

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 Siddique did not attend the meeting.

It was second consecutive time for Dr Nazli and 1st 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?

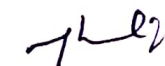
AOB:

- 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:

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|----------------------------------|---------------------------------------|
| 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



Focal person NBC



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

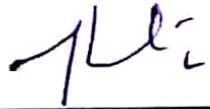
Final REC Comments:

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



Focal person NBC



Chairperson REC