



आरोग्यम् सुखं सम्पदा

सदाचार समिति  
**Institute Ethics Committee**  
अखिल भारतीय आयुर्विज्ञान संस्थान , रायपुर (छत्तीसगढ़)  
**All India Institute of Medical Sciences, Raipur(Chhattisgarh)**  
Academic Section, 2<sup>nd</sup> Floor,  
Medical College Complex, Gate No. 5  
Tatibandh, GE Road, Raipur-492 099 (CG)  
Website : [www.aiimsraipur.edu.in](http://www.aiimsraipur.edu.in)  
Email : [iec@aiimsraipur.edu.in](mailto:iec@aiimsraipur.edu.in)  
Ethics Committee Registration No.: ECR/714/Inst/CT/2015/RR-18

Letter No.: 1453 /IEC-AIIMSRPR/2021

Date: 16 /02/2021

### CERTIFICATE OF APPROVAL

**To** : **Dr. Sanjay Singh Negi** (Principal Investigator)  
Associate Professor, Department of Department of  
Microbiology, AIIMS Raipur

**Project Title** : Genetic analysis of circulating SARS-CoV-2 strains obtained  
from symptomatic and asymptomatic patients of COVID-19  
in Chhattisgarh.

**IEC Proposal No.** : **AIIMSRPR/IEC/2021/705**

**IEC Review Date** : 16.01.2021

**Research Cell** : Approved

**Approval Status** (Vide Letter No. OW/RC/AIIMS-RPR/2020/481 dated  
20.11.2020) – Intramural funded project.

The Institute Ethics Committee, All India Institute of Medical Sciences, Raipur (Chhattisgarh) reviewed and discussed your above referenced research proposal in the meeting held on 16.01.2021.

The following documents were reviewed:

1. Covering Letter
2. Research Project Proposal (version 1.0)
3. Case Record Form/Questionnaire (version 1.0)
4. Patient information sheet (English & Hindi) (version 1.0)
5. Consent Form for participants more than 18 years of age (English & Hindi) (version 1.0)
6. Undertaking regarding GCP guidelines and study not being initiated yet.

The following members of Institute Ethics Committee were present at the meeting held on 16.01.2021 at 10.30 AM at Committee Hall, AIIMS Raipur.

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**Ref: 1453 /IEC-AIIMSRPR/2021, dated: 16 / 02 /2021**

<b>Sr. No.</b>	<b>Name of IEC Member</b>	<b>Designation</b>
1	<b>Dr. P. K. Patra</b> Director Professor, Department of Biochemistry, Pt. J.N.M.C. Raipur (Chhattisgarh)	<b>Chairman</b>
2	<b>Dr. Vijay Motghare</b> Professor & Head, Department of Pharmacology Govt. Medical College, Nagpur	Pharmacologist (Basic Medical Scientist)
3	<b>Dr. Yogendra Keche</b> Additional Professor Department of Pharmacology AIIMS Raipur (Chhattisgarh)	Pharmacologist (Basic Medical Scientist)
4	<b>Dr. Suprava Patel</b> Associate Professor Department of Biochemistry AIIMS Raipur (Chhattisgarh)	Basic Medical Scientist
5	<b>Dr. Rashmi Dubey,</b> Associate Professor Department of Anaesthesiology AIIMS Raipur (Chhattisgarh)	Clinician
6	<b>Dr. Keshao Nagpure</b> Assistant Professor Department of General Medicine AIIMS Raipur (Chhattisgarh)	Clinician
7	<b>Dr. Bhagwant Singh</b> Professor & Head Department of Philosophy & Yoga Pt. Ravishankar Shukla University Raipur (Chhattisgarh)	Philosopher
8	<b>Justice Pradeep Kumar Dave</b> Retired District Session Judge Plot no. 7/1, Radhika Nagar, Supela Bhilai, District-Durg (Chhattisgarh)	Legal Expert
9	<b>Mrs. Prabha Minj</b> Principal, Kendriya Vidhyalaya-2, Pandit Deendayal Uppdhyay Nagar, Raipur (Chhattisgarh)	Social Scientist
10	<b>Dr. Hemlata Tiwari</b> Behaviour Therapist & Counsellor 5, Sarswati Vihar, Behind Science College, GE Road, Raipur (Chhattisgarh)	Layperson from Community

11	<b>Dr. Tushar B. Jagzape</b> Additional Professor Department of Paediatrics AIIMS Raipur (Chhattisgarh)	<b>Member Secretary</b>
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**Clear statement of decision reached:**

At Institute Ethics Committee meeting held on 16.01.2021, the committee reviewed the research project and the study related documents and discussed the ethical issues involved.

No ethical issue was identified. Hence, IEC decided to **approve** the above referenced project.

As Principal Investigator, you are responsible for fulfilling the following requirements of approval:

1. PI shall ensure data collection techniques.
2. PI shall ensure validity of data.
3. Interim analysis of data shall be done periodically; all the co-investigators and IEC-AIIMS Raipur must be kept informed.
4. This approval is valid for entire duration of the study (i.e. **01 year**). The review application must be submitted to the IEC-AIIMS Raipur in order to continue the study beyond the approved period.
5. All the co-investigators must be kept informed of the status of the project.
6. Changes, amendments, and addendum to the protocol or the consent form, must be submitted to the IEC-AIIMS Raipur for re-review and approval prior to the activation of the changes.
7. Any change of study site, change of investigator/s, termination of study (with reason to do so) should also be informed to IEC-AIIMS Raipur.
8. The IEC proposal number assigned to the project should be cited in any correspondence.
9. Any Serious Adverse Event (SAE) occurring during the course of the study should be reported to the IEC-AIIMS Raipur.
10. New information that becomes available which could change the risk: benefit ratio must be submitted promptly for IEC review.
11. Only approved consent forms are to be used in the enrolment of participants. All consent forms signed by subjects and/or witnesses should be retained on file. The

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IEC may conduct audits of all study records, and consent documentation may be part of such audits.

12. The study progress report should be made available for the IEC review on every 6 months.
13. The final report of the study must be submitted to IEC-AIIMS Raipur after the completion of the study.

It is, hereby, confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

Sincerely,



**Dr. P. K. Patra**  
**Chairman**

Institute Ethics Committee  
All India Institute of Medical Sciences  
Raipur 492099 (C.G.)



**Dr. Tushar Jagzape**  
**Member Secretary**

Institute Ethics Committee  
All India Institute of Medical Sciences  
Raipur 492099 (C.G.)