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 Expedited 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?

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 study? *

3.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	☐	☐	☐	☐	

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: