



Government of Nepal  
**Nepal Health Research Council (NHRC)**  
Estd. 1991

Ref. No.: 1944

Date: 29 January 2021

**Prof. Dr. Buddha Basnyat**

Principal Investigator, Oxford University Clinical Research Unit\Nepal

**Dr. Pradip Gyanwali**

Principal Investigator, Nepal Health Research Council

**Ref: Approval of research proposal**

Dear Prof. Dr. Basnyat and Dr. Gyanwali,

This is to certify that the following protocol and related documents have been granted approval by the Ethical Review Board, NHRC for implementation.

If the researcher requires transfer of the bio-samples to other countries, the investigator should apply to the NHRC for the permission. The researchers will not be allowed to ship any raw/crude human biomaterial outside the country, only extracted and amplified samples can be taken to laboratories outside of Nepal for specific study, as per the protocol submitted and approved by the NHRC. The remaining samples of the lab should be destroyed as per standard operating procedure and the process should be documented and informed to the NHRC timely.

ERB Protocol No	787/2020 P	Sponsor Protocol No	NA
Principal Investigator/s	Prof. Dr. Buddha Basnyat Dr. Pradip Gyanwali	Sponsor Institute	University of Oxford
Title	Randomised Evaluation of Covid-19 Therapy (RECOVERY) Trial		
Protocol Version No	12.1	Version Date	16 December 2020
ICF Version No. (V.N.)	10.1	Version Date	21 November 2020
Other Documents			
1. Data collection tools 2. Acceptance letter from the study sites 3. Donor agreement letter 4. Letter of Sponsorship 5. Approval from the UK 6. DMC Charter 7. RECOVERY intervention_ASPIRIN 8. RECOVERY intervention_Colchicine 9. RECOVERY intervention_TOCI			
Members of research team	1. Dr. Meghnath Dhimal 2. Dr. Suman Pant		



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	3. Dr. Suchita Shrestha 4. Dr. Abhilasha Karkey 5. Dr. Anup Bastola 6. Dr. Bimal Sharma Chalise 7. Dr. Roshan Kumar Jha 8. Dr. Binay Kumar Adhikari 9. Mr. Anil Shrestha 10. Ms. Samita Rijal			
Study Site	1. Sukraraj Tropical and Infectious Disease Hospital 2. Armed Police Force Hospital (APF)			
Type of Review	<input type="checkbox"/>	Expedited	Duration of Approval 27 January 2021 to 27 January 2022	Frequency of continuing review At least once in a year
	<input checked="" type="checkbox"/>	Full Board		
	Meeting Date: 27 January 2021			
Total budget of research	NRs 4,85,95,418.00			
Ethical review processing fee	NRs 14,57,862.54			
<b>Investigator Responsibilities</b> <ul style="list-style-type: none"><li>Any amendments shall be approved from the ERB before implementing them</li><li>Submit Serious Adverse Events (SAE) and Suspected Unexpected Serious Adverse Reaction (SUSAR) reports to the ERB within 48hours</li><li>Submit progress report every 3 months</li><li>Submit final report after completion of protocol procedures at the study site</li><li>Report protocol deviation / violation within 7 days</li><li>Comply with all relevant international and NHRC guidelines</li><li>Abide by the principles of Good Clinical Practice and ethical conduct of the research</li></ul>				

If you have any questions, please contact the Ethical Review M & E Section at NHRC.

Thanking you,

Prof. Dr. Ramesh Kant Adhikari  
Acting Chairperson  
Ethical Review Board, NHRC