

Minutes of the REC meeting held on 14-2-2023

The Research Ethics Committee (REC) zoom meeting was held on February 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. Marie Andraes	Member
5. Prof. Dr. Amjad Mehboob	Member
6. Mrs. Sualeha Siddiqui Shekhani	Member
7. Dr. Farkhanda Ghafoor	Member
8. Dr. Faiza Bashir	National Coordinator
9. Mr. Khalid Mehmood	Assistant (NBC-Secretariat)
10. Mr. Waryal Ali Daheri	L.D.C (NBC-Secretariat)

The following projects reviewed / discussed:

NBC-912:

Title: **CONcordance of CARDiometabolic Diseases and Risk Factors in Pakistani Households.**

Principal Investigator: **Dr. Romaina Iqbal**
Department of Community Health Sciences
Aga Khan University, **Karachi**

Final REC Comments:

1. The communities need to be identified prior to approval.
2. Will patients being referred to AKUH with high BP or cholesterol be facilitated in any way? What if they cannot afford to go there?
3. MTA mentions back dates.

NBC-913:

Title: **Factors Influencing Patients' Decisions to Seek Non-Conventional Treatments for Tuberculosis– A Qualitative Study in Pakistan.**

Principal Investigator: **Dr. Saman Ahmed**
Usher Institute, University of Edinburgh Old Medical School, Teviot
Place, Edinburgh, EH8 9AG, Scotland, **United Kingdom**

Final REC Comments:

1. Please ask PI to send proposal on NBC form.

NBC-914:

Title: **Knowledge and attitude of parents towards childhood hearing loss in Rawalpindi city, Pakistan.**

Principal Investigator: **Prof. Dr. Rafidah Mazlan**
The National University Of Malaysia, Audiology Programme, Center
for Rehabilitation and Special Needs, Faculty of Health Sciences,
Universiti Kebangsaan Malaysia, Jalan Raja Muda Abdul Aziz, 50300
Kuala Lumpur, Malaysia.

Final REC Comments:

1. NBC-REC recommends that the PI collaborate with centers in Pakistan dealing with children with hearing loss and collect data from their parents.

COVID-135:

Title: **A Multi-center, Randomized, Blinded, Placebo-controlled, Phase 3 Clinical Study to Evaluate the Efficacy, Safety and Immunogenicity of SARS-CoV-2 Bivalent mRNA Vaccine (LVRNAO21) as Booster in participants Aged 18 Years and Older Who Completed Primary/i Booster Dose(s) of SARS-CoV-2 Vaccination.**

Principal Investigator: **Dr. Muneeba Ahsan Sayeed**
Sindh Infectious Diseases Hospital & Research Center, Dow University
of Health Sciences, **Karachi, Pakistan.**
Dr. Sadia Noor
Director Institute of Biological Biochemical & Pharmaceutical
Sciences, Dow University of Health Sciences, **Karachi, Pakistan.**

Final REC Comments:

1. MTA is not attached.
2. Insurance document needs to be seen.
3. IRB approvals from other sites is required.
4. Where will study participants be treated in case of any adverse events?
5. The CV of the PI needs to be attached. Does the PI have any experience in vaccine research?
6. There is no mention of reimbursement (PKR 12,000/-) in Informed Consent Form.
7. Why are participants being checked for HIV?
8. Where are trainings being provided?
9. Why is 15 ml of blood required at each visit?
10. There is no guidance to participants about contraceptives' to prevent pregnancy.

Next meeting:

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

1. NBC-911
2. NBC-937
3. Also discuss NBC-844 (PI Fatima Mir Project)



Focal person NBC



Chairperson REC

Minutes of the REC meeting held on 21-2-2023

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

1. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2. Prof. Dr. Jamshed Akhtar	Member
3. Prof. Dr. Amjad Mehboob	Member
4. Mrs. Sualeha Siddiqui Shekhani	Member
5. Dr. Farkhanda Ghafoor	Member
6. Dr. Nighat Murad	Focal Person (NBC)
7. Mr. Khalid Mehmood	Assistant (NBC-Secretariat)
8. Mr. Waryal Ali Daheri	L.D.C (NBC-Secretariat)

The following projects reviewed / discussed:

NBC-911:

Title: LEARN: Learning and Exploring Afghan Refugee Needs and lived experiences in Pakistan.

Principal Investigator: Ms. Saima Siyal
DREAM project Office, Alshifa Medical Center near Wapda Colony
main road Tharushah,
District Naushahero Feroze, Sindh Pakistan (67370)

Final REC Comments:

1. Project Approved.

NBC-937:

Title: A Phase III, Randomized, Comparator-Controlled Double-Blind, Multicentre Study to Evaluate the Immunogenicity, Safety and the Consistency of Three Consecutive Lots of a PIKA Rabies Vaccine (Vero cell) for Human Use, Freeze-Dried in Healthy Adult Subjects using a Post-Exposure Prophylaxis Schedule..

Principal Investigator: Prof. Dr. Ume Sughra
Al-Shifa Research Centre / Al-Shifa Trust Eye Hospital,
Rawalpindi

Final REC Comments:

1. We need clarity as to why this is a Phase 3 trial when you are looking for adverse events and immune responses?
2. The protocol mentions post exposure prophylaxis whereas, recruitment is of healthy adults. Should it not be pre-exposure? Would the regimen given be the same?
3. Where have the Phase 1 and Phase 2 been conducted?
4. Is DRAP approval valid for the sites mentioned considering that this is a vaccine trial for rabies? Would it not be better to include sites which deal with dog bite and rabies cases?
5. Will Pakistani population benefit by participating in this trial in terms of vaccine provision if proven effective?

Minutes of the REC meeting held on 28-2-2023

The Research Ethics Committee (REC) zoom meeting was held on February 28, 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. Amjad Mehboob	Member
6. Mrs. Sualeha Siddiqui Shekhani	Member
7. Dr. Farkhanda Ghafoor	Member
8. Dr. Nighat Murad	Focal Person (NBC)
9. Mr. Waryal Ali Daheri	L.D.C (NBC-Secretariat)

The following projects reviewed / discussed:

NBC-919:

Title: **EZAFFAW - Efficacy of Zinc Fortified Fermented Wheat: Product development and Randomized Controlled Trial.**

Principal Investigator: Dr. Jai K Das Dept of Paediatrics & Child Health, Aga Khan University, Karachi.

Final REC Comments:

1. What will happen to participants who have incidental findings (like iron deficiency anemia) in their blood tests? How will that be incorporated into the trial?
2. If the seed proves to benefit the population, will the country be dependent upon the seed? Or is there a self-propagating mechanism for the making more seed?
3. What is the post trial access for the community? It would be brutal to deny a child from a meal after feeding him for six months. Is there some welfare initiative built in the study for food support?
4. Is there a risk of stigmatization to participants who are coming for free meals?

NBC-920:

Title: **Comprehensive Profiling of Social Mixing Patterns in Pakistan.**

Principal Investigator: Dr. Abdul Momin Kazi
Department of Paediatrics & Child Health, Faculty office building (FOB),
Aga Khan University Hospital
Karachi.

Final REC Comments:

1. The protocol has been cut and pasted from a similar study in Latin America. It has to be made culturally sensitive.
2. Please provide more details about the proximity sensor. How does it affect the privacy of an individual?
3. How are COVID-19 precautions still feasible in this day and age when there is no social distancing and no masking?
4. Please send us the Data Transfer Agreement if any.

NBC-933:

Title: Health Policy Analysis for Health Taxes: Lessons from Countries - Pakistan Case Study.

Principal Investigator: Dr Zafar Mirza
Onto Global Ltd, Vancouver, 777 Richards Street 3901 Vancouver BC
V6B 0M6, Canada / Pakistan

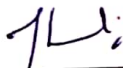
Final REC Comments:

1. Please share with us details about study participants and how they will be contacted.
2. We would like to see the data collection tool/instrument.
3. Informed consent form needs to be revised accordingly.

Next meeting:

The next zoom meeting will be held at 03:00 pm on March 7, 2023. The following projects will be reviewed:

1. NBC-922
2. NBC-923



Focal person NBC



Chairperson REC