

Institutional Review Board Statement

18/01/2022

To,

The Editor

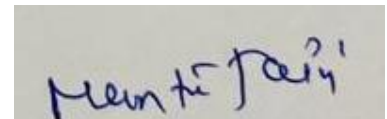
World Journal of Orthopaedics

Dear Sir

I, Mantu Jain the corresponding author the manuscript titled “**Histological differences in ligamentum flavum between degenerative lumbar canal stenosis and non-stenotic group: A prospective, comparative study**” declare that Institutional approval was taken from AIIMS Bhubaneswar for the study. Th approval letter is attached below.

Thanking you

Yours sincerely

A rectangular box containing a handwritten signature in blue ink. The signature appears to be 'Mantu Jain' written in a cursive style.



INSTITUTIONAL ETHICS COMMITTEE

Registration No: ECR/534/Inst/OD/2014/RR-17)

All India Institute of Medical Sciences Bhubaneswar

Level 3 Academic Block, AIIMS Bhubaneswar (At Sijua)
Bhubaneswar 751019, Odisha
Email: iec.aiimsbbsr@gmail.com Phone: 0674-2476083

Date: January 05, 2019

Chairperson

Dr Suresh Chandra Dash

Members

Dr Manaswini Mangaraj
(Basic Scientist)

Ms Navaneeta Rath
(Social Scientist)

Ms Swarna Misra
(General community
representative)

Mr. Santanu Sarangi
(Legal Person)

Dr Sandip Mishra
(Basic Scientist)

Dr S. Manwar Ali
(Clinician)

Dr Bikram Kishore Behera
(Clinician)

Dr Rituparna Maiti
(Pharmacologist)

Dr Somnath Mukherjee
(Clinician)

Dr Amit Ghosh
(Basic Scientist)

Member- Secretary

Dr Arvind Kumar Singh

Dr Mantu Jain
Assistant Professor,
Department of Orthopaedics,
AIIMS, Bhubaneswar

Ref Number: T/IM-F/18-19/43

Subject: Histological difference of ligamentum flavum in patients with Lumbar canal stenosis and Non lumbar canal stenosis.

Dear Dr Mantu Jain,

This is regarding your above-mentioned project proposal which was discussed in the Institutional Ethics Committee, AIIMS Bhubaneswar meeting held on November 17, 2018 (Saturday) and your subsequent letter dated January 04, 2019 responding to queries raised during IEC meeting.

The study is approved from ethical angle prospectively with effect from **January 05, 2019** till the entire period of the conduct of study according to the study duration mentioned in the protocol under direct responsibility of Dr Mantu Jain, Principal Investigator.

As a Principal Investigator, you are responsible for following requirements

1. All co-investigators must be kept informed of the status of the project.
2. No significant change to the protocol should be made and implemented without prior intimation and approval of the IEC
3. IEC should be reported about all Serious Adverse Events (SAEs) occurring during the study.
4. Only approved informed consent form and participant information sheet to be used for enrolment of the participants. All consent forms and other documents must be archived safely with PI for IEC audit
5. A six-monthly study progress report of the project must be submitted to IEC
6. It is hereby confirmed that neither you nor any of the study team members have participated in the voting/ decision making process of Institute Ethics Committee of AIIMS Bhubaneswar related to this study.

Member who attended the meeting and voted in favour:

1. Dr Suresh Chandra Dash (Chairperson)
2. Ms Navaneeta Rath
3. Ms Swarna Misra
4. Mr. Santanu Sarangi
5. Dr Sandip Mishra
6. Dr Bikram K Behera
7. Dr Somnath Mukherjee
8. Amit Ghosh
9. Arvind Kumar Singh

Chairperson
(IEC AIIMS Bhubaneswar)