

## Minutes of the REC meeting held on 07-03-2023

The Research Ethics Committee (REC) zoom meeting was held on March 7, 2023. The following members of REC attended the meeting:

1. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2. Prof. Dr. Munir Saleemi	Member
3. Prof. Dr. Jamshed Akhtar	Member
4. Prof. Dr. Marie Andrades	Member
5. Prof. Dr. Saqib Mehmood	Member
6. Prof. Dr. Nazli Hossain	Member
7. Prof. Dr. Amjad Mehboob	Member
8. Mrs. Sualeha Siddiqui Shekhani	Member
9. Dr. Faiz Bashir	National Coordinator (NBC-R)
10. Mr. Waryal Ali Daheri	L.D.C (NBC-R-Secretariat)

The following projects reviewed / discussed:

### NBC-922:

Title: Occupational Participation and Quality of Life among Persons with Paraplegic Spinal Cord Injury in Pakistan.

Principal Investigator: Faizan Jameel Khanzada (Occupational therapist)  
House No: 3/964, Shah Faisal Colony No: 3 Karachi Pakistan..

### Final REC Comments:

1. The study site mentions Civil Hospital Karachi and other sites. Please specify which are these sites and attach their IRB approvals.
2. According to the Gant chart the study has already been conducted in March 2022.
3. Is the tool validated for the Pakistani population?
4. The study mentions physical assessment to be done on participants. How will the researcher achieve this?

### NBC-923:

Title: Country Case Studies Towards WHO Postpartum Haemorrhage (PPH) Summit -A case study of Pakistan.

Principal Investigator: Dr Lumaan Sheikh  
Department of Obstetrics and Gynaecology (Obgyn),  
Aga Khan University Hospital  
Karachi.

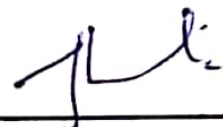
### Final REC Comments:

1. How have the sites been chosen? Do they adequately represent Pakistan? Only Sindhi consent is attached so our concern for representation.
2. Was the PI and Co-PI involved in the project under study?
3. We would like to see the complete budget.
4. Are patients not included in the study as stakeholders?
5. Will the results be shared with a govt. body or Ministry of Health?

**Next meeting:**

The next zoom meeting will be held at 03:00 pm on March 14, 2023. The following projects will be reviewed:

1. NBC-924
2. NBC-926
3. NBC-927



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**Focal person NBC**



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**Chairperson REC**

## Minutes of the REC meeting held on 14-03-2023

The Research Ethics Committee (REC) zoom meeting was held on March 14, 2023.  
The following members of REC attended the meeting:

1. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2. Prof. Dr. Munir Saleemi	Member
3. Prof. Dr. Jamshed Akhtar	Member
4. Prof. Dr. Marie Andrades	Member
5. Prof. Dr. Saqib Mehmood	Member
6. Prof. Dr. Nazli Hossain	Member
7. Prof. Dr. Amjad Mehboob	Member
8. Dr. Farkhanda Ghafoor	Member
9. Mrs. Sualeha Siddiqui Shekhani	Member
10. Dr. Faiz Bashir	National Coordinator (NBC-R)
11. Mr. Waryal Ali Daheri	L.D.C (NBC-R-Secretariat)

The following projects reviewed / discussed:

### NBC-924:

Title: Mesenchymal stem cells infusion in patients with Autoimmune diseases - A Phase II clinical trial.

**Principal Investigator:** **Maj Gen Qamar-Un-Nisa Chaudhry**  
Armed forces bone marrow transplant center, AFBMTC / NIBMT,  
**Rawalpindi.**

### Final REC Comments:

1. More details are required for this study. Please provide information as to how these stem cells will be collected. Who will be the donors? Informed consent for donor will be specific for donation with information about possible side effects and whom to contact in case of need or further query.
2. We would like to see results of Phase 1 study? Where was it conducted?
3. Please clarify which autoimmune disease is being targeted. How will participants be identified and approached for the study? Who are the controls? What will they be receiving? Informed consent form for this population will explain the research and possible harms. How will participants be compensated or remunerated for their involvement?
4. Does the PI have experience of doing this type of research? Please provide CVs of all investigators from various sites.
5. Has the DSMB of this study been formed? Please provide details.

### NBC-926:

Title: Construction of a Healthy synthetic gut microbiome community for the Pakistani rural community.

**Principal Investigator:** **Dr. Asad Ali**  
Department of Pediatrics, Aga Khan University, Near Stadium Road,  
**Karachi.**

### Final REC Comments:

1. How is a stool sample from Matiari representative of the Pakistani population? Why cannot these samples be collected from another area rather than this community that has been over-researched for at least two decades?

2. How will this community benefit?
3. What would happen if screening tests come to be positive? How will that be managed?
4. Does the microbiome have a correlation with age? Can the results be extrapolated to another population of a different age group?
5. Does water supply or water contamination of the ground affect the microbiome under study?
6. Is there a possibility of development of a commercial product and will it be provided to our population as a post trial benefit?
7. MTA needs to be attached.

**NBC-927:**

Title: **Clinical response of Nuberol Forte (Paracetamol Orphenadrine combination) in Pakistani Subjects with Chronic Neck Pain in routine rehabilitation centres "NOTICE".**

**Principal Investigator:** **Dr. Zahoor Ahmed (Consultant Neurologist)**  
Karachi Medical Complex, Mehran Extension, Block 16 Gulshan-e-Iqbal,  
**Karachi, Sindh.**


**Final REC Comments:**

1. The rationale of the study seems unclear. This looks to be a post marketing study by pharmaceutical company. What is their role?
2. Which are the sites involved? Are they approved by DRAP? Who are the different site PIs? Please provide names and CVs.
3. Does the PI have previous research experience of this kind?
4. Please provide details of the PMA-ERC. Who are its members and do they have the required experience in terms of research review?

**Next meeting:**

The next zoom meeting will be held at 03:00 pm on March 21, 2023. The following projects will be reviewed:

1. NBC-928
2. NBC-929
3. NBC-931

  
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**Focal person NBC**

  
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**Chairperson REC**



## Minutes of the REC meeting held on 21-03-2023

The Research Ethics Committee (REC) zoom meeting was held on March 21, 2023. The following members of REC attended the meeting:

1. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2. Prof. Dr. Munir Saleemi	Member
3. Prof. Dr. Jamshed Akhtar	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-928:

Title: Diagnostic accuracy of lung ultrasonography in under-five children with pneumonia in resource-poor settings- a feasibility study.

**Principal Investigator:** Prof. Wasim Akhtar Mirza  
Associate Professor  
Department of Radiology, Aga Khan University,  
Karachi, Pakistan.

### Final REC Comments:

1. Why has Makli been chosen as a site whereas this study can be carried out anywhere within and around the parent institution? Pneumonia is a common illness and this pilot study can be carried out anywhere.
2. The ethical approval from other collaborators and its institutions is missing. We could not find ERC approval from AKUH.
3. What is the sustainability of the intervention? Will it be translated to providing some service to the community?
4. What is the role of the PI? Are any pediatricians on board this study? What about stakeholders from the govt. programs like IMCI?
5. A technician will be trained to carry out the LUS. Who is responsible for training the technician? Is this training certified?

### NBC-929:

Title: A mHealth intervention (mTB-Tobacco) for smoking cessation in people with tuberculosis: a two- stage adaptive design, randomized trial (Quit4TB).

**Principal Investigator:** Prof. Dr. Kamran Siddiqi  
(Overall lead, UK) University of Edinburgh UK,  
Ark Foundation, Bangladesh.

**Dr. Amina Khan (Pakistan lead)**  
The Initiative, Bani Gala, Islamabad, Pakistan.

### Final REC Comments:

1. There is no country specific protocol and it wasted the time of the reviewers when no essential information was provided.

**NBC-931:**

**Title: Viral surveillance and pathogen discovery' in Pakistan, Abbott Pandemic Defense Coalition Site in Pakistan.**

**Principal Investigator:** **Dr. Erum Khan**  
Section of Microbiology, Pathology and Laboratory Medicine,  
Aga Khan University, **Karachi.**

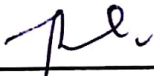
**Final REC Comments:**

1. We would like to know more about the Abbot Coalition. Is it linked with any government Organization of Pakistan? How will the country benefit? Who are the other stakeholders?

**Next meeting:**

The next zoom meeting will be held at 02:00 pm on April 4, 2023. The following projects will be reviewed:

1. NBC-932
2. NBC-934
3. COVID-136



**Focal person NBC**



**Chairperson REC**