Institutional review Board

To,

The Editor

World journal of Clinical cases

Dear Sir

I, Mantu Jain the corresponding author state that IRB approval was taken for the study titled "Effect of Correction of Flexion Deformity of Osteoarthritic Knee by Total Knee Arthroplasty on The Sagittal Alignment in Indian Population - A Prospective Study". It is attached below

Thanking you

Yours sincerely

Menti Tairi 15/0/2022



INSTITUTIONAL ETHICS COMMITTEE

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

All India Institute of Medical Sciences Bhubaneswar

Level 3 Academic Block, AllMS Bhubaneswar (At Sijua) Bhubaneswar 751019, Odisha Email: <u>iec@aiimsbhubaneswar.edu.in</u>, **Phone**: 0674-2476083

Date: February 26, 2020

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Dr Suresh Chandra Dash

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Dr Manaswini Mangaraj (Basic Scientist)

Ms Navaneeta Rath (Social Scientist)

Ms Swarna Misra (General community representative)

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Dr Rituparna Maiti (Pharmacologist)

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Dr Amit Ghosh (Basic Scientist)

Member-Secretary

Dr Arvind Kumar Singh

Dr Lubaib K P

Post Graduate Student Department of Orthopaedics, AIIMS, Bhubaneswar

Ref Number: IEC/AIIMS BBSR/PG Thesis/2019-20/94

Through Guide: Dr. Mantu Jain

Subject: Effect of correction of flexion deformity of osteoarthritic knee by total knee arthroplasty on the sagittal alignment in Indian population- A prospective study.

Dear Dr Lubaib K P

This is regarding above-mentioned **post graduate thesis protocol** which was discussed and reviewed in the Institutional Ethics Committee, AIIMS Bhubaneswar meeting held on December 14, 2019 and your subsequent letters dated January 26, 2020 & February 25, 2020 responding to queries raised during IEC meeting.

The protocol has been approved from ethical angle prospectively with effect from February 26, 2020 till the entire period of the conduct of study according to the study duration mentioned in the protocol under guidance of Dr Mantu Jain, thesis guide.

Student and guide are responsible for following requirements

- 1. All co-guides must be kept informed of the status of the project
- No significant change to the protocol should be made and implemented without prior intimation and approval of the IEC
- IEC should be reported about all Serious Adverse Events (SAEs) occurring during the study.
- 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
- 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:

 Ms Swarna Misra 2. Dr Manaswini Mangaraj 3. Mr. Santanu Sarangi 4. Dr Sandip Mishra 5. Dr Rituparna Maiti 6. Dr S. Manwar Ali 7. Dr Bikram Kishore Behera 8. Dr Arvind Kumar Singh.

Member Secretary (IEC AIIMS Bhubaneswar)