

INSTITUTIONAL ETHICS COMMITTEE APPROVAL CERTIFICATE

To: Dr. Anjali Tiwari
Research Analyst
Orthopedic Surgery Department
Sir H.N. Reliance Foundation Hospital & Research Centre,
Raja Ram Mohan Roy Road,
Mumbai 400 004.
Reference: **IEC Protocol No.** HNH/IEC/2021/OCS/ORTH/56

Date: 30.6.2021

Dear Dr. Anjali Tiwari,

The Institutional Ethics Committee (IEC) of the Sir H.N. Reliance Foundation Hospital & Research Centre has studied, reviewed and discussed your application to conduct the Research Study “**Classification of fracture patterns and implant detection using Artificial Intelligence (Computer Vision)**” in the department of **Orthopedic Surgery** during the IEC meeting held on **Saturday, June 12, 2021, at 1.30 PM, via ZOOM, our online virtual platform** of Sir H.N. Reliance Foundation Hospital, Raja Ram Mohan Roy Road, Mumbai 400 004.

The attendance of the **Institutional Ethics Committee (IEC)** at the meeting held on 12 June, 2021 to discuss, analyse and approve the submitted research proposals are as follows:

Sr. no.	Name of IEC Members	Designation in IEC	Attendance
1	Dr. Rajan P Nerurkar	Chairperson - Basic Scientist	Present
2	Dr. Rahul Verma	Member Secretary - Clinician	Present
3.	Dr. Sujeet Rajan	Member - Clinician	Present
4.	Dr. Pradnya Talawadekar	Member – Medico Legal Expert	Present
5.	Dr Jayesh Bellare	Member – Scientist	Present
6.	Ms. Anuradha Prasad	Member – Lay Person	Present
7.	Mr. Percy Ghaswala	Member – Social Scientist	Present

8.	Ms. Manisha Parthasarathy	Member – Social Scientist	Present
9.	Dr. Manish Agarwal	Member – Clinician	Present
10.	Dr Satish Khadilkar	Member – Clinician	Absent
11.	Dr Prabha Yadav	Member – Clinician	Present
12.	Ms. Kanika Vaid	Member – Lay Person	Present

The study along with the documents enumerated below have been submitted to the IEC and is approved in its present form:

Sr. No.	Document	Version No. & Date
1.	Application form for submission of Research proposal	Version 2.0, Dated 04/06/2021
2.	Research Protocol Submission Form	Version 3.0, Dated 16/06/2021
3.	Waiver of Consent	Granted

Institutional Ethics Committee APPROVES the above-mentioned study in its present form.

The approval is valid until one year from the date of sanction. You may make a written request for renewal / extension of the validity, along with the submission of annual status report.

Following points must be noted:

1. IEC should be informed of the completion of the study, as **duration of the study is for 1 year.**
2. **IEC has approved recruitment of 1000 samples in this study.**
3. PI and other investigators should co-operate fully with IEC members or appointed expert to monitor the trial from time to time.
4. The decision was arrived at through consensus. Neither PI nor any of proposed study team members was present during the decision making of the IEC.
5. At the time of PI's retirement/intention to leave the institute, study responsibility should be transferred to colleague after obtaining clearance from HOD. Status report, including accounts details should be submitted to HOD, IEC and sponsors.
6. The IEC functions in accordance with the ICH-GCP/ICMR/New Drugs Clinical Trial Rules.
7. It is hereby confirmed that neither you nor any of the study members have participated in voting/decision making procedures of the committee

8. In case of any new information or any SAE, which could affect any study, the same must be informed to IEC and sponsors as per the DCGI guidelines. The PI should report SAEs occurred for IEC approved studies within 24 hrs of the occurrence of the SAE. If the SAE is 'Death', the IEC Secretariat will receive the SAE reporting form within 24 hours of the occurrence.
9. In the events of any protocol amendments, IEC must be informed and the amendments should be highlighted in clear terms as follows:
 - a. The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project. (Page no., Clause no. etc.)
 - b. Alteration in the budgetary status should be clearly indicated and the revised budget form should be submitted
 - c. If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Ethics Committee for approval.
 - d. If the amendment demands a re-look at the toxicity or side effects to patients, the same should be documented.
 - e. If there are any amendments in the protocol design, these must be incorporated in the protocol, and other study documents. These revised documents should be submitted for approval of the SRC and IEC, only then can they be implemented.
 - f. Approval for amendment changes must be obtained prior to implementation of changes. Without including all the above points, the amendment is unlikely to be approved by the Institutional Ethics committee.
 - g. Any deviation/violation/waiver in the protocol must be informed to the IEC.

RPNerurkar

Dr. Rajan P Nerurkar
Head of Pharmacology
T.N. Medical College & BYL Nair Hospital
& Chairman of the IEC,
Sir H.N. Reliance Foundation Hospital
& Research Centre.

Rahul Verma

Dr. Rahul Verma
Director Academics and Research,
Sir H.NRFHRC
& Secretary of the IEC
Sir H.N. Reliance Foundation Hospital
& Research Centre.

SCIENTIFIC ADVISORY COMMITTEE APPROVAL CERTIFICATE

To: Dr. Anjali Tiwari
 Research Analyst
 Orthopedic Surgery Department
 Sir H.N. Reliance Foundation Hospital & Research Centre,
 Raja Ram Mohan Roy Road,
 Mumbai 400 004.
 Reference: **IEC Protocol No.** HNH/IEC/2021/OCS/ORTH/56

Date:

Dear Dr. Anjali Tiwari,

The Scientific Advisory Committee (SAC) of the Sir H.N. Reliance Foundation Hospital & Research Centre has studied, reviewed and discussed the scientific aspect of your application to conduct the Research Study Titled **“Classification of fracture patterns and implant detection using Artificial Intelligence (Computer Vision)”** in the department of **Orthopedic Surgery** during the SAC meeting held on **Wednesday, June 2, 2021, at 2 PM, via TEAMS, our online virtual platform** of Sir H.N. Reliance Foundation Hospital, Raja Ram Mohan Roy Road, Mumbai 400 004.

Attendance of the members of the SAC was as follows:

Sr. no.	Name of SAC Members	Designation in SAC	Attendance
1	Dr. Tarang Gianchandani	Chairperson	Present
2	Dr. Rahul Verma	Member Secretary	Present
3	Dr. Abhijit Thakur	Member	Present
4.	Dr. Rekha Daver	Member	Present
5.	Dr. Joy Desai	Member	Present
6.	Dr. Mayur Patel	Member	Present
7.	Dr. Nimit Shah	Member	Absent
8.	Dr. Nimish Shah	Member	Present
9.	Dr. Marzi Mehta	Member	Absent
10.	Dr. Rochan Pant	Member	Present
11.	Dr. Shruti Tapiawala	Member	Absent

12.	Dr. Charulata Pamnani	Member	Absent
13.	Dr. Mohan Menon	Member	Absent
14.	Dr. Shaila Khubchandani	Member	Absent
15.	Dr. Shailaja Saxena	Member	Absent
16.	Dr. Ashwin Shetty	Member	Present
17.	Dr. Maninder Setia	Statistician	Present
18.	Ms. Elizabeth David	Member	Absent
19.	Dr. Maulik Parekh	Member	Absent
20.	Dr. Nikhilesh Borkar	Member	Present
21.	Dr. Shobna Bhatia	Member	Present
22.	Dr. Kavita Shalia	Basic Scientist	Present
23.	Dr. Deepak Modi	Basic Scientist	Present

SAC APPROVES the above-mentioned study in its present form.

Declared Financial expectation is approximately is Rs 6, 50,000 (Non-Sponsored Study)

This study should be initiated only after Approval of the Institutional Ethics Committee of Sir H N Reliance Foundation Hospital and Research Centre.



Dr. Tarang Gianchandani
CEO, Sir H.N. Reliance Foundation
Hospital & Research Centre
& Chairperson of the SAC
Sir H.N. Reliance Foundation Hospital
& Research Centre.



Dr. Rahul Verma
Director Academics and Research,
Sir HNRFHRC
& Secretary of the SAC
Sir H.N. Reliance Foundation Hospital
& Research Centre.