

## Minutes of the REC meeting held on 3-1-2023

The Research Ethics Committee (REC) zoom meeting was held on January 3, 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. Dr. Farkhanda Ghafoor	Member
5. Prof. Marie Andraes	Member
6. Dr. Faiza Bashir	National Coordinator
7. Mr. Khalid Mehmood	Assistant (NBC-Secretariat)
8. Mr. Waryal Ali Daheri	L.D.C (NBC-Secretariat)

Ms Sualeha and Dr Jamshed submitted their comments to the Chairperson. Prof Dr Nazli Hussain, Dr Saqib Mehmood and Ms Sualeha Siddiqe did not attend the meeting.

It was second consecutive time for Dr Nazli and 1<sup>st</sup> for Prof Saqib and Ms Sualeha.

However, Ms Sualeha submitted her reviews for this meeting.

The following projects were reviewed / discussed:

### NBC-886:

Title: TO ASSESS THE BURDEN OF HEARING LOSS AND LANGUAGE DELAYS AMONGST CHILDREN UNDER 5 YEARS IN A PERI-URBAN DISTRICT OF THE PROVINCE OF SINDH.

**Principal Investigator:** Shabina Ariff  
Pediatrics and Child Health, Aga Khan University, Stadium Road  
Karachi

### Final REC Comments:

1. What mechanism is in place to benefit the community from this study? It mentions patients to be referred to AKUH but who will pay for transport, cost of travel, consultation etc?
2. How is the study being funded and what does the budget entail?
3. There seems to be a disconnect with local authorities within Matiari and the PI's institute. How can that be bridged for benefiting the population?

### NBC-887:

Title: HYPOFERRITINEMIA WITHOUT ANEMIA AMONG REPRODUCTIVE AGE FEMALES: FREQUENCY, DETERMINANTS AND TREATMENT OUTCOMES.

**Principal Investigator:** Dr. Shehla Javed Akram, University of Lahore, Lahore, Punjab.

### Final REC Comments:

1. It is not ethical to have a placebo group with no supplementation as it is a symptomatic population with anemia in evolution.
2. The indications for oral iron and parenteral iron may be different so it would not be possible to randomize them blindly.
3. This is a clinical study, so there should be clinicians involved in monitoring of the patients. Please provide details as from where patients will be recruited and who will assume responsibility for conducting of the trial.

4. It seems wrong that the PhD student is funding this study. This should be the responsibility of the University conferring the PhD degree.

**NBC-888:**

Title: **A NON-INTERVENTIONAL, MULTICENTER, COHORT STUDY INVESTIGATING THE OUTCOMES AND SAFETY OF ATEZOLIZUMAB UNDER REAL- WORLD CONDITIONS IN PATIENTS TREATED IN ROUTINE CLINICAL PRACTICE.**

**Principal Investigator:** **Dr. Munira Moosajee**  
The Aga Khan University, Karachi, Pakistan- Stadium Road, **Karachi**  
**Dr. Umme Kalsoom Awan**  
Shaukat Khanum Memorial Cancer Hospital and Research Centre  
(SKMCH&RC), **Lahore, Pakistan**

**Final REC Comments:**

1. Project Approved

**COVID-131:**

Title: **A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE III CLINICAL TRIAL TO EVALUATE THE EFFICACY AND SAFETY OF SCTV01E (ALPHA/BETA/DELTA/OMICRON VARIANTS S-TRIMER COVID-19 VACCINE) IN POPULATION AGED ≥18 YEARS.**

**Principal Investigator:** **Prof. Dr. M. Raza Shah T.I.**  
Center for Bioequivalence studies and Clinical Research (CBSCR),  
ICCBS, **University of Karachi.**

**Final REC Comments:**

1. Site specific protocols should elaborate as to how the trial will be conducted at each study site, who is the Co-PI responsible etc?
2. MTA needs to be attached.
3. DRAP approvals (updated) to be submitted on each study site.
4. How will insurance claims be dealt with? Management of adverse events in patients?
5. Please mention composition of DSMB.
6. How many patients to be recruited from Pakistan?
7. How much of FTE (full time equivalent) will the PI invest in this project? Is it humanly possible considering his other ongoing projects?

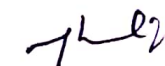
**AOB:**

- It was discussed that Clinical trials submitted for NBC approval must also be asked to submit the proof of DRAP approval of the clinical sites IRB approvals and Data Safety and Monitoring Board information.
- The NC will draft the Guidelines for DSMBs and their composition inline with international best practices for review of REC.

**Next meeting:**

The next zoom meeting will be held at 03:00 pm on January 10, 2023. The following projects will be reviewed:

1. NBC-889
2. NBC-893
3. NBC-916
4. COVID-132



**Focal person NBC**



**Chairperson REC**

## Minutes of the REC meeting held on 10-1-2023

The Research Ethics Committee (REC) zoom meeting was held on January 10, 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. Dr. Farkhanda Ghafoor	Member
5. Prof. Dr. Nazli Hossain	Member
6. Dr. Sualeha Siddiqui Sheikhani	Member
7. Prof. Marie Andraes	Member
8. Prof. Dr. Amjad Mehboob	Member
9. Dr. Nighat Murad	Focal Person NBC
10. Mr. Khalid Mehmood	Assistant (NBC-Secretariat)
11. Mr. Waryal Ali Daheri	L.D.C (NBC-Secretariat)

The following projects reviewed / discussed:

### **NBC-889:**

Title: **A QUALITATIVE ASSESSMENT OF THE IMPACT OF LAW ON ACCESS TO SAFE ABORTION SERVICES FOR WOMEN IN SINDH, PAKISTAN.**

**Principal Investigator:** Dr. Sheena Hadi, Aahung D-78, Khayaban-e-Saadi, Block -2, Clifton, Karachi.

### **Final REC Comments:**

1. Please provide more clarity as to the stakeholders being interviewed and how they will be approached.
2. The protocol needs to be revisited within our local context. Abortions are used as a means of emergency contraception/family planning services in our country so it needs to be tailored accordingly.
3. It seems that the project is more focused on the perception of our Laws rather than the laws itself which is fine but needs clarity in the protocol.

### **NBC-893:**

Title: **ENGAGING PRIVATE PROVIDERS FOR IMMUNIZATION-INTEGRATED SERVICES IN HIGH-RISK UCS OF KARACHI.**

**Principal Investigator:** Dr. Shehla Zaidi  
Ground floor – faculty offices, Ibn Ridwan Building, Aga Khan University, Stadium Road, Karachi.

### **Final REC Comments:**

Project Approved



**NBC-916:**

Title: **HOW CAN TECHNOLOGY SOLUTIONS SUPPORT PAKISTANI WOMEN TO OVERCOME BARRIERS TO ENTREPRENEURSHIP?.**

**Principal Investigator:** Elor Nkereuwem  
Johns Hopkins University School of Advanced International Studies  
1740 Massachusetts Ave., N.W., Washington, DC 20036,  
United States of America

**Final REC Comments:**

1. We are not sure as to who is the PI of said study? What is the role of Javeria Rana?
2. How will Pakistan or Pakistani society benefit from the results of this study?

**COVID-132:**

Title: **A MULTICENTER, DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED, PHASE II/III STUDY TO EVALUATE THE EFFICACY, SAFETY AND PHARMACOKINETICS OF JT001 (VV116) FOR THE EARLY TREATMENT OF CORONAVIRUS DISEASE 2019 (COVID-19) IN PARTICIPANTS WITH MILD TO MODERATE COVID-19.**

**Principal Investigator:** Dr. Ume Sughra (Country PI)  
Al-Shifa Research Centre- Al-Shifa Trust Eye Hospital, Jhelum Road,  
Rawalpindi

**Final REC Comments:**

1. The country specific documents are not found.
2. The study participants will not be paid for this trial as mentioned in ICF. Any specific reason for this strategy?
3. MTA, DSMB, Insurance related issues are not found.
4. Will study participants shall be shared with the results?
5. Who shall pay for expenses if during course of illness patient develops severe disease and requires hospital admission?
6. Types of blood tests that shall be performed must be mentioned in ICF.
7. Details how specimens shall be discarded and future use should be clearly mentioned.
8. How many subjects shall be enrolled from each trial site?
9. Are all trial sites having updated DRAP approval?
10. Are all co PI involved previously in such research projects?
11. Are vaccinated individuals being enrolled in the study?
12. Is this study looking at the new variants now emerging in China?
13. What will happen of patient's transition to moderate or severe disease?

**Next meeting:**

The next zoom meeting will be held at 03:00 pm on January 17, 2023. The following projects will be reviewed:

1. NBC-900
2. NBC-896
3. COVID-133



**Focal Person NBC**



**Chairperson REC**

## Minutes of the REC meeting held on 17-1-2023

The Research Ethics Committee (REC) zoom meeting was held on January 17, 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. Dr. Farkhanda Ghafoor         | Member                                |
| 5. Prof. Dr. Amjad Mehboob       | Member                                |
| 6. Dr. Nighat Murad              | Focal Person NBC                      |
| 7. Mrs. Tayyeba Rahat            | Statistical Officer / Co-opted Member |
| 8. Mr. Khalid Mehmood            | Assistant (NBC-Secretariat)           |
| 9. Mr. Waryal Ali Daheri         | L.D.C (NBC-Secretariat)               |

The following members regret to attend the meeting:

- |                                   |                      |
|-----------------------------------|----------------------|
| 1. Dr. Sualeha Siddiqui Sheikhani | Member               |
| 2. Prof. Marie Andraes            | Member               |
| 3. Dr. Faiza Bashir               | National Coordinator |

The following projects reviewed / discussed:

### NBC-896:

Title: **A PHASE 3, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO EVALUATE THE EFFECT OF BI-26 (STRAIN OF BIFIDOBACTERIUM LONGUM, B. INFANTIS) SUPPLEMENTATION VERSUS PLACEBO ON WEIGHT GAIN IN UNDERWEIGHT INFANTS.**

**Principal Investigator:** Dr. Major Gen Aamer Ikram (Country PI)  
National Institute of Health - National Institutes of Health (NIH)  
Park Road, Chak Shahzad, Islamabad, Pakistan

### Final REC Comments:

1. Do all study sites have updated DRAP approval for conducting this study?
2. There is no MTA.
3. Informed consent form could not be found.
4. What benefit will be available to the Pakistani population if this product is found to be effective?
5. The storage of this product to maintain the cold chain will be problematic in a hot country like Pakistan with frequent power outages.
6. How will the Al shifa eye hospital recruit pediatric patients for this?

### NBC-900:

Title: **NIHR GLOBAL HEALTH GROUP ON EQUITABLE ACCESS TO QUALITY HEALTH CARE FOR INJURED PEOPLE IN FOUR LOW- OR MIDDLE-INCOME COUNTRIES: EQUI-INJURY.**

**Principal Investigator:** Dr Junaid Razzak  
Aga Khan University, Karachi, Pakistan, National Stadium Road,  
P.O. Box 3500, Karachi.

### Final REC Comments:

Project Approved

**COVID-133:**

Title: **A PHASE 3 RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO EVALUATE THE EFFICACY AND SAFETY OF BEMNIFOSBUVIR IN HIGH-RISK OUTPATIENTS WITH COVID-19. [AT-03A-017].**

**Principal Investigator:** **Dr. Nida Hussain (Lead Country PI)**  
Ziauddin University-4/B, Shahrah-e-Ghalib Rd, Block 6 Clifton,  
**Karachi**

**Final REC Comments:**

1. Any particular reason for choosing Pakistan as a study site? Are any other developing countries involved?
2. We are jittery to approve a trial on high-risk patients with a placebo drug. In such a patient one would include antivirals as a standard of care. How would the study team take this into account?
3. How will the Pakistani population benefit from this research?
4. How will adverse events be taken care of and by whom? Please mention people responsible in each trial site.
5. MTA is not attached.
6. Details about DSMB needs to be given.

**Next meeting:**

The next zoom meeting will be held at 03:00 pm on January 31, 2023. The following projects will be reviewed:

1. NBC-905
2. NBC-908
3. NBC-910
4. COVID-134



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**Focal person NBC**



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**Chairperson REC**

## Minutes of the REC meeting held on 31-1-2023

The Research Ethics Committee (REC) zoom meeting was held on January 31, 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. Saqib Mehmood	Member
5. Prof. Marie Andraes	Member
6. Prof. Dr. Amjad Mehboob	Member
7. Dr. Sualeha Siddiqui Shekhani	Member
8. Dr. Farkhanda Ghafoor	Member
9. Dr. Faiza Bashir	National Coordinator
10. Mr. Khalid Mehmood	Assistant (NBC-Secretariat)
11. Mr. Waryal Ali Daheri	L.D.C (NBC-Secretariat)

The following projects reviewed / discussed:

### **NBC-905:**

Title: **Culturally Adapted Psychosocial Interventions for Early Psychosis in A Low-Resource Setting: A Large Multi-Center RCT.**

**Principal Investigator:** **Muhammad Omair Husain**  
Centre for Addiction and Mental Health (CAMH), 100 Stokes Street,  
Toronto, ON, Canada.

### **Final REC Comments:**

1. A similar project was conducted by PILL earlier. Please share the outcome of that.
2. Please provide CV of PI.
3. Please provide details of various sites and co-investigators involved.
4. What clinical end points are the investigators looking at to see an improvement in psychosis?

### **NBC-908:**

Title: **Clinical Characterisation Protocol for Severe and Emerging Respiratory Infections- Pakistan.**

**Principal Investigator:** **Prof.Dr. Madiha Hashmi**  
South East Asian Research & Education in Critical care Health  
(SEARCH), 199-E, Street No 6, Cavalry Grounds  
Lahore Cantt

### **Final REC Comments:**

1. Where will lab investigations and genetic studies be conducted? if being sent abroad an MTA is required.
2. Is there a linkup with IDSR (Infectious Disease Surveillance and Response) team or any govt. team?
3. What is the capacity of lab facilities in proposed sites so that common organisms are not missed?



## **NBC-910:**

**Title:** **A Phase II, Randomized, Observer-blinded, Placebo Controlled Trial to Evaluate the Safety and Immunogenicity of Hecolin® in Healthy Pregnant Women between Gestational Age 14-34 weeks and Non-Pregnant Women of 16-45 years old.**

**Principal Investigator:** **Dr. Muhmmad Imran Nisar,**  
Department of Pediatrics and Child Health, The Aga Khan University,  
Stadium Road, **Karachi 73500**

### **Final REC Comments:**

1. Why are study subject being recruited from the community when they can be recruited from AKUH and its offsite clinics?
2. As this is a Phase 2 trial, there is no need to venture into the community.
3. Who are the obstetricians involved in the study?
4. We could not find the Informed Consent Form.
5. AKUH ERC approval was missing.
6. How much compensation is being provided to the participants? Who is paying for tests and ultrasounds?
7. Questions related to whether it is an unwanted pregnancy, history of rape and plans for giving child up for adoption are not culturally relevant to this study.
8. Urdu translation has been taken from Google which makes no sense. Route of administration has been literally translated as "intizaamiya"
9. Will Pakistan have any post-trial benefits?
10. How much blood is being drawn from the newborn? It mentions 30+ ml...Is this all at once?

## **COVID-134:**

**Title:** **A Randomized, Double-blind, Physiological Saline - controlled Clinical Study to Evaluate the Efficacy, Safety, and Immunogenicity of SARS CoV-2 Variant (BA.4/5) mRNA Vaccine (ABO1020) in Healthy Subjects Aged 18 Years and Older Who Have Completed the Full Vaccination Protocol No.: ABO1020-301.**

**Principal Investigator:** **Maj. Gen Prof. Dr. Aamer Ikram SI(M)**  
National Institute of Health (NIH) Park Road, Chak Shahzad,  
**Islamabad, Pakistan**

### **Final REC Comments:**

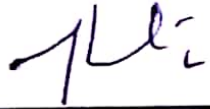
1. The project write-up needs to be improved upon.
2. We are not sure if this is a Phase 2 study or a Phase 3 study and interchangeable terms are used in different parts of the document.
3. The methodology needs clarity....How will the study participants be captured and recruited?
4. The Informed consent form needs to be simplified. It is too long for a layperson to read and comprehend. Please do not use harsh terms in the form...e.g. you will not be punished for so and so....
5. Where will samples be tested? Is there a central lab abroad? If so, MTA will be required.
6. Why are placebo participants receiving 35,000/- PKR??
7. It mentions that non-pregnant women will be recruited. Will pregnancy test be conducted on all women? How will the PI ensure that women do not become pregnant during the study? Will contraceptive advice be given??
8. Why are study participants being referred to a local health facility for treating complications whereas all sites are hospitals themselves?
9. ERC approvals from local sites is required.



**Next meeting:**

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

1. NBC-912
2. NBC-913
3. NBC-914
4. COVID-135



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**Focal person NBC**



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**Chairperson REC**

## 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

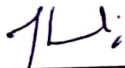
**Final REC Comments:**

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**

## 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.

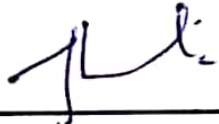
### Final REC Comments:

1. How have the sites been chosen? Do they adequately represent Pakistan? Only Sindh 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



**Focal person NBC**



**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.**

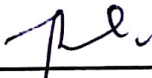
**Final REC Comments:**

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**



## Minutes of the REC meeting held on 7-4-2023

The Research Ethics Committee (REC) zoom meeting was held on April 4, 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-946:**

Title: **TENDENCY (The Fatty Liver, Cirrhosis an Liver Cancer Study).**

**Principal Investigator:** **Dr. Ahmad Karima Malik**  
Department of hepatology, Pakistan Kidney and Liver Institute and  
Research Centre. PKLI Avenue, DHA Phase 6  
**Lahore**

### **Final REC Comments:**

1. It is unclear why controls are being recruited from the UK and not from Pakistan. This makes no sense for a case-control study which should be matched by age, gender and ethnicity.
2. MTA needs to be attached.
3. What does self-funded (PKR 19,000/-) mean in the budget?
4. The informed consent form should provide more details about privacy and confidentiality of data.
5. What is the role of the local PI in terms of intellectual input?

### **COVID-136:**

Title: **A Randomized, Blind, Active-controlled Phase I/II/III study to Investigate the Safety and Immunogenicity of Bivalent mRNA vaccine (RBMRNA-909) as a Booster dose in COVID-19 vaccine-experienced Healthy Adults.**

**Principal Investigator:** **Prof. Dr. M. Raza Shah T.I.**  
Center for Bioequivalence studies and Clinical Research (CBSCR),  
ICCBS, University of Karachi,  
**Karachi.**

### **Final REC Comments:**

1. We need complete documentation of the Co-PIs from other sites along with IRB approval letters.
2. What biospecimens and/or genetic material is being collected? It was not clear in the proposal. If samples are being sent abroad then MTA needs to be attached.
3. How is Dr. Iqbal Afridi, a psychiatrist involved in a vaccine trial? Has he such experience before?
4. Please provide constitution of the DSMB.
5. The current project cannot be approved with all three phases. We recommend that PI starts with Phase 1 trial and present the findings before moving onto Phase 2 and 3.

**Next meeting:**

The next zoom meeting will be held at 02:30 pm on May 2, 2023. The following projects will be reviewed:

1. NBC-932
2. NBC-934
3. NBC-936
4. NBC-938
5. NBC-939
6. NBC-940



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**Focal person NBC**



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**Chairperson REC**

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

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

- |                                  |                              |
|----------------------------------|------------------------------|
| 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 9<sup>th</sup>, 2023. The following projects will be reviewed:

1. NBC-941
2. NBC-942

  
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**Focal person NBC**

  
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**Chairperson REC**

## Minutes of the NBC-R meeting held on 06-06-2023

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on June 6<sup>th</sup>, 2023. The following members of NBC-R 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. Saqib Mehmood	Member
5. Associate Prof. Amjad Mehboob	Member
6. Ms. Sualeha Shekhani	Member
7. Dr. Farkhanda Ghafoor	Member
8. Dr. Faiza Bashir	National Coordinator (NBC-R)
9. Ms. Ayesha Abid	Assistant (NBC-R-Secretariat)

**The following projects reviewed / discussed:**

Title: **PLASMA METAGENOMICS.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBC-954</b>	<p><b>Dr. Imran Nisar</b> The Aga Khan University Hospital, Stadium Road, Karachi.</p>	<ul style="list-style-type: none"> <li>Study duration is mentioned as July 2022....This means the study has already begun?</li> <li>We could not understand the implication of this research with vaccine development? You are testing a genomic method with standard of care (blood culture) to see the response to early diagnosis and management of sepsis. Where does a vaccine come in?</li> <li>There is an impressive budget but what will the participants gain out of it?</li> <li>Will any samples be sent abroad? Please attach MTA if so.</li> <li>What other tests will be done on the samples?</li> <li>Are there any post trial benefits for our population?</li> <li>We would like to see approval from AKUH ERC.</li> </ul>

Title: **BUILDING A QUALITATIVE UNDERSTANDING OF TRUST IN HPV VACCINE PROGRAMMES AMONG COMMUNITIES.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBC-961</b>	<p><b>Charlotte Vangsgaard</b> ReD Associates Kronprinsessegade 20, 2, 1306 Copenhagen, Denmark</p>	<ul style="list-style-type: none"> <li>We were not clear about the methodology of doing this study? Kindly elaborate as to how the data will be collected and by whom? How will 3500 people be contacted in the communities?</li> <li>The informed consent form needs to be revised. It does not state clearly the intent of this being research and its utility for participant involvement.</li> <li>This is a health research but a company involved in marketing is carrying out the study? Is this not an inherent bias and likely to affect the results? How will this bias be accounted for?</li> <li>Is there an involvement of govt. health agencies as they are the major stakeholders for ensuring implementation of EPI programs in the provinces? It mentions letters of intent but have they been taken on board and is there any proof of this?</li> </ul>

		<ul style="list-style-type: none"> <li>• Why is upper arm circumference being measured? Is there another study embedded to check nutritional status?</li> <li>• Why are only girls being involved in this research whereas adolescent boys should also be at the receiving end of HPV vaccines? This is likely to create confusion and hesitancy within our context. On the other hand whereas polio eradication has been a major problem in our country we are skeptical as whether HPV vaccination will have the same effects in terms of acceptance or hesitancy.</li> </ul>
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Title: **PRIORITIZING INTERSECTORAL ACTIONS FOR HEALTH AND WELL-BEING: DEVELOPING A SYSTEMATIC APPROACH.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-963	Dr. Wafa Aftab Institute of Global Public Health and Primary Care, University of Bergen, Overlege Danielsens Hus, Årstadveien 21, 5009, Bergen, Norway.	<ul style="list-style-type: none"> <li>• Project Approved.</li> </ul>

**Next meeting:**

The next zoom meeting will be held at 02:30 pm on June 13<sup>th</sup>, 2023. The following projects will be reviewed:

**Projects will be discussed.**

1. NBC-954
2. NBC-961
3. NBC-963



**Focal person NBC-R**



**Chairperson NBC-R**

## Minutes of the REC meeting held on 13-06-2023

The Research Ethics Committee (REC) zoom meeting was held on June 13<sup>th</sup>, 2023. The following members of REC attended the meeting:

1. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2. Dr. Farkhanda Ghafoor	Member
3. Prof. Dr. Amjad Mehboob	Member
4. Dr. Munir A. Saleemi	Member
5. Prof. Dr. Saqib Mehmood	Member
6. Dr. Jamshed Akhtar	Member
7. Dr. Marie Andrades	Member
8. Dr. Faiza Bashir	National Coordinator (NBC-R)
9. Ms. Ayesha Abid	Assistant (NBC-R Secretariat)

The following projects were reviewed / discussed:

### **NBC-956:**

**Title: Prevention of Iron Deficiency Anaemia Post-delivery (PRIORITY Trial)**

**Principal Investigator:**

**Dr. Saleem Jessani**  
Department of Community Health Sciences,  
Aga Khan University Stadium Road, P.O. Box 3500,  
**Karachi.**

**Final REC Comments:**

- We would like to ERC approvals from AKUH and JPMC.
- How is the partnering public sector organization benefitting from this trial?
- What formulation of iron is being used?
- Please provide details. How will adverse events be managed and by whom?
- Is any indemnity insurance being provided to participants?
- Is there a DSMB formed to assess for these adverse events?
- Please provide details are there any monetary benefit for trial participants, like travel, daily allowance etc.?

### **NBC-958:**

**Title: Implementation research on postpartum IV iron in Global Network sites, A Prevention of Iron Deficiency Anemia Post-delivery (PRIORITY) sub-study**

**Principal Investigator:**

**Dr Narjis Rizvi**  
Department of Community Health Sciences,  
Aga Khan University National Stadium Road  
**Karachi**

**Final REC Comments:**

- **This study can only be approved after we give approval for NBC 956.**




**NBC-959:**

**Title: Exploration of Early Childhood Development (ECD) Practices in District Ghizer through Human-Centered Design (HCD).**

**Principal Investigator: Dr. Seema Lasi**  
Department of Human Development Program  
Aga Khan University  
**Karachi.**

**Final REC Comments:**

- **Study Approved.**



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**Focal person NBC**



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**Chairperson REC**

## Minutes of the REC meeting held on 20-06-2023

The Research Ethics Committee (REC) zoom meeting was held on June 20<sup>th</sup>, 2023. The following members of REC attended the meeting:

1. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2. Dr. Farkhanda Ghafoor	Member
3. Prof. Dr. Amjad Mehboob	Member
4. Dr. Munir A. Saleemi	Member
5. Dr. Jamshed Akhtar	Member
6. Dr. Marie Andrades	Member
7. Ms. Sualeha Siddique Shekhani	Member
8. Dr. Faiza Bashir	National Coordinator NBC-R
9. Ms. Ayesha Abid	Assistant (NBC-R Secretariat)

The following projects were reviewed / discussed:

### **NBC-960:**

Title: **Correlation of HIV-1 subtype diversity in Pakistani epidemic with drug resistance mutations.**

#### **Principal Investigator:**

**Dr. Syed Faisal Mahmood**  
Aga Khan University  
Stadium Road, Karachi-74800,  
**Pakistan.**

#### **Final REC Comments:**

- We would like to see the complete list of Co-PIs and their CVs.
- Please send IRB approval letters from all centers involved.
- Who is taking responsibility of the HIV centers in Larkana?
- If children are included in the study, then assent form will be required.
- Samples are being sent abroad for which an MTA needs to be attached.
- If drug resistance is detected in a patient, how will he or the treating physician be informed?
- Is our National AIDS control program on board with this study as its results will affect our guidelines for treating Pakistani patients with HIV?

### **NBC-962:**

Title: **Redefining Maternal Anemia in Pregnancy and Postpartum (ReMAPP): A multicenter, international, population-based study to establish global hemoglobin thresholds for maternal anemia**

#### **Principal Investigator:**

**Dr. Imran Nisar**  
Department of Paediatrics and Child Health,  
Aga Khan University (AKU),  
Stadium Road, Karachi,  
**Pakistan.**

#### **Final REC Comments:**

- Why is the population of Ibrahim Hyderi and Rehri Goth being involved in this study whereas maternal anemia would also be prevalent in the parent institute?

- Moreover, the vulnerable and over-researched population mentioned would not be representative of the entire country.
- Why is depression being assessed whereas the idea is to recruit healthy pregnant women.
- What is the role of Vital Pakistan Trust in this study?
- MTA was not attached.

**NBC-965:**

**Title: An Evaluation Of Costs Borne By Tb-Affected Households In Pakistan: Study Protocol**

**Principal Investigator:**

**Dr Razia Fatima**

Research Unit, Block F, EPI Building,

Near National Institute Of Health (NIH)

(Prime Minister's National Health Complex), Park Road, Islamabad,

**Pakistan**

**Final REC Comments:**

- We would like to know the funding source of this study.



**Focal person NBC-R**



**Chairperson NBC-R**

## Minutes of the NBC-R meeting held on 04-07-2023

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on July 4, 2023. The following members of NBC-R 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. Saqib Mehmood	Member
5. Prof. Dr. Marie Andrades	Member
6. Associate Prof. Dr. Amjad Mehboob	Member
7. Ms. Sualeha Shekhani	Member
8. Dr. Farkhanda Ghafoor	Member
9. Dr. Faiza Bashir	National Coordinator (NBC-R)
10. Ms Ayesha Abid	Assistant (NBC-R-Secretariat)

### The following projects reviewed / discussed:

Title: **INVESTIGATING THE INSIGHT AND PERSPECTIVES OF PHYSICAL THERAPISTS AT DISTRICT LEVEL REGARDING THE CURRENT PERFORMANCE AND CAPACITY OF THE WORKFORCE FOR REHABILITATION AND FUTURE OPPORTUNITIES IN KHYBER-PAKHTUNKHWA (KP) AND SINDH PROVINCES IN PAKISTAN.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBC-966</b>	<p><b>Prof. Dr. Haider Darain, PhD (UK), MSc (Pak), BSPT (Pak), CHPE</b>                      Dean Faculty of Allied Health Sciences,                      Professor Physical Therapy, Institute of Physical Medicine and Rehabilitation, KMU, Peshawar</p>	<ul style="list-style-type: none"> <li>We were unsure as to what are the ground realities faced by Physical Therapists in KPK and Sindh. Has the PI done some ground work as to where these professionals are housed and what are their current job descriptions? This would give clarity as to what the objectives of this study are.</li> <li>Who is the co-PI in Sindh? Please submit CVs of PI and co-PIs. Are they experienced in doing qualitative research? What is the role of Dr. Zia who is probably the VC?</li> <li>Why is this study being done in Uganda?</li> <li>Urdu format is difficult to read. Is it required for Physiotherapists who would be able to understand English (or so we presume).</li> </ul>

Title: **THE EFFECIEY AND SAFTEY OF DAPAGLIFLOZIN VS SITAGLIPTIN IN THE PATIENTS WITH UNCONTROLLABLE TYPE-2 DAIBETIES-A QUASI-EXPERIMENTAL STUDY.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBC-968</b>	<p><b>Dr. Ayesha Waqar Niazi</b>                      Islamabad Medical Complex                      Islamabad</p>	<ul style="list-style-type: none"> <li>The rationale is weak as both drugs are included in standard of care of uncontrolled DM.</li> <li>What are the inclusion/exclusion criteria for enrolment?</li> <li>Study design is flawed and sampling not mentioned.</li> <li>What is the interest of the hospital to fund this study?</li> <li>How will bias be controlled?</li> </ul>



Title: **FEASIBILITY AND ACCEPTABILITY OF EYE MOVEMENT DESENSITIZATION & REPROCESSING (EMDR) FOR MANAGEMENT OF SUBSTANCE USE DISORDERS (SUD).**

Project #	PI Name & Address	Final NBC-R Comments
NBC-969	Prof Nasim Chaudhry Pakistan Institute of Living & Learning (PILL), Suite No. 201, 2nd Floor, The Plaza, Karachi	<ul style="list-style-type: none"><li>Please ask PI to give more details about the co-PIs who will be assisting this study. We would also like to see information leaflet regarding the study.</li></ul>

**Next meeting:**

The next zoom meeting will be held at 02:30 pm on July 18, 2023. The following projects will be reviewed:

**Projects will be discussed.**

1. NBC-970
2. NBC-972
3. NBC-973



**Focal person NBC-R**



**Chairperson NBC-R**

## Minutes of the REC meeting held on 18-07-2023

The Research Ethics Committee (REC) zoom meeting was held on July 18<sup>th</sup>, 2023. The following members of REC attended the meeting:

1. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2. Dr. Farkhanda Ghafoor	Member
3. Prof. Dr. Amjad Mehboob	Member
4. Dr. Munir A. Saleemi	Member
5. Prof. Dr. Saqib Mehmood	Member
6. Dr. Jamshed Akhtar	Member
7. Dr. Marie Andrades	Member
8. Ms. Sualeha Siddique Shekhani	Member
9. Dr. Faiza Bashir	National Coordinator (NBC-R)
10. Ms. Ayesha Abid	Assistant (NBC-R Secretariat)

The following projects were reviewed / discussed:

### **NBC-970:**

**Title: Patient and caregiver experience of bipolar disorder in Pakistan**

**Principal Investigator:**

- 1. Dr. Madeha Umer**  
University of Toronto 27 King's College Circle  
Toronto, Ontario M5S 1A1 **Canada.**

**Final REC Comments:**

- The current study seems to be linked to a previous study of PILL on the same topic. Has that been published and what were the results that led to development of this study?
- Please explain in detail your participant recruitment strategy. Who are the relevant communities involved?
- The questionnaires of patient and caregivers seem to be the same whereas their context would be different.
- The Urdu translation needs to be looked at again.
- Who are collaborators from Punjab?
- It mentions Drs. Kinza and Saima. What are their qualifications and roles in this study?

### **NBC-972:**

**Title: Evaluating pneumococcal carriage and changes in serotype distribution after a switch from PCV10 to PCV13 in children in a rural site in Matiari, Pakistan from 2023-2025.**

**Principal Investigator:**

**Muhammad Imran Nisar**  
Aga Khan University, **Karachi**

**Final REC Comments:**

- Why is Matiari a study site and not the main hospital in Karachi?
- Is there a link with a local hospital in Matiari where subjects can receive care in case of any adverse events?
- Is the Sindh Health Dept. or Ministry of Health on board with this study?
- The results would impact our national immunization program.
- Budget clarification is required.
- What is the role of or agreement with Pfizer in this study?
- Will they have claims to the data as they are manufacturers of Pneumococcal vaccine?
- The consent form is quite vague. It should mention if genetic samples are being stored or sent abroad.


**NBC-973:**

**Title: Tobacco control policies and the health of Adolescents in Pakistan (TAP).**

**Principal Investigator: Dr Amina Khan**  
Executive Director Public Health Consultant,  
The Initiative Orange Grove Farm, Banigala,  
**Islamabad.**

**Final REC Comments:**

- **Project Approved.**

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**Focal person NBC**

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**Chairperson REC**

## Minutes of the NBC-R meeting held on 1-8-2023

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on August 1<sup>st</sup>, 2023. The following members of NBC-R 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. Nazli Hossain	Member
5. Associate Prof. Dr. Amjad Mehboob	Member
6. Ms. Sualeha Shekhani	Member
7. Dr. Farkhanda Ghafoor	Member
8. Dr. Faiza Bashir	National Coordinator (NBC-R)
9. Ms. Ayesha Abid	Assistant (NBC-R-Secretariat)

### The following projects reviewed / discussed:

Title: **CLINIC-BASED SURVEY OF ACQUIRED HIV DRUG RESISTANCE IN PAKISTAN, 2023.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBC-974</b>	<b>Dr. Faisal Mahmood,</b> Dept of Medicine, AKU, Karachi, Pakistan.	<ul style="list-style-type: none"> <li>We would like to see the MTA.</li> <li>AKUH ERC approval was not attached.</li> <li>How will treatment for resistant cases be coordinated throughout the country at different sites?</li> </ul>

Title: **HIV SECOND GENERATION SURVEILLANCE IN PAKISTAN-ROUND 6.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBC-975</b>	<b>Dr. Shahzad Ali Khan</b> Health Services Academy, Chak Shahzad, Islamabad	<ul style="list-style-type: none"> <li>Can we have information as to the results of previous rounds? What has been achieved till now and how will Round 6 be different?</li> <li>What will happen to patients who test positive? How will their treatment be coordinated?</li> <li>MTA needs to be attached.</li> <li>Consent form needs to be more elaborate for patients to comprehend what they are signing up for. It mentions taking 10 minutes of time but they questions are way more and it will take longer.</li> <li>How will patients and their families be educated, treated and rehabilitated in this study?</li> <li>What will stored samples be used for and how long will they be stored?</li> </ul>

Title: **ACCEPTABILITY AND SCALABILITY CHARACTERISTICS OF AN APP DESIGNED TO TRIAGE NCD RISK BY LHWS IN PAKISTAN – A MIXED METHOD PILOT STUDY.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBC-976</b>	<b>Dr. Zeerak</b> Aga Khan University, Stadium Road, Karachi	<ul style="list-style-type: none"> <li>Project Approved</li> </ul>



**Next meeting:**

The next zoom meeting will be held at 02:30 pm on 8<sup>th</sup> August, 2023. The following projects will be reviewed:

**Projects will be discussed.**

1. NBC-977
2. NBC-978
3. NBC-979



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**Focal person NBC-R**



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**Chairperson NBC-R**

## Minutes of the NBC-R meeting held on 8-8-2023

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on August 8<sup>th</sup>, 2023. The following members of NBC-R 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. Associate Prof. Dr. Amjad Mehboob	Member
6. Ms. Sualeha Shekhani	Member
7. Dr. Farkhanda Ghafoor	Member
8. Dr. Faiza Bashir	National Coordinator (NBC-R)
9. Ms. Ayesha Abid	Assistant NBC-R Secretariat

**The following projects reviewed / discussed:**

Title: **MEM VEDANTA DAC TRIAL PLANNING GRANT.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-977	<b>Dr. Fyezah Jehan</b> Dept of Paediatrics and Child Health AKU, Karachi	<ul style="list-style-type: none"> <li>• Project Approved.</li> </ul>

Title: **A PHASE 2, OPEN-LABEL STUDY TO ASSESS THE SAFETY AND EFFICACY OF BEMNIFOSBUVIR (BEM) AND RUZASVIR (RZR) IN SUBJECTS WITH CHRONIC HEPATITIS C VIRUS (HCV) INFECTION.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-978	<b>Dr. Saeed Hamid</b> Department of Medicine AKU, Karachi	<ul style="list-style-type: none"> <li>• Project Approved.</li> </ul>

Title: **ACCEPTABILITY AND SCALABILITY CHARACTERISTICS OF AN APP DESIGNED TO TRIAGE NCD RISK BY LHWS IN PAKISTAN – A MIXED METHOD PILOT STUDY.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-979	<b>Dr. Mehreen Zaigham</b> Harvard Medical School, Boston, USA and Lund University, Lund, Sweden.	<ul style="list-style-type: none"> <li>• The rationale of this project needs strengthening. If C-section is being carried out in Pakistan then it is standard practice to monitor them after surgery. Is the PI checking the device and comparing it to monitoring by a nurse? Then why can this study not be done in parent institute of the PI or her home country?</li> <li>• Is there any potential conflict of interest? Will this device be commercialized if found useful?</li> <li>• Will the device be available for the Pakistani population if found successful? How will our country/population benefit from this research?</li> <li>• Please re-look at references...most are more than 5 years old. Please give latest information.</li> </ul>

**Next meeting:**

The next zoom meeting will be held at 02:30 pm on 15<sup>th</sup> August, 2023. The following projects will be reviewed:

**Projects will be discussed.**

1. NBC-980
2. NBC-981
3. NBC-982



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**Focal person NBC-R**



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**Chairperson NBC-R**

## Minutes of the NBC-R meeting held on 15-8-2023

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on August 15<sup>th</sup>, 2023. The following members of NBC-R attended the meeting:

1. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2. Prof. Dr. Munir Saleemi	Member
3. Prof. Dr. Jamshed Akhtar	Member
4. Associate Prof. Dr. Amjad Mehboob	Member
5. Ms. Sualeha Shekhani	Member
6. Dr. Farkhanda Ghafoor	Member
7. Dr. Faiza Bashir	National Coordinator (NBC-R)
8. Ms. Ayesha Abid	Assistant (NBC-R-Secretariat)

**The following projects reviewed / discussed:**

Title: **INVESTIGATING EARLY PERIPHERAL MIRNA BIOMARKERS FOR INTRAUTERINE GROWTH RESTRICTION (IUGR) DUE TO FETAL HYPOXIA IN A COHORT OF PREGNANT WOMEN ADMITTED TO THE AGA KHAN UNIVERSITY HOSPITAL, KARACHI, PAKISTAN.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-980	<b>Dr. Waqasuddin Khan</b> Aga Khan University Karachi	<ul style="list-style-type: none"> <li>Please clarify who are the control groups as we were uncertain on that account. Are they normal pregnant women with healthy fetuses or is the control group pregnant women with IUGR NOT due to hypoxia?? How will consent be taken from this control group?</li> <li>We felt giving 15 minutes to these women for consent may be too less and may put an added burden on them to say yes. Let us know your reasoning behind this. Perhaps we may have misunderstood.</li> </ul>

Title: **BARREIRS AND FACILITIES FOR IMPLEMENTING A SMART-PHONE BOARD TELECOMUNICATION PROGRAM (RAABTA) TO SUPPORT PREGNANT WOMEN RISK FOR PREECLAMPSIA IN A HOSPITAL SETTING QUALITATIVE STUDY.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-981	<b>Dr Emily Seto</b> Institute of Health Policy, Management and Evaluation, University of Toronto Health Sciences Building, 155 College Street, Suite 425, Toronto, ON M5T 3M	<ul style="list-style-type: none"> <li>We suggest the PI to get institutional approval from all the institutions involved before applying to NBC.</li> <li>We were unclear as to who is the PI and Co-PIs.</li> <li>We are also not clear about who/ which institute owns the RAABTA application?</li> <li>Is there a budget document?</li> </ul>

Title: **EFFECTS OF ERTUGLIFOZIN ON LIVER FAT, LIVER FIBROSIS & GLYCEMIC CONTROL IN SUBJECTS WITH TYPE 2 DIABETES MELLITUS (T2DM) & NON-ALCOHOLIC FATTY LIVER DISEASE / NON-ALCOHOLIC STEATOHEPATITIS.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-982	<b>Dr. Umar Yousuf Raja</b> Shifa International Hospital 3rd Road, G- 10/4, Islamabad	<ul style="list-style-type: none"> <li>Will the PIs have a competing interest considering that this study is being funded by the Pharmaceutical company? What is there to stop the investigators from prescribing this drug to patients?</li> <li>Several different centers are mentioned ....are they all</li> </ul>

		<p>affiliated with the institutions that have given IRB approval? Please mention these affiliations.</p> <ul style="list-style-type: none"><li>• Will study participants be provided the drug free of cost? What form of compensation will they be given to cover costs of travel, appointments, lab investigations etc?</li><li>• How long will the study last as this is a Phase IV trial?</li></ul>
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**Next meeting:**

The next zoom meeting will be held at 02:30 pm on 29<sup>th</sup> August, 2023. The following projects will be reviewed:

**Projects will be discussed.**

1. NBC-983
2. NBC-984
3. NBC-985



**Focal person NBC-R**



**Chairperson NBC-R**



## Minutes of the NBC-R meeting held on 29-8-2023

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on August 29<sup>th</sup>, 2023. The following members of NBC-R 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. Nazli Hossain	Member
5. Ms. Sualeha Shekhani	Member
6. Dr. Farkhanda Ghafoor	Member
7. Dr. Faiza Bashir	National Coordinator (NBC-R)
8. Ms. Ayesha Abid	Assistant (NBC-R-Secretariat)
9. Waryal Ali Daheri	LDC (NBC-R-Secretariat)

**The following projects reviewed / discussed:**

Title: **A MULTICENTER, RANDOMIZED, CONTROLLED, OPEN-LABEL, PHASE IIB STUDY TO ASSESS EFFICACY AND SAFETY OF HH-003 INJECTION IN SUBJECTS WITH CHRONIC HEPATITIS DELTA VIRUS INFECTION.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBC-983</b>	<b>Dr. Saeed Hamid</b> Aga Khan University, Karachi <b>Dr. Zaigham Abbas</b> Ziauddin University Hospital, 4/B Shahrah-e- Ghalib Rd, Block 6 Clifton, Karachi <b>Dr. Syed Nayab                      Haider</b> The Central Park Teaching Hospital, 31- KM, Ferozpur Road, Lahore.	<ul style="list-style-type: none"> <li>• Project Approved.</li> </ul>

Title: **THIRD-PARTY ASSESSMENT OF EPI COVERAGE IN LAHORE.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBC-984</b>	<b>Mr. Imtiaz Hussain</b> Centre of Excellence in Women and Child Health, The Aga Khan University, Karachi.	<ul style="list-style-type: none"> <li>• Project Approved.</li> </ul>

Title: **SOCIAL MEDIA CAMPAIGN TARGETING BURN-RELATED STIGMA, PREVENTION, AND RISK ASSESSMENT AMONG COMMUNITIES, WORKPLACES, AND INDUSTRIES BASED ON PHOTOVOICE.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBC-985</b>	<b>Prof Nasim Chaudhry</b> Pakistan Institute of Living & Learning (PILL), Suite No. 201, 2nd Floor, The Plaza, Karachi	<ul style="list-style-type: none"> <li>• We would like to see IRB approvals from the centers collaborating with PILL on this project.</li> </ul>

**Next meeting:**

The next zoom meeting will be held at 02:30 pm on 5<sup>th</sup> September, 2023. The following projects will be reviewed:

**Projects will be discussed.**

1. NBC-986
2. NBC-987
3. NBC-988



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**Focal person NBC-R**



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**Chairperson NBC-R**

## Minutes of the NBC-R meeting held on 05-09-2023

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on September 5<sup>th</sup>, 2023. The following members of NBC-R attended the meeting:

1. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2. Prof. Dr. Muneer Akhtar Saleemi	Member
3. Prof. Dr. Jamshed Akhtar	Member
4. Dr. Farkhanda Ghafoor	Member
5. Prof. Marie Andraes	Member
6. Prof. Dr. Saqib Mehmood	Member
7. Prof. Dr. Amjad Mehboob	Member
8. Mrs. Sualeha Siddiqui Shekhani	Member
9. Mr. Waryal Ali Daheri	L.D.C (NBC-R-Secretariat)

The following projects reviewed / discussed:

### **NBC-986:**

Title: **Implementation Adaptation and Effectiveness of Early Childhood Newborn Parenting Education Program at Primary Health Care Facilities of Pakistan and Afghanistan: A Feasibility Study.**

**Principal Investigator:**

**Dr. Shelina Bhamani**

Department of Obstetrics and Gynaecology, Aga Khan University,  
**Karachi**

### **Final NBC-R Comments:**

- **Project Approved**

### **NBC-R-987:**

Title: **PLHIV Stigma Index Study 2.0.**

**Principal Investigator:**

**Dr. M. Usman Ali Awan**

United Nations Development Program (UNDP), 5th Floor Serena  
Business Complex, **Islamabad**

### **Final NBC-R Comments:**

- We would like to see the CV of the PI. Does he have the relevant background to do this type of sensitive research?
- There are around 200 questions to be asked so it will take longer to fill the questionnaire than mentioned.
- Please identify the centers where participants will be interviewed. Do all centers have the relevant infrastructure to maintain privacy.
- Please mention in informed consent form the amount to be disbursed/compensated.
- There are several typo errors in Urdu questionnaire. Please revisit.

**NBC-988:**

Title: **A multicenter, open-label, randomized, phase III clinical trial to evaluate efficacy and safety of PF-114 versus imatinib at 600 or 800 mg daily in adult patients with Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) in the chronic phase (CP) resistant to imatinib at daily doses of 400 or 600 mg.**

**Principal Investigator:** Dr. Asad Latif  
Department of Anaesthesiology, The Aga Khan University Stadium  
Road, P.O Box 3500 **Karachi.**

**Final REC Comments:**

- Project Approved

**NBC-943:**

Title: **Global genomics surveillance of Pneumococcus Consortium (GPS2).**

**Principal Investigator:**  
**Dr Anna Qamar Uz Zaman**  
Zia Uddin University Hospital, Plot 5, Block III, Gol Market, Nazimabad,  
**Karachi.**

**Final REC Comments:**

- We would like to see the approval letter from Ziauddin University Hospital before giving NBC approval.

**Next meeting:**

The next zoom meeting will be held at 02:30 pm on September 12<sup>th</sup>, 2023. The following projects will be reviewed:

1. NBC-989
2. NBC-990
3. NBC-991



**Focal person NBC-R**



**Chairperson NBC-R**

## Minutes of the NBC-R meeting held on 12-09-2023

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on September 12<sup>th</sup>, 2023. The following members of NBC-R attended the meeting:

1.	Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2.	Prof. Dr. Muneer Akhtar Saleemi	Member
3.	Prof. Dr. Jamshed Akhtar	Member
4.	Dr. Farkhanda Ghafoor	Member
5.	Prof. Marie Andraes	Member
6.	Prof. Dr. Saqib Mehmood	Member
7.	Prof. Dr. Amjad Mehboob	Member
8.	Mrs. Sualeha Siddiqui Shekhani	Member
9.	Mr. Waryal Ali Daheri	L.D.C (NBC-R-Secretariat)

The following projects reviewed / discussed:

### **NBC-989:**

Title: **FREE HEPATITIS C SCREENING AND TESTING AND LINKAGE TO CARE AMONG KEY POPULATIONS IN PUNJAB AND SINDH USING ELECSYS HCV DUO ASSAY.**

Project Number	PI Name & Address	Final NBC-R Comments
<b>NBC-989</b>	<b>Dr. Huma Qureshi</b> Doctors Plaza, Clifton, <b>Karachi</b>	<ul style="list-style-type: none"> <li>We need more details as to which communities are involved and which CBOs are being approached.</li> <li>Who are the co-PIs in this study who will be involved in the research?</li> <li>Why is there a need to study this in the community when all the PI needs to do is go to the labs and compare these two tests with one another?</li> <li>Which labs are involved for conducting the tests?</li> <li>The literature review mentions HCV prevalence but our point of interest in this case is the new diagnostic kit and comparing it with the standard. We need to know if this new kit has been used elsewhere or not? What is the sensitivity and specificity reported?</li> <li>Budget mentions travel to Islamabad...why is that required if the study is being done in Sindh and Punjab?</li> <li>The informed consent form needs to be revamped and simplified. Why is CNIC a requirement in this study?</li> </ul>

Title: **LIVING WITH GENETIC PREDISPOSITION TO CANCER: CO-CREATION OF VISUAL ILLUSTRATIONS TO DESIGN ACCESSIBLE PATIENT RESOURCES.**

Project Number	PI Name & Address	Final NBC-R Comments
NBC-990	<b>Dr. Raza Sayyed</b> ST-18, Block-4, Gulshan-e-Iqbal, <b>Karachi</b>	Project Approved



**NBC-991:**

Title: **SYNCHRONOUS MUTATIONS WORSEN THE CLINICAL PICTURE IN RENAL STONE PATIENTS.**

<b>Project Number</b>	<b>PI Name &amp; Address</b>	<b>Final NBC-R Comments</b>
NBC-991	<b>Dr. Syed Raziuddin Biyabani</b> Aga Khan University <b>Karachi</b>	<ul style="list-style-type: none"><li>• Will the participants of the study know that DNA is being stored and transferred outside for a period of 5 years? The consent form is quite sketchy in this regard.</li><li>• Who will bear the cost (test and travel) of the 24 hour urine sample that is required?</li></ul>

**Next meeting:**

The next zoom meeting will be held at 02:30 pm on September 19<sup>th</sup>, 2023. The following projects will be reviewed:

1. NBC-992
2. NBC-993
3. NBC-995



**Focal person NBC-R**



**Chairperson NBC-R**

## Minutes of the NBC-R meeting held on 19-09-2023

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on September 19<sup>th</sup>, 2023. The following members of NBC-R attended the meeting:

1. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2. Prof. Dr. Jamshed Akhtar	Member
3. Dr. Farkhanda Ghafoor	Member
4. Prof. Marie Andraes	Member
5. Prof. Dr. Amjad Mehboob	Member
6. Mrs. Sualeha Siddiqui Shekhani	Member
7. Mr. Waryal Ali Daheri	L.D.C (NBC-R-Secretariat)

**The following projects reviewed / discussed:**

Title: **ADDRESSING THE “YOUTH” GAP IN THE PAKISTAN DEMOGRAPHIC AND HEALTH SURVEY (PDHS) BY IMPLEMENTING A YOUTH-LED DIGITAL SURVEY FOR DIAGNOSING AND STRENGTHENING THE YOUTH FP MARKET IN SINDH.**

Project Number	PI Name & Address	Final NBC-R Comments
<b>NBC-992</b>	<b>Xaher Gul</b> Pathfinder International F-57/1 Parklane, Clifton block 5, Karachi Pakistan	<ul style="list-style-type: none"> <li>Asking 15 year olds about sexual behaviour seemed problematic for us considering our cultural context. Could there be a legal issue involved if the team gets to know about adultery in this age group?</li> <li>We had a debate about the rationale of this study among ourselves. Could the questions be rephrased so that it does not seem that promiscuous behaviour is being encouraged through this study?</li> </ul>

Title: **DEVELOP AND IMPLEMENT A REAL-TIME GLOBALLY HARMONISED NATIONAL BURNS REGISTRY FOR THE PREVENTION AND MANAGEMENT OF BURN INJURIES IN PAKISTAN.**

Project Number	PI Name & Address	Final NBC-R Comments
<b>NBC-993</b>	<b>Prof Nasim Chaudhry</b> Pakistan Institute of Living & Learning (PILL) Suite No. 201, 2nd Floor, The Plaza, Karachi	<ul style="list-style-type: none"> <li>Should a psychiatrist be the main lead for a Burns Registry? Who are the other stakeholders in this project?</li> <li>What will be the format for data collection, where will data be stored and what governance rules will apply to this data? Meaning who can access this data.</li> </ul>

Title: **PATERNAL EPIGENETIC ASSOCIATION WITH INFANT BIRTH WEIGHT.**

Project Number	PI Name & Address	Final NBC-R Comments
<b>NBC-994</b>	<b>Syed Asad Ali</b> Dept of Community Health Sciences Aga Khan University, Karachi	<ul style="list-style-type: none"> <li>Why is Matiari the research site? Why can this study not be done in AKUH?</li> <li>Will participants be expected to travel to Hyderabad for delivery even if not needed?</li> <li>MTA needs to be attached as samples are being sent to the US.</li> <li>Hypothetically, what if an epigenetic cause of stunting becomes identified? How will that affect the family or families of our country? We hope the PI and his team reflect on this aspect.</li> </ul>

**Next meeting:**

The next zoom meeting will be held at 02:30 pm on September 26<sup>th</sup>, 2023. The following projects will be reviewed:

1. NBC-996
2. NBC-998
3. NBC-999



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**Focal person NBC-R**



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**Chairperson NBC-R**

## Minutes of the NBC-R meeting held on 26-09-2023

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on September 26<sup>th</sup>, 2023. The following members of NBC-R attended the meeting:

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

**The following projects reviewed / discussed:**

Title: **MODELLING SUBNATIONAL TB PREVALENCE IN PAKISTAN TO SUPPORT MORE EFFICIENT ALLOCATION OF RESOURCES FOR MORE EFFICIENT TB CASE-FINDING.**

Project Number	PI Name & Address	Final NBC-R Comments
<b>NBC-996</b>	<p><b>Dr. Ente Rood</b>                      KIT Royal Tropical                      Institute Mauritskade                      641092 AD Amsterdam  <b>The Netherlands</b></p>	<ul style="list-style-type: none"> <li>We are not sure of how this study will be conducted on the field. The PI is based in the Netherlands. Who are the collaborating partners who will take responsibility for this research?</li> <li>Most of us were not aware of Pakistan Common Management Unit. Does it have an IRB/ERC? Who are its members from which IRB approval be sought?</li> <li>Please provide details about the government organizations involved in this project.</li> <li>There is mention of chest camps. Who will conduct them? Where and how? How will a political angle be eliminated because in our setting such camps are viewed with a political intent?</li> </ul>

Title: **COGNITIVE THERAPY FOR DEPRESSION IN TUBERCULOSIS TREATMENT (CONTROL)” MULTICENTRE PRAGMATIC HYBRID TYPE 1 PARALLEL ARM RANDOMIZED CONTROL TRIAL WITH AN INTERNAL PILOT.**

Project Number	PI Name & Address	Final NBC-R Comments
<b>NBC-998</b>	<p><b>Dr Saeed Farooq and Dr Zohaib Khan</b>                      School for Primary,                      Community and Social                      Care Keele University,                      Staffordshire, ST5 5BG</p>	<ul style="list-style-type: none"> <li>We need to see ERC approval from KMU and the affiliated institutions where this project is being carried out.</li> <li>We need to know the co-PIs who will be collaborating on this project on the ground and if there are any letters of intent between these organizations.</li> <li>Is there any agreement on data transfer to another country like the UK? How will that affect or could it possibly stigmatize our population?</li> <li>What about personal protection of the PIs and co-PIs? They will be interviewing patients with active TB or even drug resistant TB....What mechanisms are in place so that they do not catch the disease?</li> </ul>

Title: **A 3-ARM MULTI-CENTER EXPLORATORY TRIAL OF UNIVERSALLY DELIVERED INTERVENTIONS FOR PREVENTION OF ANXIETY AND DEPRESSION IN YOUNG PEOPLE IN PAKISTAN.**


<b>Project Number</b>	<b>PI Name &amp; Address</b>	<b>Final NBC-R Comments</b>
<b>NBC-999</b>	<b>Dr Tayyeba Kiran</b> Suite no 201, 2nd floor The shopping Palaza, Do Talwar Clifton, <b>Karachi</b>	<b>• Project Approved.</b>

**Next meeting:**

The next zoom meeting will be held at 02:30 pm on October 3<sup>rd</sup>, 2023. The following projects will be reviewed:

**Projects will be discussed.**

1. NBC-1000
2. NBC-1001
3. NBC-1002



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**Focal person NBC-R**



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**Chairperson NBC-R**

## Minutes of the NBC-R meeting held on 03-10-2023

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on October 3<sup>rd</sup>, 2023. The following members of NBC-R attended the meeting:

1. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2. Prof. Dr. Saqib Mehmood	Member
3. Prof. Dr. Munir A. Saleemi	Member
4. Prof. Dr. Jamshed Akhtar	Member
5. Dr. Farkhanda Ghafoor	Member
6. Prof. Dr. Amjad Mehboob	Member
7. Ms. Sualeha Shekhani	Member
8. Dr. Faiza Bashir	National Coordinator
9. Ms. Ayesha Abid	Assistant (NBC-R-Secretariat)
10. Mr. Waryal Ali Daheri	L.D.C (NBC-R-Secretariat)

### The following projects reviewed / discussed:

Title: **A DOUBLE-BLIND, RANDOMIZED CLINICAL STUDY OF THE EFFICACY AND SAFETY OF MONOTHERAPY WITH BCD-264 AND DARZALEX® IN SUBJECTS WITH RELAPSED AND REFRACTORY MULTIPLE MYELOMA.**

Project Number	PI Name & Address	Final NBC-R Comments
<b>NBC-1000</b>	<p><b>Dr. Qasim Mahmood Buttar</b>                      Shaheed Zulfiqar Ali Bhutto Medical University G8 markaz PIMS Islamabad</p>	<ul style="list-style-type: none"> <li>We need to see the CV of the PI and co-PIs plus we need to see the approvals from institutional IRBs before granting NBC approval.</li> <li>The MTA attached is very generic. We need to see what samples are being sent abroad and where? For how long will they be stored and who would have access to this data?</li> <li>What is the DSMB composition? Who will review the data generated and how frequently?</li> <li>How is the Pakistani population benefiting from this research in the short term and in the long run?</li> </ul>

Title: **A DOUBLE-BLIND, RANDOMIZED CLINICAL STUDY OF THE EFFICACY AND SAFETY OF BCD-263 AND OPDIVO® AS MONOTHERAPY IN SUBJECTS WITH ADVANCED MELANOMA OF THE SKIN.**

Project Number	PI Name & Address	Final NBC-R Comments
<b>NBC-1001</b>	<p><b>Dr. Muhammad Abbas Khokhar</b>                      Mayo Hospital, New Anarkali, Neela Gumabad, Lahore</p>	<ul style="list-style-type: none"> <li>We need to see the CV of the PI and co-PIs plus we need to see the approvals from institutional IRBs before granting NBC approval.</li> <li>The MTA attached is very generic. We need to see what samples are being sent abroad and where? For how long will they be stored and who would have access to this data?</li> <li>What is the DSMB composition? Who will review the data generated and how frequently?</li> <li>How is the Pakistani population benefiting from this research in the short term and in the long run?</li> </ul>



Title: **LINKAGE TO CARE AND HEALTH EDUCATION FOR PROMOTING WATER, SANITATION AND HYGIENE (WASH) AND PRIMARY HEALTHCARE SERVICES IN UNDERSERVED COMMUNITIES OF ISLAMABAD, PAKISTAN.**

<b>Project Number</b>	<b>PI Name &amp; Address</b>	<b>Final NBC-R Comments</b>
<b>NBC-1002</b>	<b>Dr. Hassan Mahmood</b> M/o NHR&C, Pak Secretariat Kohsar Complex, Third Floor, <b>Islamabad</b>	<ul style="list-style-type: none"><li>• Please elaborate on the rationale of this study. What is not known in the scientific literature that mandates the necessity of this study?</li><li>• Please reflect if this is actually research which will advance scientific knowledge.</li><li>• Where is the link to provision of sanitation and hygiene to an underserved community in Islamabad??</li><li>• The budget is impressive but it does not seem to be working on improving infrastructure responsible for sanitation and hygiene.</li></ul>

**Next meeting:**

The next zoom meeting will be held at 02:30 pm on October 10<sup>th</sup>, 2023. The following projects will be reviewed:

**Projects will be discussed.**

1. NBC-1003
2. NBC-1004
3. NBC-1005



**Focal person NBC-R**



**Chairperson NBC-R**

## Minutes of the NBC-R meeting held on 10-10-2023

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on October 3<sup>rd</sup>, 2023. The following members of NBC-R attended the meeting:

1. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2. Prof. Dr. Munir A. Saleemi	Member
3. Prof. Dr. Jamshed Akhtar	Member
4. Prof. Dr. Saqib Mehmood	Member
5. Prof. Dr. Amjad Mehboob	Member
6. Ms. Sualeha Shekhani	Member
7. Dr. Faiza Bashir	National Coordinator
8. Mr. Waryal Ali Daheri	L.D.C (NBC-R-Secretariat)

**The following projects reviewed / discussed:**

Title: **ASSESSING THE KNOWLEDGE, UNDERSTANDING, ATTITUDE, AND BEHAVIOR OF CLIMATE CHAMPIONS REGARDING THE IMPACT OF CLIMATE CHANGE ON HEALTH AND SEXUAL AND REPRODUCTIVE HEALTH (SRH).**

Project Number	PI Name & Address	Final NBC-R Comments
<b>NBC-1003</b>	<b>Shazia Noor</b> Pathfinder International Bungalow No. F-57/1, Park Lane, Block 5, Clifton – <b>Karachi</b> .	<ul style="list-style-type: none"> <li>The rationale of the project needs to be streamlined as the reviewers were struggling with the idea of connecting Climate Change with Sexual and Reproductive health. The study seems to be targeting mostly women and young girls, correct us if we are wrong.</li> <li>Is this a quasi-experimental study with pre and post test design?? or is it focus group led? This was confusing as it is mentioned differently in the proposal and NBC form.</li> <li>If it is determined that knowledge is insufficient then will some knowledge be provided? If yes, how?</li> <li>This project is being funded by a Pharmaceutical company. Please clarify their interests in this study.</li> <li>The questionnaire design can be improved upon. There are some questions which would be inappropriate for 15 year olds.</li> <li>How will Climate Champions be recruited into the study?</li> <li>How will the various districts be approached? There is mention of Sindh and KPK. Please elaborate on this.</li> <li>An assent form needs to be attached for the under 18 participants.</li> <li>Please attach CVs of PI and Co-PIs</li> </ul>

Title: **EXPLORING LIVED EXPERIENCES OF PARENTS OF ADULTS WITH INTELLECTUAL DISABILITY IN PAKISTAN.**

Project Number	PI Name & Address	Final NBC-R Comments
<b>NBC-1004</b>	<b>Dr Tayyeba Kiran</b> Suite no 201, 2nd floor The shopping Palaza, Do Talwar Clifton, <b>Karachi</b>	<ul style="list-style-type: none"> <li>Study Approved.</li> </ul>

Title: **COLLABORATIVE CARE FOR DEPRESSION IN PRIMARY CARE; STRENGTHENING PRIMARY CARE TO RECOGNISE AND TREAT DEPRESSION STUDY**”(SHORT NAME: SPIRIT-D.

Project Number	PI Name & Address	Final NBC-R Comments
NBC-1005	<b>Prof. Najma Siddiqi</b> Department of Health Sciences, University of York, UK. <b>Dr Amna Khan</b> The initiative, Flat no. 103, Iqbal heights, Bani Gala Islamabad. <b>Dr Faiza Aslam</b> Institute of Psychiatry, Rawalpindi Medical University, Benazir Bhutto Hospital, Murree Road, <b>Rawalpindi</b>	<ul style="list-style-type: none"><li>• Study Approved.</li></ul>

**Next meeting:**

The next zoom meeting will be held at 02:30 pm on October 17<sup>th</sup>, 2023. The following projects will be reviewed:

**Projects will be discussed.**

1. NBC-1008
2. NBC-1009
3. NBC-1010



**Focal person NBC-R**



**Chairperson NBC-R**

## Minutes of the NBC-R meeting held on 18-10-2023

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on October 18, 2023. The following members of NBC-R attended the meeting:

1. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2. Prof. Dr. Jamshed Akhtar	Member
3. Prof. Dr. Saqib Mehmood	Member
4. Prof. Dr. Marie Andrades	Member
5. Prof. Dr. Amjad Mehboob	Member
6. Ms. Sualeha Shekhani	Member
7. Dr. Farkhanda Ghafoor	Member
8. Dr. Faiza Bashir	National Coordinator (NBC-R)
9. Ms. Ayesha Abid	Assistant (NBC-R-Secretariat)
10. Mr. Waryal Ali Daheri	L.D.C (NBC-R-Secretariat)

### The following projects reviewed / discussed:

Title: **ENDOVASCULAR STROKE TREATMENT AND RETEPLASE (ESTAR)-PROTOCOL.**

Project Number	PI Name & Address	Final NBC-R Comments
<b>NBC-1008</b>	<p><b>Dr Adnan I. Qureshi</b>                      Zeenat Qureshi Stroke Institute                      519 Second St N, Saint Cloud, MN 56303                      USA</p>	<ul style="list-style-type: none"> <li>What is the relationship of the sponsoring organization and the PI? Please provide details of the Zeenat Qureshi Foundation. Where is it located, official email, landline number etc.?</li> <li>Why is this study not being conducted in the USA?</li> <li>How did Rehman Medical Institute become involved? Who is the site PI taking responsibility of the research? Are there any other sites in Pakistan? If so, please provide names of site PIs.</li> <li>Where has the Phase 1 trial been conducted? What are the results of Phase 1 trial? Has it been published?</li> <li>Why is there a placebo arm in this trial when a standard of care is present? Denying one group treatment would be unethical.</li> <li>What will be the post-trial benefits if any to our population?</li> <li>Is there any insurance coverage for the participants? Please provide details. What is being covered for the participants in terms of medical costs and lab tests? A study budget would be required.</li> <li>Has a DSMB been constituted? Please provide details.</li> <li>Which pharmaceutical company will have the rights to develop this drug in Pakistan?</li> </ul>

Title: **PREVALENCE OF NEUROPSYCHIATRIC DISORDERS AND THEIR ASSOCIATED RISK FACTORS AND DISABILITY IN PAKISTAN: A POPULATION BASED CROSS SECTIONAL STUDY.**

Project Number	PI Name & Address	Final NBC-R Comments
<b>NBC-1009</b>	<p><b>Dr. M. Wasay</b>                      Dept of Medicine                      Aga Khan University                      Karachi</p>	<ul style="list-style-type: none"> <li>The co-PIs mentioned are all neurologists whereas this study is focused on neuropsychiatry. Please mention a list of all co-PIs involved with affiliations.</li> <li>What is the role of NIH/PHRC?</li> <li>Once patients are screened how will they be</li> </ul>

		referred for further care if required?
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Title: **IMPROVING OUTCOMES IN TUBERCULOSIS PATIENTS BY INTEGRATING DIABETES PREVENTION AND MANAGEMENT IN TUBERCULOSIS CARE PACKAGE.**

Project Number	PI Name & Address	Final NBC-R Comments
NBC-1010	<b>1. Dr. Saima Afaq</b> Institute of Public Health & Social Sciences, KMU, Peshawar <b>2. Prof. Kamran Siddiqi</b> Dept of Health Sciences, University of York, UK	<ul style="list-style-type: none"> <li>• Please declare any potential conflicts of interest.</li> <li>• What is the role of an agricultural university in this study?</li> <li>• What is the reason for asking questions pertaining to mental health?</li> <li>• IRB approvals from all participating sites will be required.</li> </ul>

**Next meeting:**

The next zoom meeting will be held at 02:30 pm on October 24<sup>th</sup>, 2023. The following projects will be reviewed:

**Projects will be discussed.**

1. NBC-1011
2. NBC-1012
3. NBC-1013



**Focal person NBC-R**



**Chairperson NBC-R**

## Minutes of the NBC-R meeting held on 31-10-2023

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on October 31, 2023. The following members of NBC-R attended the meeting:

1. Prof. Dr. Jamshed Akhtar	Chairperson
2. Prof. Dr. Munir Saleemi	Member
3. Prof. Dr. Saqib Mehmood	Member
4. Prof. Dr. Marie Andrades	Member
5. Prof. Dr. Amjad Mehboob	Member
6. Ms. Sualeha Shekhani	Member
7. Dr. Farkhanda Ghafoor	Member
8. Ms. Ayesha Abid	Assistant (NBC-R-Secretariat)
9. Mr. Waryal Ali Daheri	L.D.C (NBC-R-Secretariat)

### The following projects reviewed / discussed:

Title: **GLOBAL BURDEN ESTIMATION OF HUMAN PAPILLOMAVIRUS (GLOBE-HPV)-PAKISTAN.**

Project Number	PI Name & Address	Final NBC-R Comments
<b>NBC-1011</b>	<p><b>Dr Fyezah Jehan</b> Chairperson, Department of Paediatrics and Child Health, The Aga Khan University, Pakistan</p>	<p>1. Title is not reflective of the of the study being conducted.</p> <p>2. Objectives mentioned in the IRB form and those in study protocol are different. There are number of secondary objectives. The study designs are different from point prevalence. This include even matching of genotype from biological samples obtained as well as KAP study.</p> <p>3. The study sites mentioned are rural Dadu (one taluka) and peri-urban communities of Karachi (four areas). Thus the data will not be a true reflection of prevalence of Pakistan. It would of interest to know why these two sites are chosen? It is probably due to convenience as mentioned at one place in the protocol. PI may elaborate how it translates into prevalence study of Pakistan.</p> <p>4. The communities from four locations chosen from “peri” urban Karachi, at places mentioned as “urban” probably contributing repeatedly for the organization of the PI. It is would be more appropriate to be inclusive of the urban population of Karachi for a more meaningful outcome rather than ease of data collection. Karachi is divided into number of districts (towns). As prevalence is the goal of the research therefore a more representative samples may be gathered from the of population of Karachi. Same is for district Dadu rural population. A sampling frame for Karachi may be shared as done for the population based epidemiological surveys.</p> <p>5. IRB approval is still awaited from International Vaccine Institute. It may be shared once received.</p> <p>6. Is department of Health, Government of Sindh and</p>



		<p>Federal ministry of National Health Services &amp; Regulations are also on board? Any addition of vaccine in the current EPI program can only be made in collaboration with these stake holders.</p> <p>7. In response to 2.1, what measures shall be taken to address potential harms to the study subjects?</p> <p>8. The details about special sub groups is not mentioned in the IRB form. Any reason for omitting such a vulnerable group from the ethics review form?</p> <p>9. It is mentioned that a standardized questionnaire has been developed. The information that is to be obtained is not directly related to the study objectives. Why this additional “research” is being conducted which is not mentioned upfront? There are number of sensitive questions in that questionnaire as mentioned in detailed document. These questions are meant for which age group?</p> <p>10. 4.3.1.4 CSS Procedure (Commercial Sex Workers) - This again is not part of the IRB form. Selective documentation is not clear.</p> <p>11. 4.6.1.3 Blood Sample - There is a big “if” about this sample collection. PI probably is not clear about the extent of research. IRB approval is sought before all aspects are addressed.</p> <p>12. 4.7 Feedback of Results - The reason for not disclosing results to the study participants is questionable. PI approach is expected to be participant centered. Participants are used to provide not only clinical data but also urine and even vaginal samples. They are expected to be mature enough to understand the results of the tests done on them.</p> <p>13. It is not clear why participant with persistent HPV infection will be referred to the “community clinic” and at “discretion of PI”. This is a vague approach. A clear protocol is to be provided. The reason that HPV infection may be asymptomatic may be provided to the study participants and educate them rather than not disclosing the results.</p> <p>14. In case of immunocompromised participant, the results should be disclosed upfront and not at the discretion of PI. An explicit protocol is expected how these study participants shall receive the “appropriate” clinical services.</p> <p>15. It will be interest to know if any genital warts are noted during data collection how patients shall be facilitated?</p> <p>16. 4.8.3 Data Dissemination - It is noted that governmental authorities that are entrusted with the responsibility of planning EPI program and</p>
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		<p>make policies and resource allocations are not mentioned.</p> <p>17. All researches that are conducted within Pakistan in particular context, and are expected to inform the policies. The results of the data collected be shared with relevant stake holders as it is an essential step.</p> <p>18. The agreement of data sharing may be shared with NBC.</p> <p>19. 5.2 Community engagement and protection of subjects and field staff - In context of above sub heading it would be of interest to know how previous researches by the PI/ organization helped in improving the health related status of the communities. Over researched communities is an ethical issue discussed at various for a and reported in literature as well.</p> <p>20. In same background by not informing the results of the tests done on the study participants and leaving that to the discretion of PI may affect the trust developed over the years. Similarly, by not mentioning how patients with persistent HPV infection will be facilitated and keeping it vague are expected to disappoint the communities.</p> <p>21. Budget is not shared appropriately. An itemized document under heads/sub heads may be shared.</p> <p>22. The questionnaire has number of sensitive questions – under 4 SEXUAL BEHAVIOUR AND REPRODUCTIVE HISTORY - What training the research staff has received to ask these questions?</p> <p>23. If the interviewers are from the same community how will you ensure the responses provided are correct and participants may not be harmed and stigmatized?</p> <p>24. Most of the questions in this section are asked to explore the issue of illicit relationship. There are number of questions on this single aspect. This needs revision. Number of sex partners and out of wedlock relations are known risk factors for HPV infection. But this does not justify so many probing questions.</p> <p>25. 6A GENDER DYNAMICS AND VULNERABILITY – for girls and women aged 16 years and older - This section may be re visited. There is no mention in the protocol what approaches PI may adopt in such subjects.</p> <p>26. In this context PI has gone beyond her primary / summary objectives. Gender based violence is a stand-alone subject. It is merged with HPV survey which is not appropriate.</p> <p>27. In consent form there are no clear information about future research. Any DNA based</p>
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		<p>studies or others may be mentioned clearly and a separate point may be added into the consent form.</p> <p>28. It is mentioned that in case tests done on left over samples, the results will not be informed to the study participants. This needs elaboration.</p> <p>29. It is mentioned that Rs. 500 shall be given to the participants. How this amount is arrived at? Is this one-time reimbursement or for each visit?</p> <p>30. Will HPV vaccination may be provided to the eligible participants in this study? It is mentioned that at present it is not included in EPI but there is a definite place for it in our study population as mentioned in introduction.</p> <p>31. Is there any educational strategy planned for study participants / communities where study is planned? Any leaflet or information brochure prepared to facilitate this goal.</p> <p>32. Will any of the biological samples be send abroad in current or future studies? Further questions may be asked once clear information is provided. There is a definite protocol that is followed for biological samples. This may be visited at NBC website.</p> <p>33. There are improper fonts and translation used in the Urdu consent form at multiple places. Correction is warranted.</p> <p>34. Share IRB approval letters.</p> <p>35. Is there any ongoing cervical cancer related program from government of Pakistan or society of OBGY? If yes then may provide details.</p>
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Title: **ADAPTIVE ASSESSMENT OF TREATMENTS FOR INFLUENZA: A PHASE 2 MULTI-CENTRE ADAPTIVE RANDOMISED PLATFORM TRIAL TO ASSESS ANTIVIRAL PHARMACODYNAMICS IN EARLY SYMPTOMATIC INFLUENZA INFECTION (AD ASTRA).**

Project Number	PI Name & Address	Final NBC-R Comments
NBC-1012	<b>Prof. M.Asim Beg</b> Department of Pathology and Laboratory The Aga Khan University Hospital, National Stadium Road, <b>Karachi</b>	<p>1. Pakistan specific protocol is not shared. It is a general document from outside Pakistan.</p> <p>2. CV of PI is not shared. It would be of interest to know if PI is involved in similar vaccine related researches.</p> <p>3. In rationale of the study protocol it is mentioned that quantitative evidence and comparison of antiviral activity will be done in patients with influenza to develop therapeutic guidelines, and prescribing and purchasing decisions. How this is relevant in a country like Pakistan where these drugs are not available to our understanding. Please elaborate on this aspect. Cost of the drugs in future and their availability to Pakistani population are also important aspects to be elaborated.</p> <p>4. The study sites and process of enrollment of patients are not mentioned. IRB approval shall be needed from each study site.</p>

		<p>5. Informed consent is also not appropriate. It is a general document. Re submit making sure it is made specific to Pakistan and drug to be used for research.</p> <p>6. There is no contact person name in the consent form.</p> <p>7. Provide material transfer agreement. Visit NBC website for details.</p> <p>8. Amount of blood to be obtained is about 62 ml during the study. How study participants shall be motivated for this? Will results of all the tests be shared with the study participants?</p> <p>9. Provide insurance coverage document in case of adverse events.</p> <p>10. The amount paid to the study participant is for one visit or for all the possible visits during the study period?</p> <p>11. Provide details how patients shall be managed and at which medical facility, in case of adverse events.</p> <p>12. Mention what shall be done if mild influenza flares up and becomes severe. This is not an uncommon clinical situation.</p> <p>13. Provide details of DSMB, its members and functioning.</p> <p>14. Which specific drug shall be used in the intervention arm? There is no clarity in the proposal.</p> <p>15. How dose of each drug shall be calculated?</p> <p>16. Provide results of phase 1 trial of the interventional drug that PI has planned to use.\</p> <p>17. What is the cost of the drug? Will it be available if considered safe, in Pakistan and at what cost?</p> <p>18. Provide IRB approval letter. If it is a multicenter study than more details are required.</p> <p>19. Budget document does not provide details under various sub heads. An itemized budget document may be shared.</p>
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Title: **READINESS OF OXYGEN DELIVERY SYSTEMS IN PAKISTAN.**

<b>Project Number</b>	<b>PI Name &amp; Address</b>	<b>Final NBC-R Comments</b>
<b>NBC-1013</b>	<b>Dr. Shabina Ariff</b> Dept of Pediatrics and Child Health The Aga Khan University, Stadium Road, Karachi	<p>1. KAP Survey in Urdu is not readable as font style and translation is incomprehensible in many items.</p> <p>2. KAP survey is more of an examination paper. It appears threatening. It may be made more appropriate for assessing the knowledge of the study participants who are not defined.</p> <p>3. Types of healthcare workers may be defined for this survey.</p> <p>4. Why the survey is for public sector hospitals only? Why PI has not involved her own</p>

		<p>medical centers? Why private sector health facilities all over the Pakistan are not part of this project?</p> <p>5. Provide list of public sector hospitals of various level where study shall be conducted?</p> <p>6. Provide ERC approval from all the study sites.</p> <p>7. It is mentioned that audit will also be done of data (retrospective). This amounts to accessing the confidential data of different study sites. How will you approach the institutions for accessing the data?</p> <p>8. The most important stake holders for oxygen readiness and security related issues are provincial and federal health department. Are the relevant authorities on board for the conduct of this study?</p> <p>9. During COVID 19 pandemic, NCOC, PDMA, NDMA, NIH were also involved in context of availability of oxygen in Pakistan. Has PI made any contact with these governmental organizations and shared the plans?</p> <p>10. What possible outcome PI foresee and what measures shall be taken to address any gaps in terms of oxygen security?</p> <p>11. The IRB approval letter mentions the EXTENSION of this study. Elaborate if it is an ongoing project for which IRB approval from NBC was taken? A document is attached that has information about the project of year 2022.</p> <p>12. Provide itemized budget as a separate document.</p>
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**Next meeting:**

The next zoom meeting will be held at 02:30 pm on November 7<sup>th</sup>, 2023. The following projects will be reviewed:

**Projects will be discussed.**

1. NBC-1014
2. NBC-1015
3. NBC-1016



**Focal person NBC-R**



**Chairperson NBC-R**

## Minutes of the NBC-R meeting held on 07-11-2023

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on November 07, 2023. The following members of NBC-R attended the meeting:

1. Prof. Dr. Jamshed Akhtar	Chairperson
2. Prof. Dr. Munir Saleemi	Member
3. Prof. Dr. Saqib Mehmood	Member
4. Prof. Dr. Nazli Hossain	Member
5. Associate Prof. Dr. Amjad Mehboob	Member
6. Ms. Sualeha Shekhani	Member
7. Dr. Farkhanda Ghafoor	Member
8. Dr. Faiza Bashir	National Coordinator (NBC-R)
9. Ms. Ayesha Abid	Assistant (NBC-R-Secretariat)
10. Mr. Waryal Ali Daheri	L.D.C (NBC-R-Secretariat)

### The following projects reviewed / discussed:

Title: **EXPLORING THE PATTERNS OF PROVIDER BEHAVIOR AND ANTIBIOTIC PRESCRIPTION: AN ASSESSMENT OF ANTIBIOTIC STEWARDSHIP IN CLINICAL PRACTICE.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBC-1014</b>	<p><b>Dr Mehreen Arshad</b> Department of Medicine Aga Khan University Karachi</p>	<ol style="list-style-type: none"> <li>1. The name of the investigator mentioned in the consent form is not found in the ERC form.</li> <li>2. Mention against whose name the grant is obtained. Share the document.</li> <li>3. IRB approval letter is issued to a person whose name is not found in the ERC form.</li> <li>4. There is a person whose name is mentioned as supervisor. Elaborate on this role in this research.</li> <li>5. Will the results of this study be shared with the funding organization? The interest of the funder and data sharing plan may be shared.</li> <li>6. Share CV of the PI.</li> <li>7. How many CO PI are for this study? They will conduct FGDs. Share their names and CVs.</li> <li>8. Number of studies are already present on the subject from Pakistan, many of which are referred in the proposal. What new information the PI is expected to gain from current exercise? How findings from this study inform the practices?</li> <li>9. The research question mentions only physicians. However, pharmacists are also included. Clarity is needed.</li> <li>10. The duration of study is mentioned as two years. This is not clear. Kindly explain it.</li> <li>11. How will you recruit study participants – like physicians, surgeons, specialty, work experience, and others? Describe criteria for doctors and pharmacists, from both private and public sector, tertiary care (mention names). Do pharmacists dispense antibiotics of their own? What is community pharmacy in this context?</li> <li>12. The word external collaborators is mentioned in the document. Kindly elaborate on it.</li> <li>13. Only four cities are mentioned that shall be targeted. How this sample / selection is made? How it</li> </ol>

		<p>will be representative of Pakistan?</p> <p>14. Number of participants mentioned as 15 for each FGD is more than what is recommended.</p> <p>15. How privacy is ensured when it is going to be a focused group discussion?</p> <p>16. Pharmacists are not allowed to prescribe antibiotics. Their role is in dissension of medicine. Information gathered from pharmacists and doctors can be difficult to match as their roles are different. Will there be some questions that shall be for pharmacists and others for doctors?</p> <p>17. How community pharmacies are defined in this study? Their role in managing infections in not clear. This is mentioned in interview guide (item 3).</p> <p>18. As individuals belong to specific clinical set ups, therefore IRB approval from each institution may be required. Otherwise individuals cannot share the information / polices of the workplace where they work.</p> <p>19. Rupees 5000 as a token money for participation in this study may be elaborated. On what ground this amount is decided?</p> <p>20. Provide itemized budget for this study that amount to more than seven million Pakistani rupees. All interviews are through virtual link as mentioned in the documents.</p>
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Title: **INTEGRATED PARENTING INTERVENTION FOR PARENTS WITH SCHIZOPHRENIA: A FEASIBILITY RANDOMIZED CONTROLLED TRIAL IN PAKISTAN.**

<b>Project #</b>	<b>PI Name &amp; Address</b>	<b>Final NBC-R Comments</b>
<b>NBC-1015</b>	<b>Dr Tayyeba Kiran</b> Suite no 201, 2nd floor The shopping Palaza, Do Talwar Clifton, <b>Karachi</b>	<p>1. Provide the ERC approval letters from all the collaborating institutions (not individual departments).</p> <p>2. The names of study sites mentioned in 1.2 is different from what is mentioned in ERC approval section of the form. Sites mentioned are six not seven. Multan is repeated. In context of few studies, hospitals are not identified. Private sectors are also not mentioned.</p> <p>3. It appears that focus is more on public sector facilities. It will be of interest to know why private sector huge set ups in major cities of Pakistan are not included in the study. Most of these sites have been used by the institution of the PI in previous studies as well. This needs elaboration.</p> <p>4. Provide details about study site – Karwan e Hayat in Karachi</p> <p>5. Department of psychiatry civil hospital Karachi is mentioned twice in the document.</p> <p>6. Why not applicable is written against section on IRB approval?</p> <p>7. Provide CVs of co investigators from different study sites.</p> <p>8. The intervention - Learning Through Play (LTP) – Plus Culturally adapted Cognitive Behaviour Therapy (LTP Plus) has been used by the PI institution previously as well. Share the outcome of</p>



		<p>this intervention and its translation into practices for general public suffering from similar diseases conducted in the past.</p> <p>9. Provide details of the institutions / related polices / governmental agencies involved in providing integrated parenting interventions in Pakistan as mentioned in the introduction as an outcome of research that organization of PI has conducted previously. It would be of interest to know what are the baseline services that exist in Pakistan for general population at large, who are suffering from the clinical condition under research.</p> <p>10. In context of 1.3 - Elaborate more on Community Engagement and Involvement (CEI). How it has made a change in the protocols and policies of managing psychiatric patients in public sector hospitals?</p> <p>11. In context of 1.4 – share any MOU that has been reached between different institutions.</p> <p>12. 2.1 - Standard Operating Procedures are in place for any adverse event. Provide details.</p> <p>13. 3.2 – Provide details of training sessions conducted previously for the physicians and awareness sessions as well. What was short and long term outcome?</p> <p>14. It is mentioned that consent shall be taken from parents of the children. This needs elaboration.</p> <p>15. The data collection also includes anthropometric data of children who are up to three years of age. This not mentioned in consent form.</p> <p>16. Will there be any psychologist as a part of research team? It appears that there is warranted in the background of the study under consideration.</p> <p>17. Rupees 500 is mentioned as compensation for each interaction. How this amount is arrived at?</p> <p>18. Is PILL funding this study from their own budget or funding has been received from other sources?</p>
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Title: **THE PREVALENCE OF RHEUMATIC HEART DISEASE IN PREGNANT WOMEN: A PILOT STUDY.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1016	<b>Dr. Zainab Samad</b> Department of Medicine Aga Khan University Karachi	<p>1. First objective is not mentioned in the title of the study. This objective is therefore an addition. In fact, it appears to be the main focus of research is to test a device.</p> <p>2. It will be of interest to note that PI is affiliated with a tertiary care set up. However, a public sector hospital is identified for diagnosing the cardiac condition in Karachi. This needs elaboration. Why main campus and the satellite units of PI are not the study sites?</p> <p>3. Why pregnant women will be send to NICVD for treatment? Why study participants on whom a device shall be tested by PI cannot get treatment at her institution?</p> <p>4. Matiari district in Sindh as a study site is frequently used for research purposes. Over- researched</p>

		<p>communities are an ethical issue in itself. The women will send to another facility of getting further treatment. However, in Hyderabad institution of the PI runs a larger tertiary care set up where all investigations and treatment can be done.</p> <p>5. Funding is against the name of which of the institutions? It appears that almost all the work is done in a public sector set up.</p> <p>6. Share the budget set aside for the public sector hospital (NICVD) and private rural obstetric facility at Kohi Goth Karachi.</p> <p>7. Provide IRB approval letter from participating institutions (NICVD, Kohi Goth).</p> <p>a. Low middle income settings. This terminology needs elaboration.</p> <p>8. Again Gadap, Karachi, and Matiari, Sindh are mentioned with the reason being impoverished pregnant women in these areas. However, RHD pregnant women can be found in a prevalence study in different Districts of Karachi. RHD also found frequently in different socioeconomic groups. It appears a selective recruitment of the study participants from a vulnerable community. Being a prevalence study a clear sampling frame must be defined as done in epidemiological studies. Kohi Goth in Karachi Gadap town cannot be taken as sole indicator of “prevalence”</p> <p>9. It will also be of interest to know how a prevalence study is mentioned as pilot study?</p> <p>10. Affidavit is ideally made on a legal document. Translation document may be submitted as a proper document.</p> <p>11. It was interesting to read letter of Prof. Sabha Bhatti. She mentioned her experience of screening more than 6000 pregnant women for cardiovascular diseases. It would be nice if she could elaborate on frequency of RHD (which PI mentioned as prevalence) in her experience. In presence of huge data this study to find prevalence in a small hospital in Kohi Goth of Gadap Town appears redundant.</p> <p>12. It would be of interest to know why management of Kohi Goth hospital agrees to volunteer and allowed PI to test a device on their pregnant women.</p> <p>13. Share itemized budget of this study which is more than three crores Pakistani rupees.</p> <p>14. Consent form of parents in Urdu is incomprehensible. Why parent consent form is needed for a pregnant woman?</p> <p>15. It is mentioned that if echocardiography is needed for confirmation than participant has to pay. Why this is not done out of project funding?</p> <p>16. Why data will be kept on the server of the company that manufactures device?</p> <p>17. Name of funding organization is not found.</p> <p>18. Device related details are not present.</p> <p>19. It is a study on pregnant women, however obstetric care in general is not mentioned anywhere in the document. Will gynecologist / obstetrician be involved</p>
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		in the research? 20. If Doppler ultrasound reports fetal anomalies or any maternal conditions, what shall be done?
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**Next meeting:**

The next zoom meeting will be held at 02:30 pm on November 14<sup>th</sup>, 2023. The following projects will be reviewed:

**Projects will be discussed.**

1. NBC-1017
2. NBC-1018
3. NBC-1019



**Focal person NBC-R**



**Chairperson NBC-R**

## Minutes of the NBC-R meeting held on 14-11-2023

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on November 14, 2023. The following members of NBC-R 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. Saqib Mehmood	Member
5. Associate Prof. Dr. Amjad Mehboob	Member
6. Ms. Sualeha Shekhani	Member
7. Dr. Farkhanda Ghafoor	Member
8. Dr. Faiza Bashir	National Coordinator (NBC-R)
9. Ms. Ayesha Abid	Assistant (NBC-R-Secretariat)
10. Mr. Waryal Ali Daheri	L.D.C (NBC-R-Secretariat)

**The following projects reviewed / discussed:**

Title: **EARLY DETECTION OF POSTPARTUM HAEMORRHAGE AND TREATMENT USING THE WORLD HEALTH ORGANIZATION MOTIVE ‘FIRST RESPONSE’ BUNDLE: AN E-MOTIVE BEFORE-AND-AFTER.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBC-1017</b>	<b>Dr. Lumaan Shaikh</b> Dept of Obs and Gyne AKUH, <b>Karachi</b>	<ul style="list-style-type: none"> <li>What is the current status of this project? It seems that it was implemented in 2021.</li> <li>We would like to know more about the 8 recruiting sites and their site PIs/co-PIs. How have they been identified?</li> <li>Why have similar countries like India and SL excluded from the project now?</li> <li>The Sindhi forms need to be re-looked at.</li> <li>Is there a budget for capacity building of the sites from where patients will be recruited?</li> <li>Is there a data sharing policy with the country PI and the University of Birmingham. Please share details if so.</li> </ul>

Title: **MENTAL HEALTH INTERVENTIONS IN SINDH, PAKISTAN: A STUDY OF MENTAL HEALTH EXPERTS.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBC-1018</b>	<b>Laila Rajani</b> University of Edinburgh Old College, <b>Edinburgh, UK, EH8 9LD</b>	<ul style="list-style-type: none"> <li>Project Approved.</li> </ul>

Title: **EARLY DETECTION OF ORAL PRE-CANCEROUS LESIONS AMONG SMOKELESS TOBACCO USERS’ ADOLESCENTS BY ANALYZING SALIVARY METABOLITES AND CYTOKINES. AN ANALYTICAL CROSS-SECTIONAL STUDY.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBC-1019</b>	<b>Dr. SHAFQUAT ROZI</b> Dept of Community Health Sciences AKU, <b>Karachi</b>	<ul style="list-style-type: none"> <li>The PI is from AKUH but the tests are being conducted in DUHS? This was not clear to us as to why.</li> <li>What is the role of Karachi University in this project?</li> <li>Why in particular was 6th-10th grade students selected? Smokeless tobacco use is prevalent in all age groups. This age group may not be old enough to show pre-cancerous lesions.</li> <li>What if a suspect lesion is picked up? How will the adolescent be facilitated for further workup?</li> <li>Are any samples being sent abroad? Is so MTA needs to be attached.</li> </ul>

**Next meeting:**

The next zoom meeting will be held at 02:30 pm on November 21<sup>st</sup>, 2023. The following projects will be reviewed:

**Projects will be discussed.**

1. NBC-1020
2. NBC-1021
3. NBC-1022



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**Focal person NBC-R**



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**Chairperson NBC-R**

## Minutes of the NBC-R meeting held on 21-11-2023

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on November 21, 2023. The following members of NBC-R 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. Saqib Mehmood	Member
5. Prof. Dr. Marie Andrades	Member
6. Prof. Dr. Nazli Hossain	Member
7. Associate Prof. Dr. Amjad Mehboob	Member
8. Ms. Sualeha Shekhani	Member
9. Dr. Farkhanda Ghafoor	Member
10. Dr. Faiza Bashir	National Coordinator (NBC-R)
11. Ms. Ayesha Abid	Assistant (NBC-R-Secretariat)
12. Mr. Waryal Ali Daheri	L.D.C (NBC-R-Secretariat)

### The following projects reviewed / discussed:

Title: **E-HEALTH SUPPORTED MHGAP INTERVENTION PROGRAMME FOR IMPROVING CARE FOR YOUNG PEOPLE WITH SUBSTANCE USE DISORDER IN PAKISTAN.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBC-1020</b>	<b>Dr Ishrat Yousaf</b> Capital University of Science & Technology, Expressway, Kahuta Road, Zone-V, Islamabad, Pakistan	<ul style="list-style-type: none"> <li>We would like to see the CV of the PI. Does he have the experience of doing this type of research?</li> <li>Has this project been approved by the ERC/IRB of CUST? Please show us the evidence.</li> <li>Is there an MoU between PILL and CUST? Please provide evidence.</li> <li>Please give us more details about the study sites. Where are they placed? Who is the responsible person at each site?</li> </ul>

Title: **ASSESSMENT OF DAILY SODIUM AND POTASSIUM CONSUMPTION AMONG RURAL AND URBAN ADULTS AND THEIR KNOWLEDGE, ATTITUDES, AND BEHAVIORS TOWARDS SALT INTAKE IN PAKISTAN: A MIXED-METHODS PILOT STUDY.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBC-1021</b>	<b>Dr. Romaina Iqbal</b> Department of Community Health Sciences AKU, Karachi	<ul style="list-style-type: none"> <li>Study Approved.</li> </ul>

Title: **UNDERSTANDING THE CURRENT CHILDHOOD PNEUMONIA MANAGEMENT PRACTICES IN A FEW SELECTED LOW-AND MIDDLE-INCOME COUNTRIES.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBC-1022</b>	Dr Zamir Hussain Suhag Trust for Vaccines & Immunization Suite#301, Al-Sehat Center, Adj. Regent Plaza Hotel, Rafiqi Shaheed Road, Karachi	<ul style="list-style-type: none"> <li>Study Approved.</li> </ul>

**Next meeting:**

The next zoom meeting will be held at 02:30 pm on November 28<sup>th</sup>, 2023. The following projects will be reviewed:

**Projects will be discussed.**

1. NBC-1023
2. NBC-1024
3. NBC-1025



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**Focal person NBC-R**



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**Chairperson NBC-R**



## Minutes of the NBC-R meeting held on 28-11-2023

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on November 28, 2023. The following members of NBC-R 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. Saqib Mehmood	Member
5. Associate Prof. Dr. Amjad Mehboob	Member
6. Ms. Sualeha Shekhani	Member
7. Dr. Farkhanda Ghafoor	Member
8. Dr. Faiza Bashir	National Coordinator (NBC-R)
9. Mr. Waryal Ali Daheri	L.D.C (NBC-R-Secretariat)

**The following projects reviewed / discussed:**

Title: **PREGNANCY RISK, INFANT SURVEILLANCE, AND MEASUREMENT ALLIANCE (PRISMAV2.0) MATERNAL AND NEWBORN HEALTH (MNH) STUDY: A MULTI-CENTER, PROSPECTIVE COHORT STUDY OF MATERNAL, NEWBORN, AND INFANT HEALTH.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBC-1023</b>	Dr. Zahra Hoodbhoy Dept of Pediatrics and Child Health, The Aga Khan University Karachi	<ul style="list-style-type: none"> <li>What does the previous data of studies done in the same population suggest with regards to rationalizing the mentioned project?</li> <li>How are the researchers connecting with the Primary Physician/ Obstetrician who are responsible for patient care? Their names were not mentioned.</li> <li>Which other countries are taking part in this project?</li> <li>Please review the Urdu translation of the Informed Consent Form. It is not understandable in its present form with a literal translation.</li> </ul>

Title: **IMPLEMENTING A STEPPED CARE MODEL FOR IMPROVING PARENTAL MENTAL HEALTH IN GILGIT AND CHITRAL: INTEGRATING MENTAL HEALTH SERVICES INTO ROUTINE CARE.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBC-1025</b>	<b>Ms. Falak Madhani</b> Brain and Mind Institute Aga Khan University Stadium Road Karachi	<ul style="list-style-type: none"> <li>Study Approved.</li> </ul>

Title: **ROLE OF METABOLOMIC SIGNATURE OF PLASMA ACYL CARNITINES AND URINE ORGANIC ACIDS IN DIFFERENTIATING BENIGN AND MALIGNANT OVARIAN TUMORS: A CROSS SECTIONAL STUDY.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBC-1026</b>	<b>Prof Aysha Habib Khan</b> Dept of Pathology and Laboratory Medicine, Aga Khan University, Stadium Road, Karachi	<ul style="list-style-type: none"> <li>The NBC-R would like to know the role of Randox in this study?</li> </ul>

**Next meeting:**

The next zoom meeting will be held at 02:30 pm on December 5<sup>th</sup>, 2023. The following projects will be reviewed:

**Projects will be discussed.**

1. NBC-1028
2. NBC-1029
3. NBC-1030



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**Focal person NBC-R**



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**Chairperson NBC-R**

## Minutes of the NBC-R meeting held on 05-12-2023

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on December 5, 2023. The following members of NBC-R 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. Saqib Mehmood	Member
5. Prof. Dr. Nazli Hossain	Member
6. Prof. Dr. Marie Andrades	Member
7. Associate Prof. Dr. Amjad Mehboob	Member
8. Ms. Sualeha Shekhani	Member
9. Dr. Farkhanda Ghafoor	Member
10. Dr. Faiza Bashir	National Coordinator (NBC-R)
11. Mr. Waryal Ali Daheri	L.D.C (NBC-R-Secretariat)

### The following projects reviewed / discussed:

Title: **PREVALENCE OF HUMAN PAPILLOMA VIRUS (HPV) INFECTION AND CERVICAL ABNORMALITIES DETECTED THROUGH VISUAL INSPECTION OF CERVIX BY ACETIC ACID (VIA) AMONGST WOMEN SEEKING CARE AT OBSTETRICS AND GYNAECOLOGY (OBS/GYN) AND MATERNAL, NEONATAL AND CHILD HEALTH (MNCH) CLINICS IN GILGIT-BALTISTAN (GB).**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBC-1028</b>	<b>Dr Uzma Chishti</b> Dept of Obstetrics and Gynaecology, AKU, Karachi.	<ul style="list-style-type: none"> <li>The title appears to be misleading, as it suggests a focus solely on determining the prevalence of HPV infection through visual inspection of the cervix using acetic acid. However, on reading the objective #1 and methodology it becomes apparent that the researchers are also collecting pap swabs to and identifying HPV genotypes through Polymerase Chain Reaction (PCR). This additional aspect of the study, involving genotyping, is a significant departure from the initial impression given by the title.</li> <li>Clarity in the objectives of a research project is crucial for the understanding and interpretation of its findings. If the researchers intend to validate the findings of visual inspection with acetic acid by employing PCR methods for genotyping, this should be explicitly stated in the project's objectives. Moreover, such validation processes should ideally be reflected in the project title to accurately represent the scope and methodologies employed.</li> <li>Additionally, attention should be given to the translation of terms into Urdu. The use of direct transliterations for medical conditions, such as cervical cancer, may not resonate well with Urdu-speaking audiences. It is advisable to incorporate commonly used and appropriate Urdu terms for medical conditions, ensuring that the translation is both accurate and culturally sensitive. Further consent form and patient information sheet should be translated into the regional languages also.</li> </ul>

Title: **EXPLORING KNOWLEDGE, ATTITUDES, AND PRACTICES RELATED TO COVID-19 VACCINE DECISION-MAKING AMONG PREGNANT PEOPLE IN PAKISTAN.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBC-1029</b>	<b>Dr. Saleem Jessani</b> Dept of Community Health Sciences AKU, Karachi.	<ul style="list-style-type: none"> <li>Is COVID 19 vaccine a relevant issue in the last quarter of 2023. Vaccination drive and KAP data is extensively reported from Pakistan involving all age groups and different status.</li> <li>Furthermore, the updated version of the vaccine is not available in Pakistan</li> <li>Why is JPMC a study site? There is no mention of other hospitals from Pakistan in collaboration section of IRB form.</li> </ul>

		<p>No study site co PI from JPMC. There is IRB approval from JPMC as well as share in the budget of this KAP study.</p> <ul style="list-style-type: none"> <li>• This is not a trial which is mentioned in consent section of IRB Form.</li> <li>• In section 1 it is mentioned that new vaccines shall be available in future for pregnant women. This need elaboration. Why COVID 19 condition which is not relevant at present is chosen?</li> <li>• The study can be conducted independent of COVID 19 if only vaccine administration related attitude and practices are to be gauged.</li> <li>• Age group should be in reproductive age. However, questionnaire also includes older age women. Similarly divorced and widowed are also parts of the study.</li> </ul>
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Title: **ASSESSING HEALTH VULNERABILITY DUE TO CLIMATE CHANGE IN PAKISTAN – A PILOT STUDY.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1030	Dr. Ahsana Nazish Dept of Community Health Sciences AKU, Karachi	<ul style="list-style-type: none"> <li>• Study Approved.</li> </ul>

**Next meeting:**

The next zoom meeting will be held at 02:30 pm on December 12<sup>th</sup>, 2023. The following projects will be reviewed:

**Projects will be discussed.**

1. NBC-1031
2. NBC-1032



**Focal person NBC-R**



**Chairperson NBC-R**

## Minutes of the NBC-R meeting held on 12-12-2023

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on December 12, 2023. The following members of NBC-R 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. Saqib Mehmood	Member
5. Prof. Dr. Marie Andrades	Member
6. Associate Prof. Dr. Amjad Mehboob	Member
7. Ms. Sualeha Shekhani	Member
8. Dr. Farkhanda Ghafoor	Member
9. Dr. Faiza Bashir	National Coordinator (NBC-R)
10. Mr. Waryal Ali Daheri	L.D.C (NBC-R-Secretariat)

### The following projects reviewed / discussed:

Title: **EMPATHI- EMERGENCY ASSOCIATED MENTAL HEALTH ISSUES OF PAKISTANI FRONT LINE HEALTH WORKERS AND THEIR MANAGEMENT THROUGH TELE HEALTH INTERVENTION.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1031	<b>Dr Khalid Rehman</b> Institute of Public Health & Social Sciences, Khyber Medical University, Hayatabad Phase 5 Hayatabad, <b>Peshawar.</b>	<ul style="list-style-type: none"><li>• Why is NBC approval being sought at this stage when the project is almost near completion?</li><li>• Is the COVID 19 background still valid for mental health issues management? Are these tele health services still being utilized as such?</li><li>• What safety measures are in place for protection of these patients with depression/anxiety etc? Are they referred elsewhere if needed? If yes, how?</li></ul>

Title: **IMPLEMENTATION RESEARCH ON TAILORED, MULTIDISCIPLINARY NCD PREVENTION IN YOUTH: TARGETING TOBACCO AND AIR POLLUTION EXPOSURE FOR MID- TO LATE ADOLESCENTS IN DISADVANTAGED POPULATIONS.**


Project #	PI Name & Address	Final NBC-R Comments
NBC-1032	<b>Dr. Amina Khan</b> The Initiative Islamabad Orange Grove Farm Bani Gala Islamabad <b>Dr Saima Saeed</b> Indus Hospital & Health Network, The Indus Hospital, Opposite Crossing, Darussalam Society Korangi, Karachi	<ul style="list-style-type: none"><li>• Study Approved.</li></ul>

### Next meeting:

The next zoom meeting will be held at 02:30 pm on January 2<sup>nd</sup>, 2024. The following projects will be reviewed:

### Projects will be discussed.

1. NBC-1033
2. NBC-1034
3. NBC-1035

  
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Focal person NBC-R

  
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Chairperson NBC-R