

Minutes of the REC meeting held on 02-05-2023

The Research Ethics Committee (REC) zoom meeting was held on May 2nd, 2023. The following members of REC attended the meeting:

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|----------------------------------|------------------------------|
| 1. Prof. Dr. Saima Pervaiz Iqbal | Chairperson |
| 2. Prof. Dr. Munir Saleemi | Member |
| 3. Prof. Marie Andraes | Member |
| 4. Prof. Dr. Amjad Mehboob | Member |
| 5. Dr. Farkhanda Ghafoor | Member |
| 6. Dr. Faiz Bashir | National Coordinator (NBC-R) |
| 7. Mr. Waryal Ali Daheri | L.D.C (NBC-R-Secretariat) |

The following projects reviewed / discussed:

NBC-932:

Title: **The Pragmatic Observation of Labor, Exercise Tolerance, and Respiratory Impairment After Treatment of TB (PrOLETARIAT).**

Principal Investigator: **1. Dr. Faiz Ahmad Khan & Dr. Saima Saeed**
Indus Hospital & Health Network (IHHN)
C-76, Sector 31/5, Opposite 'Crossing 'Darussalam Society Sector 39
Korangi Crossing, **Karachi, Pakistan.**

2. Dr. Dennis Jensen
The Research Institute of McGill University and Health Centre (RI-MUHC). 1001 Décarie Montreal Blvd, Montreal, Quebec H4A 3J1,
Canada.

Final REC Comments:

Project Approved.

NBC-934:

Title: **Mapping the Early Childhood Gut across Ancestry, Geography and Environment.**

Principal Investigator: **Dr. Imran Nisar,**
Dr. Junaid Iqbal,
Dr Kamran Sadiq
Department of Paediatrics and Child Health, Aga Khan University
(AKU), Stadium road, **Karachi,**

Final REC Comments:

1. We would like to know why only underprivileged communities are being included in this study. The fact that cost of the procedure will be paid for during the research is a serious inducement to participate.
2. It is suggested that all healthcare providers working at institute of the PI, main and satellite centers may be asked to participate. It would be difficult for non-medical parents to understand this type of research. Consent form should cover all the tests being conducted and sent abroad.
3. Some tests are temperature bound. How will they be transported to the main lab?
4. Submitting toe nail clippings may not be culturally appropriate in our setting. Please explain your participant recruitment strategy.
5. MTA needs to be attached as well as IRB approval from US sites.
6. Please submit detailed budget plan.
7. CVs of Co-PIs also needs to attached.

NBC-936:

Title: **HELP Trial: Efficacy of L-ornithine L-aspartate and Polyethylene Glycol in Cirrhotic Patients with Overt Hepatic Encephalopathy.**

Principal Investigator: **Dr. Zeeshan Ali**
Medical Unit IV, Ward-23, JPMC Rafiqi H.J. Shaheed Road,
Karachi.

Final REC Comments:

1. There are overall inconsistencies in the study sites and their site PIs and Co-PIs. We need details as to sites involved and who is taking responsibility of this trial in each site.
2. We are not clear as to who is the funding agency. Is pharmaceutical company involved? If yes, how?
3. Informed consent form needs to mention that this is a trial and benefit is not proven. It should also include which tests are being done on participants
4. Taking consent from a surrogate is problematic for research. How will the PI address this issue in terms in compromised mental capacity?
5. Please explain how randomization will be done?
6. Is this trial registered somewhere? Would any indemnity insurance be provided in case if patient lands in ICU?
7. Please explain composition of DSMB.

NBC-938:

Title: **The Burden of Antimicrobial Resistance and Antibiotic Treatment Failure in Low-, Middle- and High-Income Countries.**

Principal Investigator: **Prof. Timothy R. Walsh**
Research Services, University of Oxford Boundary Brook House,
Churchill Drive, **Oxford OX3 7GB Office: +44 (0)1865 282585.**

Final REC Comments:

1. REC would like to know if the national AMR Focal point will be involved as this data is crucial in national interest.

NBC-939:

Title: **Genomics of Klebsiella Pneumoniae and Escherichia. Coli in Pediatric Population in Pakistan.**

Principal Investigator: **Dr. Imran Nisar**
The Aga Khan University, Stadium Road, P.O. Box 3500,
Karachi.

Final REC Comments:

1. We will await AKUH ERC approval.

NBC-940:

Title: **A Clinically-Oriented Antimicrobial Resistance Surveillance Network for Healthcare-associated infections (ACORN-HAI).**

Principal Investigator: **Dr. Faisal Mahmood**
Department of Infectious Diseases, Aga Khan University Hospital,
Stadium Road, **Karachi.**


Final REC Comments:

1. We would like to know if this data will be shared with our National bodies like MoH.
2. Why are samples being sent to Singapore? MTA needs to be attached.
3. IRB approvals from all collaborating sites are required.

Next meeting:

The next zoom meeting will be held at 02:30 pm on May 9th, 2023. The following projects will be reviewed:

1. NBC-941
2. NBC-942



Focal person NBC



Chairperson REC