations

1. Purpose

The purpose of this SOP is to outline the policies and procedures for the training of new and existing members of the Institutional Ethics Committee (IEC) and the operational framework for IEC functions, in adherence to the Indian Council of Medical Research (ICMR) Ethical Guidelines for Biomedical Research involving Human Participants, 2017.

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2. Scope

This SOP applies to all IEC members, including the Chairperson, Member Secretary, scientific and non-scientific members, legal experts, and laypersons, involved in the ethical review of biomedical and health research proposals.

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3. Responsibilities

- **Chairperson:** Ensures compliance with training requirements and oversees the effective functioning of the IEC.
- **Member Secretary:** Coordinates training sessions, records attendance, and maintains relevant documentation.
- **IEC Members:** Participate in all required training and adhere to the operational procedures outlined in this SOP.
- **Institution:** Provides necessary resources for the training and functioning of the IEC.

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4. Policy on Training

4.1 Induction Training for New Members

- **Objective:** To familiarize new members with their roles, responsibilities, and the ethical review process.
- **Content:**
    - Overview of the ICMR Ethical Guidelines (2017).
    - Roles and responsibilities of IEC members.
    - Basics of research ethics (autonomy, beneficence, non-maleficence, and justice).
    - Review process for research protocols.
    - Confidentiality and conflict of interest policies.
- **Methodology:**

    - Classroom-based lectures.
    - Interactive case studies.
    - Hands-on training with mock protocol reviews.
- **Timeline:** Within one month of appointment.

4.2 Refresher Training for Existing Members

- **Objective:** To update members on the latest ethical guidelines, regulations, and practices.
- **Frequency:** Annually.
- **Content:**
    - Updates to ICMR guidelines or other regulatory requirements.
    - Emerging ethical issues in research.
    - Review of challenging cases and lessons learned.
- **Methodology:**
    - Webinars.
    - Group discussions.
    - Workshops.

4.3 Documentation

- Attendance records and training completion certificates shall be maintained for all members.
- Training materials will be archived for future reference.

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5. Operational Procedures for IEC

5.1 Scheduling Meetings

- IEC meetings will be scheduled monthly or as required based on the volume of submissions.
- The agenda will be circulated to members at least seven days in advance.

5.2 Review of Protocols

- Proposals will be reviewed in accordance with ICMR Ethical Guidelines (2017).
- Reviews will include assessments of scientific validity, ethical considerations, risk-benefit analysis, and participant safety.
- Each proposal will be assigned a primary reviewer.

5.3 Decision-Making Process

- Decisions will be made by consensus or majority vote.

- Quorum requirements: At least 50% of members, including one scientific member, one non-scientific member, and one layperson.

5.4 Record-Keeping

- Minutes of meetings, correspondence, and reviewed protocols will be documented and securely stored for a minimum of five years.

5.5 Monitoring Approved Research

- Periodic progress reports will be reviewed to ensure ongoing compliance.
- Site visits may be conducted as needed.

5.6 Handling Complaints and Non-Compliance

- Complaints or instances of non-compliance will be investigated by an ad hoc subcommittee.
- Actions may include suspension or termination of research approval.

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6. Compliance with Ethical Guidelines

This SOP aligns with the ICMR Ethical Guidelines (2017) to safeguard the rights, safety, and well-being of research participants.

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7. References

- ICMR Ethical Guidelines for Biomedical Research Involving Human Participants, 2017.

Terms of Reference of Spine Research Foundation Ethics Committee

The Terms of Reference (TOR) for the Ethics Committee of the Spine Research Foundation are as follows:

Objective

- To ensure the ethical conduct of all research involving human participants undertaken by the Foundation.

Functions

1. Review and approve research proposals for their scientific validity and ethical compliance.
2. Monitor the ongoing studies for adherence to approved protocols and ethical guidelines.
3. Protect the rights, safety, and well-being of research participants.
4. Evaluate informed consent processes to ensure transparency and voluntariness.
5. Provide feedback and recommendations to investigators for improving the ethical and scientific aspects of their research.

Responsibilities

- Ensure compliance with ICMR guidelines, regulatory frameworks, and international ethical standards.
- Conduct timely reviews and communicate decisions to investigators.
- Maintain records of all meetings, communications, and decisions.
- Periodically review and update SOPs to reflect emerging ethical challenges and changes in guidelines.

Authority

The EC has the authority to:

1. Approve, modify, or reject research proposals based on ethical considerations.
2. Suspend or terminate studies in case of ethical violations or participant safety concerns.
3. Seek additional expert opinions or consultations as needed.

Terms of reference will be maintained in the office of Spine Research Foundation IEC. This includes

- Membership Requirements
- Terms of Appointment with reference to the duration of the term,
- 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.

The SOPs will be updated periodically based on the changing requirements. The term of appointment of members could be extended for another term and a defined percentage of members could be changed on regular basis. Preferably, IEC would 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 by a member due to illness or other unforeseen circumstances.