

## Minutes of the NBC-R meeting held on 07-01-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on January 7<sup>th</sup>, 2025. 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. Munir Saleemi	Member
4. Prof. Dr. Marie Andrades	Member
5. Prof. Dr. Saqib Mehmood	Member
6. Dr. Farkhanda Ghafoor	Member
7. Ms. Tayyaba Rahat	National Coordinator NBC-R
8. Mr. Waryal Ali Daheri	LDC (NBC-R-Secretariat)

### The following projects reviewed / discussed:

Title: **Serum Sampling of Dog-Bite Victims in Karachi, Pakistan, to Investigate the Pre- and Post-RABV Treatment Immune Response".**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1194	<b>Dr. Naseem Salahuddin,</b> The Indus Hospital, Opposite Darussalam Society, Korangi Crossing, Karachi	<ul style="list-style-type: none"><li>• Please specify which anti-rabies vaccine is being tested?</li><li>• The proposal claims that PCR-based diagnostic methodologies for rabies are currently unavailable for assessing active viral infections. However, this is contrary to the existing literature. For instance, the LN34 Pan-Lyssavirus RT-qPCR assay has been shown to demonstrate 100% sensitivity and 98% specificity outperforming traditional methods such as the direct fluorescent antibody test (dFAT). The proposal should acknowledge the availability and efficacy of such assays and clearly articulate whether this study seeks to validate or integrate these techniques into the local diagnostic framework.</li><li>• Which cytokines are being measured? Can any of these tests be done in Pakistan? If not, is there any capacity development in the pipeline?</li></ul>

Title: **Increasing Middle School Enrolment: Testing the Efficacy of Targeted Solutions in Locations with Unrestricted Middle-School Access/Middle School Transition study (DARE-MST).**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1195	<b>Dr. Zainab Latif</b> Oxford Policy Management, Pakistan Plot 271, St No.1, Sector I-9/3, Islamabad	<ul style="list-style-type: none"><li>• Why in particular has district Khushaaba been selected?</li><li>• Has permission been taken from the school Principals or Education department for this study?</li><li>• Please mention who is doing the school and class observation.</li><li>• There is no mention of duration required for focus group sessions.</li><li>• The proposal also states asking for contact numbers of students. Would that be culturally appropriate especially where girls are concerned?</li></ul>

Title: **Effect of maternal multiple micronutrient supplementation from preconception through lactation on child growth and development in rural Pakistan: A follow-up study..**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1196	Dr. Zulfiqar Bhutta Distinguished University Professor & Founding Director Institute for Global Health and Development , Aga Khan university University Stadium 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 14<sup>th</sup> January, 2025. The following projects will be reviewed:

**Projects will be discussed.** NBCR-1197, NBCR-1198 & NBCR-1199

## Minutes of the NBC-R meeting held on 14-01-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on January 14<sup>th</sup>, 2025. The following members of NBC-R attended the meeting:

9. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
10. Prof. Dr. Jamshed Akhtar	Member
11. Prof. Dr. Munir Saleemi	Member
12. Prof. Dr. Saqib Mehmood	Member
13. Prof. Dr. Marie Andrades	Member
14. Dr. Farkhanda Ghafoor	Member
15. Prof. Dr. Amjad Mehboob	Member
16. Ms. Tayyaba Rahat	National Coordinator NBC-R
17. Ms. Ayesha Abid	Assistant (NBC-R-Secretariat)

### The following projects reviewed / discussed:

Title: **Trial: Does Folinic Acid Supplementation Affect the Outcome in Neonate with Hypoxic Ischemic Encephalopathy?**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1197</b>	<b>Dr. Bushra Fatima,</b> Department of Neonatology, University of Child Health Sciences and Children's Hospital , Lahore	<ul style="list-style-type: none"> <li>• Please give a rationale as to why this study needs to be done in Pakistan only? Why can it not be done in the UK as well as hypoxic ischemic encephalopathy is prevalent there as well.</li> <li>• Please clarify the methodology of an RCT. How will randomization be done? This also needs to be reflected on the informed consent form, that one group will be given a placebo.</li> <li>• Will baseline folinic acid levels be conducted on all CSF samples?</li> <li>• How will Pakistan benefit by being involved in this study? Is there a mechanism of sharing the benefits if folinic acid is found to be useful? Will it be available to our population?</li> <li>• Who is paying for all the tests being conducted?</li> <li>• Is the site approved by DRAP?</li> <li>• The PI/co-PI is involved in sending CSF samples to the UK in previous studies. Have those studies been approved by NBC or any other ethical review body?</li> </ul>

Title: **Development and Piloting of AI-based Digital Learning Platform for Immunization in Pakistan.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1198</b>	<b>Dr. Zahid Memon</b> Department of Community Health Sciences Aga Khan University Karachi"	<ul style="list-style-type: none"> <li>• Study Approved.</li> </ul>

Title: **Trial: Prospective Performance Diagnostic Accuracy Study of a New Rapid Diagnostic Test (RDT) for the Detection of Antibodies to Hepatitis C Virus.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1199	<b>Prof. Dr. Saleem Ahmed Khan</b> National University of Medical Sciences, The Mall, Rawalpindi, Pakistan	<ul style="list-style-type: none"><li>• Please provide information about the local tool kit that is being tested for diagnostic accuracy. With what tool is it being compared against?</li><li>• From where will samples be collected? Who are the volunteers for giving samples? Please specify.</li><li>• What is the Data Management Agreement with the CRO that is involved? Why will they be storing samples and for what purpose?</li><li>• Does this study really require a DSMB? This is more of a validation study.</li></ul>

**Next meeting:**

The next zoom meeting will be held at 02:30 pm on 21<sup>st</sup> January, 2025. The following projects will be reviewed:

**Projects will be discussed.** NBCR-1201, NBCR-1202 & NBCR-1203

## Minutes of the NBC-R meeting held on 21-01-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on January 21<sup>st</sup>, 2025. The following members of NBC-R attended the meeting:

18. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
19. Prof. Dr. Jamshed Akhtar	Member
20. Prof. Dr. Munir Saleemi	Member
21. Prof. Dr. Nazli Hossain	Member
22. Prof. Dr. Saqib Mehmood	Member
23. Prof. Dr. Marie Andrades	Member
24. Dr. Farkhanda Ghafoor	Member
25. Prof. Dr. Amjad Mehboob	Member
26. Ms. Tayyaba Rahat	National Coordinator NBC-R
27. Mr. Waryal Ali Daheri	LDC (NBC-R-Secretariat)

### The following projects reviewed / discussed:

Title: **Trial: “Efficacy of vitamin D supplementation and metformin compared to metformin alone in infertile females with polycystic ovary syndrome: a randomized open label trial”.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1201</b>	<b>Dr. Rehana Rehman</b> Dept of Biological & Biomedical Science Aga Khan University at Stadium Road Karachi	<ul style="list-style-type: none"> <li>Why has this trial been presented to the NBC now when it was initiated several years ago?</li> <li>Are the participants being tested for Vitamin D toxicity? Has it been reported in any of the cohorts?</li> <li>How will therapeutic misconception be addressed as these women would be desperate to get pregnant?</li> <li>Some of the questions are not culturally appropriate like "Have you received a suntan in the last 12 months?"</li> <li>How much blood is being drawn...5 ml or 10 ml? It should be specified in the informed consent form.</li> <li>Who is paying for the tests and ultrasound? This should be mentioned in the informed consent form.</li> </ul>

Title: **Urban PHC Policy Analysis and Evidence Generation Mixed methods research to understand the gaps in policy and implementation.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1202</b>	<b>Dr. Hina Sharif</b> SINA Health Education & Welfare Trust Plot No.1 D-21, Sector 30 Karachi.	<ul style="list-style-type: none"> <li>Study Approved.</li> </ul>

Title: **Genetic and Demographic Consequences of Consanguinity in A Large Population (GenPK).**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1203</b>	<b>Dr. Muhammad Ansar</b> Dow University of Health Sciences, Karachi, Pakistan	<ul style="list-style-type: none"> <li>This study needs to be specific in terms of its objectives. All genetic disorders cannot be encompassed into one project. If the local PI has a background in Ophthalmology then specific disorders should be targeted.</li> <li>There is no community engagement in this project. What benefits would our population gain by being involved in this study? There is an obvious lack of cultural</li> </ul>

		<p>sensitivity and this may create more problems for the people being involved.</p> <ul style="list-style-type: none"> <li>• Why can this study not be done in Pakistan? Our local Universities are developing genetic testing kits so that we need not send our human samples abroad.</li> <li>• The project mentions that in Switzerland the samples will be outsourced at the lowest price. Does this mean that funds have yet to be secured for this project?</li> <li>• There is no MTA. Approval from the IRB of DUHS is required.</li> </ul>
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**Next meeting:**

The next zoom meeting will be held at 02:30 pm on 28<sup>th</sup> January, 2025. The following projects will be reviewed:

**Projects will be discussed.** NBCR-1204, NBCR-1205 & NBCR-1206

## Minutes of the NBC-R meeting held on 28-01-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on January 28<sup>th</sup>, 2025. The following members of NBC-R attended the meeting:

28. Prof. Dr. Jamshed Akhtar	Chair the Meeting
29. Prof. Dr. Munir Saleemi	Member
30. Dr. Farkhanda Ghafoor	Member
31. Dr. Sualeha Siddiq Shekhani	Member
32. Prof. Dr. Saima Pervaiz Iqbal	Chairperson (Observations sent on email)
33. Prof. Dr. Saqib Mehmood	Member (Observations sent on email)
34. Prof. Dr. Marie Andrades	Member (Regret to Join)
35. Ms. Tayyaba Rahat	National Coordinator NBC-R

### The following projects reviewed / discussed:

Title: **Assessing the Quality of Primary Health Care (PHC) Services in the Public Sector in Pakistan.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1204	<b>Dr. Naeem Majeed</b> SPHERE Consulting 2-Justice Sardar Iqbal Rd, Gulberg 5, Lahore	<ul style="list-style-type: none"> <li>• Lot of data already exist on the subject from Pakistan. What is the need of this data collection on same subject? What were the findings of previous studies and what this research is going to find?</li> <li>• All four provinces have different PHC set ups and SOPs. How such differences shall be addressed?</li> <li>• Direct observation at PHC is threatening. Will it be prearranged? It can be a huge issue if deception is created. Why staff will let outside researcher to observe them? This can lead to harm as well.</li> <li>• There is no document found that shows a permission by the relevant health department.</li> <li>• It is very convenient to assess PHC services in major cities but that leaves the rural areas most vulnerable. This does not seem appropriate.</li> <li>• Details related to KPK and Baluchistan are not found.</li> <li>• This appears to be an audit of the PHC which is the job of the relevant authorities. They are not on board. The outside researcher may be biased in reporting data while ignoring the resources that a government can provide?</li> <li>• How they plan to send research officers into a facility? How approval shall be taken from the relevant staff? Why should they allow the outside researchers who are collecting data for other institutions?</li> <li>• Data transfer to another funder from US is an issue not addressed.</li> <li>• AKU IRB approval is suggested.</li> <li>• What is the conflict of interest of the university who has outsourced the process to a CRO?</li> <li>• Who is going to monitor or have an oversight on this project.</li> <li>• How much time they are expected to spend in the PHC?</li> <li>• Data collection tools mentions putting names of the participants. This is not appropriate.</li> <li>• In maternal health data, male is also mentioned.</li> <li>• Verbal consent is not appropriate strategy. A formal consent form is suggested as part of study from all stakeholders.</li> </ul>

		<ul style="list-style-type: none"> <li>• 2.3 is not satisfactory. Only publication is a purpose mentioned in this section.</li> <li>• It is expected that there should be a clear statement mentioning that BGMF is actually the funder.</li> <li>• The time of interaction is mentioned as 10 - 15 minutes in ICF. This is not possible.</li> <li>• The ICF is too general. Different tasks are assigned to the team at PHC. It has to be relevant to their scope of work. Same applies to the patients.</li> </ul>
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Title: **Primary Research- Primary Health Care Learning Agenda (PLA) Understanding the role of PHC in scaling up Family Planning services in Pakistan.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1205	<b>Dr. Wasim Mirza</b> Contech International 2-G Model Town, Lahore, Pakistan	<ul style="list-style-type: none"> <li>• BGMF is the actual funder. This must be mentioned in the ICF.</li> <li>• Why would any PHC allow the researchers from outside for this study?</li> <li>• There is no formal letter from concerned ministries / departments about the study and permission granted.</li> <li>• Many studies already done on the subject from Pakistan. What new is expected out of another data collection?</li> <li>• The client interviews require privacy and confidentiality and we hope the investigators are equipped to deal with such delicate questions with appropriate responses.</li> <li>• It seems that AKUH is now outsourcing its researches to CROs. What ethical oversight will the University be providing to ensure integrity and robustness of the research processes?</li> <li>• Data transfer to another funder from US is an issue not addressed.</li> <li>• AKU IRB approval is suggested.</li> </ul>

Title: **Experiences of the CEI members and Researchers working together during a Global Health Research on Stillbirth Prevention and Bereavement Care: A grounded theory study in Sub-Saharan Africa and South Asia.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1206	<b>Prof Nasim Chaudhry</b> Pakistan Institute of Living and Learning Suite No. 201, 2nd Floor, The Plaza, Karachi	<ul style="list-style-type: none"> <li>• More information is required about CEI. For how long it has been working, how many members are there? What are their ongoing agendas?</li> <li>• Country specific protocols are not present.</li> <li>• From where subjects shall be enrolled? Details are not found. If it is going to be a medical facility, then mention its name. Local IRB approval shall be needed.</li> <li>• What benefits are there for study participants?</li> <li>• Will obstetricians / gynecologist be involved in this?</li> <li>• What are the interests of funders and PI from outside Pakistan?</li> <li>• Is there a data transfer agreement available?</li> <li>• What shall be done when study is completed?</li> <li>• Do you have any framework in mind to facilitate psychological well-being of the participants?</li> </ul>



**Next meeting:**

The next zoom meeting will be held at 02:30 pm on 4<sup>th</sup> February, 2025. The following projects will be reviewed:

**Data Sharing document will be discussed.**



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**Member Secretary NBC-R**



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**Chairperson NBC-R**

## **Minutes of the NBC-R meeting held on 04-02-2025**

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on February 4<sup>th</sup>, 2025. The following members of NBC-R attended the meeting:

1. Dr. Nighat Murad	Executive Director HRI
2. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
3. Prof. Dr. Jamshed Akhtar	Member
4. Prof. Dr. Munir Saleemi	Member
5. Prof. Dr. Nazli Hossain	Member
6. Prof. Dr. Marie Andrades	Member
7. Prof. Dr. Saqib Mehmood	Member
8. Prof. Dr. Amjad Mehboob	Member
9. Prof. Dr. Sualeha Siddiq Shekhani	Member
10. Dr. Farkhanda Ghafoor	Member
11. Dr. Faiza Bashir	Focal Person NBC-R
12. Ms. Tayyaba Rahat	National Coordinator NBC-R
13. Miss. Ayesha Abid	Assistant (NBC-R-Secretariat)
14. Mr. Waryal Ali Daheri	LDC (NBC-R-Secretariat)

### **Document of the Data Sharing discussed:**

#### **Next meeting:**

The next zoom meeting will be held at 02:30 pm on 11<sup>th</sup> February, 2025. The following projects will be reviewed:

## Minutes of the NBC-R meeting held on 11-02-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on February 11<sup>th</sup>, 2025. 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. Munir Saleemi	Member
4. Prof. Dr. Nazli Hossain	Member
5. Prof. Dr. Saqib Mehmood	Member
6. Prof. Dr. Marie Andrades	Member
7. Dr. Farkhanda Ghafoor	Member
8. Dr. Sualeha Siddiq Shekhani	Member
9. Ms. Tayyaba Rahat	National Coordinator NBC-R
10. Miss. Ayesha Abid	Assistant (NBC-R Secretariat)

**The following projects reviewed / discussed:**

Title: **LU-177 BASED SYNOVECTOMY IN THE MANAGEMENT OF CHRONIC INFLAMMATORY JOINT DISEASES..**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1129</b>	<b>DR. Aakif Ullah Khan</b> Director & Chief Medical Officer, Institute of Radiotherapy and Nuclear Medicine (IRNUM), Peshawar, Pakistan	<ul style="list-style-type: none"> <li>• <b>Rationale:</b> This portion includes why this study needs to be done. It has to be for a particular joint problem and not all chronic conditions as mentioned in the proposal. How will this new therapy enhance scientific knowledge and improve patient outcomes?</li> <li>• <b>Objective:</b> Please mention what clinical end points the PI is determining to prove. Which subsets of patients are these?</li> <li>• <b>Methodology:</b> As far as we could gather, this is a clinical trial. It has to be compared with a standard of care. What is the standard of care? How will subjects be recruited? How will informed consent be administered? What of the subject refuses? How will that affect his/her care? Who are the other investigators in this research?</li> <li>• We suggest the PI to attend a workshop or collaborate with an experienced researcher to get clarity on the science of this study.</li> </ul>

Title: **GLOBAL COLLABORATIVE FOR CHANGING DIABETES IN CHILDREN GLOBAL COHORT STUDY FOR TYPE 1 DIABETES.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1207</b>	<b>Prof. Abdul Basit</b> Health Promotion Foundation Suit # 102, 1st Floor, Al-Ameera Center, Near Passport Office, Saddar, Karachi-Pakistan	<ul style="list-style-type: none"> <li>• It is our understanding that the PI is no longer in BIDE. What is the affiliation of the PI? The IRB approval should be from that center.</li> <li>• Please identify the co-PIs who are collaborating in this project and from which institutions along with their support letters.</li> <li>• Why can this study not be done in the big cities like Karachi where the patient pool would be easier to collect?</li> <li>• Is there any pharmaceutical funding involved?</li> <li>• What is the Data Transfer Agreement in place?</li> <li>• We would like to see the country specific protocol for this study.</li> </ul>

Title: **CO-ADMINISTRATION OF MULTIPLE MICRONUTRIENT AND CALCIUM SUPPLEMENTS FOR MATERNAL AND NEWBORN HEMOGLOBIN AND IRON STATUS.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1208</b>	<b>Dr. Sarah Saleem</b> Department of Community Health Sciences Aga Khan University National Stadium Road Karachi	<ul style="list-style-type: none"> <li>What will be options for women whose hemoglobin do not show any rise with MMNS?</li> <li>The investigators assume there is similarity between population of Burkino Faso and Thatta? How can this be justified?</li> <li>We see a lot of patients from the area with stained teeth, addicted to betel nut and gutka, there is no provision in the study, or they will be ineligible?</li> <li>Investigators should write explicitly whether they will store biospecimen or not? If yes, then there should be MTA for it.</li> <li>WHO is already providing this supplement to women in powder form, for women living in coastal belt?</li> </ul>

**Next meeting:**

The next zoom meeting will be held at 02:30 pm on 18<sup>th</sup> February, 2025. The following projects will be reviewed:

**NBCR-1209, NBCR-1210 and NBCR-1211.**

**Minutes of the NBC-R meeting held on 18-02-2025**

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on February 18<sup>th</sup>, 2025. The following members of NBC-R attended the meeting:

1. Prof. Dr. Jamshed Akhtar	Chair the Meeting
2. Prof. Dr. Munir Saleemi	Member
3. Prof. Dr. Nazli Hossain	Member
4. Prof. Dr. Amjad Mehboob	Member
5. Prof. Dr. Sualeha Siddiq Shekhani	Member (Sent comments on email)
6. Ms. Tayyaba Rahat	National Coordinator NBC-R
7. Miss. Ayesha Abid	Assistant (NBC-R Secretariat)

Regrets were sent by Dr. Farkhanda Ghafoor, Dr. Saima Parvaiz Iqbal and Dr. Saqib Mehmood

**The following projects reviewed / discussed:**

Title: **CARDIP FOLLOW UP STUDY: ASSESSING THE CARDIOVASCULAR DISEASE RISK FACTORS IN FOUR PROVINCES OF PAKISTAN.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1209</b>	<b>Dr. Syed Abbas Raza</b> National Hospital and National Medical Center DHA Lahore	<ul style="list-style-type: none"> <li>A pharmaceutical company is a sponsor. Is their conflict of interest?</li> <li>Why the study design is written as trial? A clarification is needed as it is an observational study.</li> <li>It has a retrospective arm that was conducted earlier as a cross sectional study and is published in JPMA. Provide previous NBC approval letter. Also provide informed consent for that study. It would be of interest to note if it contained the information that they shall be</li> </ul>

		<p>contacted in future as well and their data will be re visited.</p> <ul style="list-style-type: none"> <li>• AE and SAE reporting is meant for a trial. What are these? How it relates to this follow up study?</li> <li>• The monitoring of this study is for what purpose?</li> <li>• In what capacity Mr. Syed Abbas is sponsor of the study? This is funded by the Highnoon company?</li> <li>• Why data is the property of the funder?</li> <li>• IRB approval letters are required from other institutions and consent of the GPs.</li> <li>• List all the tests that shall be done and who will pay for it? Echocardiography is an important test, will it be included.</li> <li>• How PI has decided to finally include a number nearly 350 of the total subjects enrolled previously.</li> <li>• The present study does not include the previous investigators. How it will be ensured that same subjects are enrolled.</li> <li>• The budget does not include the costs for tests which is mentioned in the proposal that it will be covered by the study sponsor.</li> <li>• The name of the study is misleading since this is not a trial but rather a cross-sectional study.</li> <li>• A general physician can also be a consultant- this is vague in the questionnaire</li> <li>• There is a mention of an agreement but it is not clear.</li> </ul>
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Title: **Trial: MULTI-CENTER, RANDOMIZED, DOUBLE BLIND AND PLACEBO CONTROLLED CLINICAL TRIAL ON THE EFFICACY AND SAFETY OF JINHUA QINGGAN (JHQQ) GRANULES FOR THE TREATMENT OF ACUTE UPPER RESPIRATORY INFECTION (WIND-HEAT PATTERN).**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1210	<p><b>Prof. Dr. M. Raza Shah</b>  Center for Bioequivalence Studies and Clinical Research (CBSCR),  International Center for Chemical and Biological Sciences (ICCBS),  University of Karachi, Karachi</p>	<ul style="list-style-type: none"> <li>• The inclusion of two CO PI is to be justified. One is simple MBBS and other is an anesthesia person.</li> <li>• The project is about a respiratory disease.</li> <li>• PI himself need to justify being PI which is a multicenter trial on a subject related to the clinical medicine. His expertise is bioequivalence and not involved in treatment of the patients. How funding is provided to the PI for a clinical study?</li> <li>• Provide DRAP approval certificate for the two hospitals that shall be the site for THIS TRIAL. COVID 19 related permission is no more valid.</li> <li>• Chinese IRB certificate translation in English is required.</li> <li>• Why competing interests of funding agency not matter? The product is about traditional Chinese medicine and is experimented of Pakistani and Jordanian people and simultaneously at China. It is of interest to know why there is a hurry in conducting this trial in Pakistan.</li> <li>• Data of usefulness mentioned is in context of influenza. Provide details of Phase I II and III trials conducted in China.</li> <li>• Why it is a placebo control trial? What is the standard of care?</li> </ul>

		<ul style="list-style-type: none"> <li>• What these granules re expected to do? Mode of action.</li> <li>• Age group is too wide. What if patient does not improve?</li> <li>• There is a mention of simulation in the project. This is not clear.</li> <li>• Why chest radiograph is needed for URTI? Is not done as a routine.</li> <li>• No insurance document found?</li> <li>• Data transfer agreement is not found.</li> <li>• DSMB has a psychiatrist as its member. He is not a substitute for a physician. Choose appropriate members. As it is trial, and health of the volunteer is of foremost importance.</li> <li>• Informed consent form must mention that the drug is not approved in Pakistan. Reference to year 2016 is deceptive.</li> <li>• Acetaminophen is also allowed in this trial in a particular situation. Does this mean failure of the intervention? This need clarity.</li> <li>• Large number of tests are part of this trial. Which phase of trial is being conducted? What is the need of these tests? These are not done usually in URTI patients.</li> <li>• How much blood shall be drawn? Where tests shall be performed? Will reports given to the study participants?</li> <li>• Amount to be paid to the participants is not mentioned.</li> <li>• Will patient remain hospitalized during the course of treatment?</li> <li>• AE SAE related document is not found.</li> <li>• What were the results of previous studies conducted particularly during Covid-19?</li> <li>• How the participants be recruited? This is unclear</li> <li>• The informed consent form is too long, and provides unnecessary details</li> <li>• In the proposal, the collaborating site included is Creek General Hospital and Pak General Hospital. Who are the PIs from there? ERC letters will also be required from these two institutions</li> <li>• The exclusion criteria is huge, who will be paying for all these tests?</li> <li>• Will the Co-PI from Southcity Hospital include his patients?</li> <li>• Batool General Hospital is a small clinic, who will be monitoring at Batool General Hospital, which basically provides maternity services.</li> </ul>
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Title: **IMAGING THE STRUCTURAL CORRELATES OF COGNITION IN PARKINSON'S DISEASE USING PORTABLE MRI.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1211	<b>Dr. Kiran Aftab</b> Lecturer, Department of Surgery, Aga Khan University, Karachi	<ul style="list-style-type: none"> <li>• The PI is a lecturer in GS. How this may affect the conduct of study.</li> <li>• What are the conflict of interests of the UK institution where PI is probably enrolled?</li> <li>• Portable MRI findings need to be compared with regularly performed MRI. This is not found in this proposal. The portable MRI findings may not be reliable. Will that be added? If yes who will pay for it?</li> <li>• Why data will not be accessible to the patients? Will they be told the outcome?</li> <li>• What PI expect to gather from this interventional study that may help patients and their families plus volunteers?</li> <li>• What if new nervous system related condition is detected?</li> <li>• With whom this data shall be shared? Is any data sharing agreement done?</li> <li>• Some participants may still be incapacitated. How will informed consent be taken from them? There should be some form of surrogate decision-making which is acceptable in such participants</li> <li>• Is use portable MRI in other places indicated for same reason?</li> <li>• How data security will be ensured. This is an era of AI and patient's data is used for making algorithms.</li> </ul>

**Next meeting:**

The next zoom meeting will be held at 02:30 pm on 25<sup>th</sup> February, 2025. The following projects will be reviewed:

**NBCR-1212, NBCR-1213 and NBCR-1214.**

## Minutes of the NBC-R meeting held on 25-02-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on February 25<sup>th</sup>, 2025. The following members of NBC-R attended the meeting:

1. Prof. Dr. Jamshed Akhtar	Chair the Meeting
2. Prof. Dr. Munir Saleemi	Member
3. Prof. Dr. Nazli Hossain	Member
4. Prof. Dr. Saqib Mehmood	Member
5. Prof. Dr. Marie Andrades	Member
6. Prof. Dr. Amjad Mehboob	Member
7. Dr. Farkhanda Ghafoor	Member
8. Miss. Ayesha Abid	Assistant (NBC-R Secretariat)
9. Mr. Waryal Ali Daheri	LDC (NBC-R Secretariat)

### The following projects reviewed / discussed:

Title: **Trial: COMPARATIVE EVALUATION OF KA6 X-RAY HANDHELD CAMERA VERSUS CONVENTIONAL X-RAY TO SUPPORT THE DIAGNOSIS OF PULMONARY TUBERCULOSIS (TB) THROUGH CHEST X-RAY.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1212</b>	<b>Dr. Muhammad Irfan</b> Department of Medicine Aga Khan University Karachi	<ul style="list-style-type: none"> <li>Budget is mentioned as provisional. It may be elaborated.</li> <li>There is no mention of how pregnant women shall be x rayed? Any protocol for shielding will be done.</li> <li>The software if included in processing the x rays then mention how confidentiality shall be addressed.</li> <li>What is the cost of this gadget? How it compares in cost effectiveness with already existing available x ray chest machine?</li> <li>Provide satisfaction survey form. Also share feedback forms to be used.</li> </ul>

Title: **IDENTIFICATION OF PUTATIVELY DETRIMENTAL MUTATIONS ASSOCIATED WITH RECURRENT MISCARRIAGES IN PAKISTAN..**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1213</b>	<b>Dr. Farheena Iqbal Awan</b> DNA Core Facility, Center for Applied Molecular Biology (CAMB), University of the Punjab Lahore	<ul style="list-style-type: none"> <li>Are pharmacogenomics or epigenetic therapies available in Pakistan? That appears to be the actual benefit for the study participants. Other are just the risk factors and counseling can be done based upon available literature.</li> <li>Mention the details about the staff trained for this study.</li> <li>Ethical approval is still awaited from the universities. Mention name of the universities and share it with NBC.</li> <li>The informed consent is for blanket approval for all the future genetic studies. This is not appropriate. This is not mentioned in the ERC form.</li> <li>Elaborate which part of the research shall be done in Pakistan? What steps shall taken for capacity building?</li> <li>IRB approval letter of Punjab university is not on IRB letterhead.</li> <li>There is no MTA.</li> </ul>



		<ul style="list-style-type: none"> <li>• There is no data sharing agreement document.</li> <li>• There is no mention of study sites from where samples shall be collected with IRB approval in ERC form.</li> <li>• There is no mention of clinical site Co PIs. Clearly mention all the sites as it is written from all over Pakistan.</li> <li>• Budget is not at hand. It is an essential requirement.</li> <li>• Number of samples to be collected is also not mentioned.</li> <li>• The protocol is missing. Also missing is who will be taken as a case of RPL? Which definition will be used. Sample size and how many from different sites is also not found.</li> <li>• Only genetic causes are not responsible for RPL, there are number of other etiological factors. Asking if you have thyroid disorder, is not enough. The other etiological factors especially auto immune disorders need to be ruled out, before genetic cause is being ascertained. In this context mention which tests shall be done and who will pay for it? Provide details of any blood or other tests to be done on parents.</li> <li>• The amount of sample which is required should be mentioned, because the sample needs to be sent for histopathology as well, in order to rule out molar pregnancy.</li> <li>• The consent form is ambiguous, needs to be written, explaining what is being done in easy language.</li> <li>• There is no mention that results will be shared. This is unethical. These subjects are very desperate with repeated pregnancy losses. A misdirected research will make them believe that there is something inherently wrong in their genes, and they can not procreate. The pregnancy rate has been found to be reasonable after RPL.</li> <li>• Psychological counseling may be required but there is no mention of it. There is no mention of how these women shall be treated.</li> <li>• Which of the mutations PI is particularly interested in?</li> <li>• It is also mentioned, there may be change of institution if funding is not secured.</li> <li>• The PI should be suggested to resubmit in light of above comments as at present essential requirements for the evaluation of the proposal are not met.</li> </ul>
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Title: **AN OPEN LABEL CLINICAL STUDY BCD 248. RELAPSE AND REFRACTORY MULTIPLE MYELOMA.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1214</b>	<b>Dr. Munira Borhany</b> Zia Uddin University Hospital, 4/B, Sharah-e-Ghalib, Block 6, Clifton, Karachi	<ul style="list-style-type: none"> <li>• It is a phase II trial to be conducted at Four sites. Russian Drug.</li> <li>• 21 bullet in IFC is incorrect. The project is being reviewed and not approved yet.</li> <li>• Phase II does not fall under the “treatment” category. Informed consent form give this information which is deceptive. “Phase II clinical trials may also provide more information about the safety of the new treatment and</li> </ul>

		<p>how the treatment affects the body”.</p> <ul style="list-style-type: none"> <li>• A 24 page informed consent form is too long plus 5 page bio-sample data. It is mentioned that in Urdu “lamehdood” purpose. It is to be re visited.</li> <li>• It is mentioned that the trial can be stopped any time. What shall be done for the patients in this context? What alternate treatment shall be provided to them?</li> <li>• AKU IRB approval letter is not found.</li> <li>• MTA should be on a legal paper.</li> <li>• DSMB from Pakistan is not found.</li> <li>• Is insurance cover valid for Pakistan?</li> <li>• Data transfer agreement is not found.</li> <li>• Head wise budget and how much amount to be paid to each Co PI is not found.</li> <li>• How much money shall be transferred to KEMU treasury account is also not found.</li> <li>• What is the probable cost of this drug?</li> <li>• Will it be available in future in Pakistan once the study is completed?</li> <li>• What alternate treatment patients shall receive once study is completed?</li> <li>• Is the trial registered in international registry?</li> <li>• What are the other countries in which this trial is currently being carried out?</li> <li>• Share brief results of Phase I trial.</li> <li>• Is the drug approved for use in Russia? If not then The PI at the local hospital should wait for drug approval from Russian authorities.</li> <li>• These are moribund patients, who have failed with multiple drugs in achieving remission, There may be an element of therapeutic misconception. How it will be addressed?</li> </ul>
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**Member Secretary NBC-R**



**Chairperson NBC-R**

## Minutes of the NBC-R meeting held on 04-03-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on March 4<sup>th</sup>, 2025. 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. Munir Saleemi	Member
4. Prof. Dr. Nazli Hossain	Member
5. Prof. Dr. Marie Andrades	Member
6. Prof. Dr. Saqib Mehmood	Member
7. Prof. Dr. Amjad Mehboob	Member
8. Prof. Dr. Sualeha Siddiq Shekhani	Member
9. Dr. Farkhanda Ghafoor	Member

**The following projects reviewed / discussed:**

Title: **Leveraging consanguinity in Pakistan to uncover the genomic architecture of Alzheimer's disease: ENIGMA-PAK Feasibility Study.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1215</b>	<b>Prof. Salman Kirmani</b> Department of Pediatrics and Child Health, Aga Khan University, <b>Karachi</b>	<ul style="list-style-type: none"> <li>Please explain the rationale for having more samples from the peri-urban sites rather than the urban site.</li> <li>The questionnaire has been taken directly from the Indian Longitudinal Ageing Survey with terms used commonly in India. It needs a Pakistani context.</li> <li>If a participant screens positive for anxiety or depression or dementia or there is an abnormal MRI to whom will the patient be referred?</li> <li>There is no Urdu informed consent, in addition there is no informed consent for the caregiver.</li> <li>The MTA needs to be drafted onto a legal paper.</li> </ul>

Title: **Expired Platelet Concentrates (PCs) for preparation of growth factor richbiologics-Human Platelet Lysate (HPL).**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1217</b>	<b>Dr Raheela Ali</b> Hussaini Blood Bank, Head Office PLOT # ST 02, BLOCK T, QALANDARIA CHOWK, opposite Talib Chaman Park, North Nazimabad Town, <b>Karachi</b>	<ul style="list-style-type: none"> <li>Please explain why this had to come to NBC as this is not a research study but just a transfer of platelet products abroad.</li> <li>What normally happens to expired platelets in blood banks? If China is utilizing these waste products why cannot we do it in Pakistan? What capacity building is there so that Pakistan can develop HPL even if this project is approved?</li> <li>A Material Transfer Agreement needs to be developed on a legal paper.</li> </ul>

Title: **Trial: Self-Coping and Resilience in Quality of Life: An RCT of Problem-Solving Therapy for Preventing Recurrence of Myocardial Infarction and Stroke in Haripur, Pakistan.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1218</b>	<b>Dr Shahbaz Ahmed Zakki</b> The University of Haripur near swat chowk <b>Haripur 22620,</b> <b>KPK,</b>	<p>The study duration of 1 year is not sufficient to answer the 3rd objective "To monitor the recurrence of MI and stroke, along with associated risk factors, among the recruited population in Haripur, Pakistan."</p> <ul style="list-style-type: none"> <li>Informed consent needs to be rewritten. No mention of RCT, duration of study and intervention in detail.</li> </ul>

		<p>Complete rewrite required</p> <ul style="list-style-type: none"> <li>• For participants in both groups , if severe depression is found what measures will be taken?? Where will they be treated</li> <li>• Some of the questions in the questionnaire do not make sense like asking them the following. They may not know the answers <ul style="list-style-type: none"> <li>○ What are your most recent physiological measurements? (Please provide values for the following)</li> <li>○ Blood Pressure: mmHg</li> <li>○ HDL (Good Cholesterol): mg/dL</li> <li>○ LDL (Bad Cholesterol): mg/dL</li> <li>○ Weight: kg</li> <li>○ Height: cm</li> <li>○ Blood Glucose mg/dL</li> <li>○ Other relevant measurements (e.g. BMI, Waist Circumference):</li> </ul> </li> <li>• Another question in the questionnaire: Do any of your family members provide you: Social Support Psychological Support No Support. <b>This question is open for interpretation and inappropriate as puts the person in a defensive position</b></li> <li>• For weight we use KG NOT pounds as mentioned in questionnaire</li> <li>• <b>The questions need to be culturally appropriate. We don't use Shake off the Blues:</b> I felt that I could not shake off the blues even with help from my family or friends.</li> </ul>
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### **Next meeting:**

The next zoom meeting will be held at 02:30 pm on 18<sup>th</sup> March, 2025. The following projects will be reviewed:

**NBCR-1129 NBCR-1220, NBCR-1221 and NBCR-1222.**

## Minutes of the NBC-R meeting held on 18-03-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on March 18<sup>th</sup>, 2025. 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. Munir Saleemi	Member
4. Prof. Dr. Nazli Hossain	Member
5. Prof. Dr. Saqib Mehmood	Member
6. Prof. Dr. Marie Andrades	Member
7. Prof. Dr. Amjad Mehboob	Member
8. Dr. Farkhanda Ghafoor	Member
9. Dr. Sualeha Siddiq Shekhani	Member

**The following projects reviewed / discussed:**

Title: **Lu-177 based Synovectomy in the Management of Chronic Inflammatory Joint Diseases.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1129	<b>DR. Aakif Ullah Khan</b> Director & Chief Medical Officer, Institute of Radiotherapy and Nuclear Medicine (IRNUM), Peshawar, Pakistan	<ul style="list-style-type: none"> <li>Clinical Trial Classification: The proposal states that this study is not a clinical trial; however, evaluating the efficacy and safety of Lutetium-177 (Lu-177) compared to established radioisotopes (Yttrium-90 and Rhenium-188) clearly falls under the category of a clinical trial. When a study involves human participants and assesses therapeutic efficacy and safety, it must adhere to clinical trial protocols, including registration and ethical considerations.</li> <li>Study Design: To achieve a proper comparison, the study should include two distinct patient groups: <ul style="list-style-type: none"> <li>One group treated with established isotopes (Yttrium-90 or Rhenium-188).</li> <li>Another group treated with the indigenous Lu-177. This comparative approach will provide credible data on efficacy and safety.</li> </ul> </li> <li>Selection of Patients: The inclusion and exclusion criteria for the recruitment of patients is not given. It is crucial that patients are selected carefully, considering factors such as joint condition, previous treatment response, and overall bleeding risk during minor surgical procedures. Moreover, clinicians often consider general health status and comorbidities that could complicate the procedure or recovery process.</li> <li>Patient Information Sheet and Consent Form: In the previous submission, the NBC committee raised concerns about the inadequate patient information sheet and consent form. The revised proposal does not include these essential documents.</li> <li>What is the cost of Lu-177 based RIO?</li> <li>How will efficacy, safety and feasibility be measured? Please clarify your clinical end points.</li> <li>How will side effects be managed? Who will pay for them? Are there any radiation hazards?</li> <li>The aims and objectives read more like a wish list rather than actual measurable objectives.</li> <li>How will patients be recruited?</li> <li>The rationale for radioisotope therapy for hemophilia needs more convincing. Hemophilia is a condition that</li> </ul>

		will persist throughout life. Synovectomy will treat the consequence of the disease but not the disease itself.
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Title: **Nutritional Supplementation in Pregnancy to Neutralize Heat Stress.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1220	<b>Dr. Junaid Iqbal</b> Department of Paediatrics and Child Health Aga Khan University <b>Karachi</b>	<ul style="list-style-type: none"> <li>Once the study is over and if the supplementation is found to be useful how will it be provided as a post-trial benefit to the involved communities? Will it be affordable for them?</li> <li>Informed consent form needs to mention that even the non-supplementation group will have to provide their samples.</li> <li>Where patients would be referred if they have mental health issues. Is there a mental health expert on board?</li> <li>What is the exact recipe of the nutritional supplement? Will it be socially and culturally acceptable and feasible?</li> <li>Participants in the non-supplemental group may feel disadvantaged. Should they not be provided a standard meal?</li> <li>We would like to see an itemized budget of this project.</li> </ul>

Title: **WEIGHT DIVERSE Study: Prevalence of weight related complications across Diverse Weight Classifications – A large cross-sectional study in India, Pakistan, Philippines and Vietnam.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1221	<b>Dr. Abbas Raza:</b> National Hospital, Lahore <b>Dr. Mohammad Ali Arif:</b> Pakistan Institute of Medical Sciences, Islamabad <b>Dr. Amna Subhan:</b> Aga Khan University Hospital, <b>Karachi</b> <b>Dr. Bilal Afzal:</b> Mukhtar A. Sheikh Hospital, Multan <b>Dr. Azizul Hassan Aamir:</b> Peshawar General Hospital, Peshawar	<ul style="list-style-type: none"> <li>Study Approved.</li> </ul>

Title: **The Provision of Cardiac Rehabilitation in Pakistan: A National Survey.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1222	<b>Prof. Imran Bashir Chaudhry</b> Suit 201, 2nd floor, Dr. Plaza, do talwar, Clifton, <b>Karachi</b>	<ul style="list-style-type: none"> <li>Please clarify the rationale of this study by an institute that deals with mental health issues and how its results will be useful to Pakistani society. We were surprised that no cardiologists are on board.</li> <li>What is the role of Ziauddin University? Its IRB approval would be required.</li> <li>Please submit an itemized budget with funding source.</li> </ul>

**Next meeting:**

The next zoom meeting will be held at 02:30 pm on 8<sup>th</sup> April, 2025. The following projects will be reviewed:

**NBCR-1223, NBCR-1225 and NBCR-1226.**



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**Member Secretary NBC-R**



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**Chairperson NBC-R**

## Minutes of the NBC-R meeting held on 08-04-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on April 8<sup>th</sup>, 2025. The following members of NBC-R attended the meeting:

1. Prof. Dr. Jamshed Akhtar	Chair the Meeting
2. Prof. Dr. Munir Saleemi	Member
3. Prof. Dr. Nazli Hossain	Member
4. Prof. Dr. Amjad Mehboob	Member
5. Prof. Dr. Sualeha Siddiq Shekhani	Member (Sent comments on email)
6. Ms. Tayyaba Rahat	National Coordinator NBC-R
7. Miss. Ayesha Abid	Assistant (NBC-R Secretariat)

**The following projects reviewed / discussed:**

Title: **“A Phase 3 Randomized, Open-Label Study to Evaluate the Efficacy and Safety of Tobeivibart + Elebsiran Combination Therapy in Participants with Chronic HDV Infection (ECLIPSE 1)”.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1223	<b>Dr. Saeed Hamid</b> Dept of Medicine Aga Khan University, Karachi	<ul style="list-style-type: none"><li>Study Approved.</li></ul>

Title: **Exploring the psychosocial needs of teenage children of parent with breast cancer in a low-middle income country.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1225	<b>Dr. Mueen Abid</b> Pakistan Institute of Living and Learning (PILL) Karachi	<ul style="list-style-type: none"><li>Please elaborate on the rationale of this study. What will this study hope to achieve for the participants?</li><li>The project mentions that this study is an RCT but it is not in actuality.</li><li>Please explain the methodology of this study. How will the participants be contacted without feeling that their privacy has been breached?</li><li>Why has Qambar Shahdad Kot been selected as a study site whereas the study can be completed in any of the big cities?</li><li>Is there an MoU with PILL and the associated hospitals where data will be collected?</li><li>Where will the interviews be conducted?</li><li>Any compensation or token of appreciation to be offered to the participants?</li><li>Assent form has to be attached.</li></ul>

Title: **Quick Immunization Coverage Survey in High-Risk Districts.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1226	<b>Dr. Sajid Bashir Soofi</b> Dept of Paediatrics, Associate Director Centre of Excellence in Women and Child Health (CoE-WCH), Aga Khan University (AKU), Karachi.	<ul style="list-style-type: none"><li>Please clarify the operational definition of a High Risk District.</li><li>Please justify the rationale of this study as is it not a routine activity to do a survey after immunizations? What new information is being added by this study?</li><li>What about safety and security of the investigators especially if they have to collect data from conflict areas like Baluchistan?</li></ul>

**Next meeting:**

The next zoom meeting will be held at 02:30 pm on 15<sup>th</sup> April, 2025. The following projects will be reviewed:

**NBCR-1227, NBCR-1228 and NBCR-1229.**



## Minutes of the NBC-R meeting held on 15-04-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on April 15<sup>th</sup>, 2025. The following members of NBC-R attended the meeting:

1. Prof. Dr. Jamshed Akhtar	Chair the Meeting
2. Prof. Dr. Munir Saleemi	Member
3. Prof. Dr. Nazli Hossain	Member
4. Prof. Dr. Amjad Mehboob	Member
5. Dr. Farkhanda Ghafoor	Member
6. Ms. Tayyaba Rahat	National Coordinator
7. Mr. Waryal Ali Daheri	LDC

### The following projects reviewed / discussed:

Title: **Trial: Community-pharmacies managing hypertension: intervention development and evaluation in Bangladesh and Pakistan (COPE-BP).**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1227	<b>Dr. Saima Afaq</b> Institute of Public health and Social Sciences, Khyber Medical University, Peshawar, Pakistan	<ul style="list-style-type: none"> <li>There are five work packages of this proposal. This includes mere interviews to intervention trials. All are grouped at present in one application. This is not appropriate as results of package 1 will inform interventions that are not known at present to be implemented at later stage. Thus PI must de link different packages and submit proposals as separate research protocols.</li> <li>In context of Pakistan what is a community pharmacist? What are their roles and responsibilities and in which part of the KPK they exists / practice and can be verified?</li> <li>A reference and documents may be provided that should cover legal position as well in context of a pharmacist being involved in managing hypertension considering vast geographical context of Pakistan, rural, peri urban and even urban areas where pharmacies are situated in shops and non technical persons running them. DG of concerned department who has endorsed this study may provide evidence in this context.</li> <li>Pharmacists in this proposal are equated to medical doctors. Pharmacists as such are not authorized to recommend any treatment / intervention. They can only carry out the instructions and guide patients about the medicine to be used. At present in which part of KPK medicines are solely dispensed by the pharmacists? What type of collaboration at present exist between doctors and pharmacists? PM &amp;DC issues license to the registered doctors only to practice. This appears to be contradictory to the existing law of Pakistan. This may further add to misconception in minds of ordinary people and confusion may occur between roles of doctors and pharmacists. The curriculum of D Pharm may be shared and pointed out where clinical training is received by them.</li> <li>Is PI currently employed in two different institutions? This is mentioned in CV. This may be explained.</li> <li>Remove NBC address from whom to contact in informed consent form.</li> <li>The IRB approval letter lacks the details of the members and any reference to the meeting where approval was given. Dean name is also mentioned in this document which is not present in IRB form. If he is a co PI then mention his name in the main document.</li> <li>What are the responsibilities of PI in UK and Co PI in Peshawar in context of this study? How on ground they will work?</li> </ul>

Title: **Trial: Randomized trial to evaluate and compare the immunogenicity and safety of hexavalent vaccine in healthy infants in a polio-endemic country.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1228	<b>Dr. Ali Faisal Saleem</b> Department of Paediatrics and Child Health, Centre of Excellence – Women & Child Health, 2nd floor Aga Khan University, Stadium Road, Karachi	<ul style="list-style-type: none"> <li>It is suggested to involve relevant government departments at national and provincial level. There is a chance that a study by an individual who is also a member of technical advisory committee at international level may lead to a conflict of interest and by-passing government departments, EPI program lead, may be counterproductive.</li> <li>What is the cost of vaccine? Who will provide it if found useful?</li> <li>Is government of Pakistan not planning to include it in EPI program as it is already in use? This is already in practice in some countries and WHO recommendations are also found.</li> <li>Share AKU IRB approval letter.</li> <li>Share the names of DSMB members.</li> <li>Provide funding approval letter.</li> <li>What shall be amount paid as imbursement for the parents?</li> <li>At least provide a rough number of participants in IRB form that shall be enrolled and from each study site.</li> <li>How PI will tell the communities that they are not part of EPI program and are conducting study on their own?</li> <li>What impact it might cause?</li> <li>Will parents be informed about the results of the study?</li> <li>It is mentioned at a place that shall be shared. Provide details of a need of data sharing and for what purpose.</li> <li>Provide details of how biological samples shall be collected from study sites, stored and transferred to NIH? Who will pay for it?</li> <li>Will results of the study be shared with the parents?</li> </ul>

Title: **Association of MiRNA with Cardiometabolic Syndrome for Early Detection and Management.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1229	<b>Prof. Dr. Iram Murtaza</b> Department of Biochemistry, Quaid-i-Azam University, 45320 Islamabad	<ul style="list-style-type: none"> <li>Share the results of previous study done by the PI group and was NBC R approval obtained for that study.</li> <li>There is a difference between objectives and outcomes. At places PI is interested in coronary artery diseases, and other mentions cardiometabolic disorder. This needs clarification.</li> <li>Inclusion criteria also says people without cardiometabolic disorders, how will it be ascertained. Who will be paying for the plethora of tests needed to exclude it?</li> <li>Why women are excluded? They suffer from large number of cardiometabolic disorders too.</li> <li>Settings are unclear, tertiary hospitals of only KPK? Or will it also include other provinces?</li> <li>The PI has not justified the importance of the diagnostic test. The protocol only has 4 references,</li> </ul>

		<p>which are a decade old.</p> <ul style="list-style-type: none"> <li>• What will be the utility of the test, in face of rapid testing services currently available. Considering the logistics as has been explained in the protocol.</li> <li>• Will this marker be available in future in Pakistan? Considering decades old data on the subject why it is not translated into the clinical practices yet?</li> <li>• There are a number of flaws in the questionnaire. Even gender is mentioned while women are not included. Diseases are also not clearly defined.</li> <li>• Methods of harvesting blood samples are also incorrect.</li> <li>• Will patients know about the results of the test?</li> <li>• Why RMI is chosen as a study site?</li> <li>• What is included in the management of the patients? Where this management shall be done?</li> <li>• Why study cannot be done in general population? Why it is a hospital based data collection.</li> <li>• How shall results be validated in subjects who are not suffering from any cardiac ailments?</li> <li>• What if positive results are reported? What shall be the strategy from this point onwards?</li> <li>• Where the permanent equipment shall be housed that amount to about 68 lakh rupees? Is this equipment part of already ongoing project of PI which appears similar?</li> <li>• What shall be done with the instrument when study ends?</li> <li>• Will biological samples shall be used for any other purpose?</li> </ul>
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### **Next meeting:**

The next zoom meeting will be held at 02:30 pm on 22<sup>nd</sup> April, 2025. The following projects will be reviewed:

**NBCR-1231, NBCR-1232 and NBCR-1233.**

## Minutes of the NBC-R meeting held on 22-04-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on April 22<sup>nd</sup>, 2025. 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. Munir Saleemi	Member
4. Prof. Dr. Saqib Mehmood	Member
5. Prof. Dr. Marie Andradess	Member
6. Prof. Dr. Amjad Mehboob	Member
7. Dr. Farkhanda Ghafoor	Member
8. Ms. Tayyaba Rahat	National Coordinator
9. Mr. Waryal Ali Daheri	LDC

### The following projects reviewed / discussed:

Title: **An Integrated Approach to Lung Health: Innovations for Vulnerable Populations in Pakistan.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1231	Ms. KINZ UL EMAN, ACCA, MS, MGH, Ph.D (in Progress) House 57 Central Ave, Bahria Town Phase VI Phase 6 Bahria Town, Islamabad	<ul style="list-style-type: none"><li>These are 5 different projects grouped into one protocol. Each project has a different dimension and needs to be evaluated separately.</li><li>A lot of this proposal is theoretical lacking objectivity like where exactly the study will be done, which districts are involved, how will subjects be recruited, how many etc.</li><li>With whom will the biological samples be shared with? Are they being sent abroad? If so. data sharing agreement will need to be attached.</li><li>Why are pregnant women excluded?</li><li>Point 3.5 in informed consent form needs elaboration. Why will the results not be given to the participants?</li></ul>

Title: **Exploring the challenges of Polio Eradication in Pakistan..**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1232	Dr. Zubia Mumtaz School of Public Health, University of Alberta 3-309 Edmonton Clinic Health Academy 11405-87 Ave, Edmonton, Canada	<ul style="list-style-type: none"><li>Study Approved.</li></ul>

Title: **Brain Tumor Registry and Biorepository at Nationwide Children's Hospital.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1233	Dr. Naureen Mushtaq Dept of Oncology Aga Khan University 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 29<sup>th</sup> April, 2025. The following projects will be reviewed: NBCR-1235, NBCR-1236 and NBCR-1237.

## Minutes of the NBC-R meeting held on 29-04-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on April 29<sup>th</sup>, 2025. 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. Munir Saleemi	Member
4. Prof. Dr. Saqib Mehmood	Member
5. Prof. Dr. Amjad Mehboob	Member
6. Dr. Farkhanda Ghafoor	Member
7. Ms. Tayyaba Rahat	National Coordinator
8. Ms. Ayesha Abid	Assistant
9. Mr. Waryal Ali Daheri	LDC

### The following projects reviewed / discussed:

Title: **To Explore the Transmission Dynamics of HDV Infection and Health Related Quality of Life Assessment in Selected Rural Communities of Sindh, Pakistan.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1235	<b>Dr Ashraf Ali Lakho,</b> FELTP Fellow 15th Cohort, NIH Islamabad	<ul style="list-style-type: none"><li>• Please clarify for us the rationale of this proposal. What are the gaps in knowledge and how will this study help in filling these gaps?</li><li>• Will HDV positive subjects be given treatment? If yes, by whom?</li><li>• What is the role of Abbot Pharmaceuticals in this study?</li><li>• Why is the sample being collected from one district in Sindh?</li><li>• The informed consent form needs to be in Sindhi.</li><li>• How is this study aligned with National hepatitis programs?</li></ul>

Title: **Prospective Cohort Comparative-Arm Observational Study to Assess the Impact of a High Fiber Supplement on Lipid Profile in Type 2 Diabetic Patients.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1236	<b>Dr. Abbas Raza</b> National Hospital & Medical Center, Street 123, Sector L Dha Phase 1, Lahore <b>Dr Ayesha Nageen</b> Creek General Hospital, Sector 48-H, Creek Road, Sector 48 H Korangi Creek, Karachi,	<ul style="list-style-type: none"><li>• This study is not a cohort study; it is an interventional study and should be designed as such.</li><li>• Please mention the interventional product and its composition? Have previous studies been done on this product?</li><li>• Please resubmit the project according to its methodology.</li></ul>

**Title: Assessment of Blood Lead Levels in 1-6 years old Children residing in High-risk Areas across Pakistan: Evidence for Policy Action.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1237	<b>Dr. Mariyam Sarfraz,</b> Associate Professor, Health Services Academy, Islamabad	<ul style="list-style-type: none"><li>• Please clarify the rationale of this project. A lot of things are already known about lead poisoning and how is this aligned with national services.</li><li>• If a child is determined to have high lead levels, how will this be dealt with?</li><li>• The questionnaire talks about imported canned food, imported toys whereas in our society there are multifactorial causes of lead poisoning.</li><li>• What are the potential consequences if a family is known to suffer from high lead levels? What options do they have for retribution? How will water supply and industries come into play?</li></ul>

**Next meeting:**

The next zoom meeting will be held at 02:30 pm on 6<sup>th</sup> May, 2025. The following projects will be reviewed: **NBCR-1238, NBCR-1239 and NBCR-1240.**



**Member Secretary NBC-R**



**Chairperson NBC-R**

## Minutes of the NBC-R meeting held on 06-05-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on May 6<sup>th</sup>, 2025. 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. Nazli Hossain	Member
4. Prof. Dr. Saqib Mehmood	Member
5. Prof. Dr. Marie Andrades	Member
6. Prof. Dr. Sualeha Siddiq Shekhani	Member (Sent comments on email)
7. Miss. Ayesha Abid	Assistant (NBC-R)
8. Mr. Waryal Ali Daheri	LDC (NBC-R)

The following projects reviewed / discussed:

Title: **Trial: Establishing a Maternal Immunisation Readiness Network in Africa and Asia (MIRNA) to identify, characterise and support the platform, policy, and preparedness requirements for the introduction of potential new maternal vaccines to prevent infectious diseases.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1238	<b>Dr. Muhammad Imran Nisar</b> Department of Paediatrics and Child Health, The Aga Khan University, Karachi.	<ul style="list-style-type: none"><li>Study Approved.</li></ul>

Title: **Assessing and Exploring Karachi Fathers' Parenting Beliefs, Identity, and Practices During Transition to First-Time Parenthood.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1239	<b>Dr. Shelina Bhamani</b> Dept of Obstetrics and Gynecology Aga Khan University Karachi	<ul style="list-style-type: none"><li>The survey instrument does not seem to answer the research question identified. A lot seems to be out of the cultural context of Pakistan.</li><li>Do we have antenatal classes in the context that is being studied?</li><li>What classes or literature will be given to the antenatal mothers and fathers?</li></ul>

Title: **International Pleuropulmonary Blastoma / DICER1 Registry (for PPB, DICER1 and Associated Conditions).**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1240	<b>Kris Ann Schultz</b> Children's Minnesota 910 East 26th Street., Suite 40-LL08 Minneapolis, MN 55404 USA <b>Dr. Alina Sadaf</b> Head of Department of Pediatric Oncology Shaukat Khanum Memorial Cancer Hospital & Research Centre, 7A, Block R3, Johar Town, Lahore	<ul style="list-style-type: none"><li>Why should the US agency have access to the data only? Why should not the PI in Pakistan be able to access the data of our own patients as we are contributing to the registry?</li></ul>

**Next meeting:**

The next zoom meeting will be held at 02:30 pm on 13<sup>th</sup> May, 2025. The following projects will be reviewed:

**NBCR-1242, NBCR-1243 and NBCR-1244.**



## Minutes of the NBC-R meeting held on 13-05-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on May13<sup>th</sup>, 2025. 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. Nazli Hossain	Member
4. Prof. Dr. Amjad Mehboob	Member
5. Dr. Farkhanda Ghafoor	Member
6. Assistant Prof. Sualeha Siddique Shekhani	Member
7. Mr. Waryal Ali Daheri	LDC NBC-R

**The following projects reviewed / discussed:**

Title: **Trial: Asymptomatic Bacteriuria in Pregnancy in Low- and Middle-Income Countries.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1242	<b>Dr. Shiyam Sunder</b> Dept of Community Health Sciences Aga Khan University Karachi	<ul style="list-style-type: none"> <li>Has this trial been registered with <a href="https://clinicaltrials.gov/">clinical.gov</a>?</li> <li>Why can this trial not be conducted in the main AKUH hospital as there would be ample cases there? Please justify the need to go to a poor community like Makli and Sakro.</li> <li>Why is the intervention drug only Nitrofurantoin?</li> <li>It mentions that patients may be referred to civil hospital Makli if needed. Will any indemnity insurance be provided or will the patient have to bear this cost? It is mentioned on the ICF that the health insurance is the responsibility of the patient. Is that truly so?</li> <li>If a child is born premature, where will that child receive health services?</li> <li>What is the data sharing agreement with the funders and collaborators?</li> <li>Please clarify the need to follow these patients postpartum and doing additional tests like placental growth factor.</li> </ul>

Title: **Trial: Immunogenicity and Safety of a Rabies Vaccine (Serum-free Vero Cell), Freezedried in Comparison with Verorab®, in a Simulated Post-exposure Prophylaxis Regimen in Healthy Populations Aged ≥1 years: A Randomized, Double-Blind, Active-controlled Phase III Clinical Trial.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1243	<b>Prof. Dr. Ume Sughra</b> AI-Shira Research Centre, AI-Shira Trust Eye Hospital, Rawalpindi	<ul style="list-style-type: none"> <li>Please clarify what is meant by a simulated post exposure prophylaxis? Will the rabies virus be inoculated into healthy subjects to determine a response?</li> <li>Why could this study not be done in China?</li> <li>What are results of Phase 1 and Phase 2 trials?</li> <li>We are concerned about the safety of study participants. Where will enrolment and monitoring be carried out? Does Shifa Eye trust have facilities and trained manpower to monitor for adverse events?</li> <li>Will there be any indemnity insurance?</li> <li>The informed consent form and data tool needs to be revised in our context. It asks if a child is sexually active or not. Why is there a need to screen for other diseases?</li> <li>Is the trial site registered with DRAP for this trial?</li> </ul>

**Title: Sustaining Private Providers Integration for Routine Immunization-Integrated Services in Underserved Areas of Karachi.**

<b>Project #</b>	<b>PI Name &amp; Address</b>	<b>Final NBC-R Comments</b>
<b>NBCR-1244</b>	<b>Dr. Zahid Memon</b> Department of Community Health Sciences Aga Khan University Karachi	<ul style="list-style-type: none"><li>• Study Approved.</li></ul>

**Next meeting:**

The next zoom meeting will be held at 02:00 pm on 20<sup>th</sup> May, 2025. The following projects will be reviewed:

**NBCR-1245, NBCR-1246 and NBCR-1248.**

## Minutes of the NBC-R meeting held on 20-05-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on May 20<sup>th</sup>, 2025. 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. Munir Saleemi	Member
4. Prof. Dr. Amjad Mehboob	Member
5. Dr. Farkhanda Ghafoor	Member
6. Ms. Tayyaba Rahat	National Coordinator
7. Mr. Waryal Ali Daheri	LDC NBC-R

**The following projects reviewed / discussed:**

Title: **Community Mobilization and WASH Education under Rooftop Rainwater Harvesting in Murree District.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1245	<b>Dr. Fozia Parveen</b> AKU-IED 1-5/b-VII, 1-5/B Street 7, Federal B Area Karimabad Block 7 Gulberg Town, Karachi	<ul style="list-style-type: none"> <li>Study Approved.</li> </ul>

Title: **Trial: Clinical and Cost-effectiveness of an Integrated Psychosocial Care Plan for Comorbid Depression in Breast Cancer survivors In Pakistan: A Sequential Multiple Assignment Randomised Trial.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1246	<b>Prof Nasim Chaudhry</b> Pakistan Institute of Living and Learning Suite No. 201, 2nd Floor, The Plaza, Karachi	<ul style="list-style-type: none"> <li>Please clarify the rationale for doing this study. Is it not a standard of care already? All breast cancer survivor patients should be receiving some form of psychosocial care for treating their depression. Also explain what is meant by cost-effective care in our setting.</li> <li>Please mention the local collaborators from each of the sites. Will they be the ones delivering the interventions?</li> <li>Is this trial being registered with <a href="https://clinicaltrials.gov/">clinical.gov</a>?</li> <li>What is the data sharing agreement between the sponsors and the collaborating institutes?</li> </ul>

Title: **Strengthening of Routine Immunization in Polio High-Risk Districts of Balochistan.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1248	<b>Mr. Imtiaz Hussain</b> Department of Paediatrics and Child Health Aga Khan University Karachi	<ul style="list-style-type: none"> <li>In introduction many strong words are used without providing any reference in ERC form. This includes "dysfunctional EPI dispensaries, and compromised services". These may demotivate existing staff who still are involved in providing essential services wherever possible.</li> <li>It will be of interest, working in a same setup how a</li> </ul>

		<p>dramatic change is expected by the intervention that PI plans to implement. Reasons of barriers in vaccination drive are routinely uploaded in national data base of EPI.</p> <ul style="list-style-type: none"> <li>The PI mentions that the organization has the experience of running of 12 EPI Dispensaries in two very challenging districts of Balochistan Province (Killa Abdullah and Chaman). Kindly share the statistics of two districts that you have mentioned. We noticed that same districts are also mentioned in the current protocol.</li> </ul> <p><b>Under objectives it is mentioned that.</b>  <b>The primary objectives of the intervention include:</b></p> <ul style="list-style-type: none"> <li><b>Strengthening Immunization Services and Enhancing Coverage:</b> Improve the Expanded Program on Immunization (EPI) services in both static and outreach areas within the target districts to ensure wider access and increased vaccination rates.</li> <li><b>Creating Demand for Routine Vaccination:</b> Mobilize communities and raise awareness about the importance of routine immunization by engaging health counsellors and Lady Health Workers (LHWs).</li> <li><b>Supporting Governance and Accountability:</b> Monitoring of the vaccination activities both at static and outreach points through Tehsil coordinators, regular meetings with District and provincial EPI teams, and through government-supported application and dashboard (NEIR).</li> </ul> <ul style="list-style-type: none"> <li>In context of two districts where the EPI dispensaries existed how was the PI able to implement these? Support with data from EPI national program.</li> <li>What are the plans for provision of security and high migration of the population? It appears that the PI will be working in an existing administrative setup. How will this study help the Baluchistan government? It is assumed same group of administrative functionaries will be involved in it.</li> </ul>
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**Next meeting:**

The next zoom meeting will be held at 02:00 pm on 27<sup>th</sup> May, 2025. The following projects will be reviewed: **NBCR-1249, NBCR-1250 and NBCR-1251.**

## Minutes of the NBC-R meeting held on 27-05-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on May 27<sup>th</sup>, 2025. 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. Munir Saleemi	Member
4. Prof. Dr. Nazli Hossain	Member
5. Prof. Dr. Saqib Mehmood	Member
6. Prof. Dr. Marie Andrades	Member
7. Prof. Dr. Amjad Mehboob	Member
8. Dr. Farkhanda Ghafoor	Member
9. Ms. Tayyaba Rahat	National Coordinator
10. Ms. Ayesha Abid	Assistant
11. Mr. Waryal Ali Daheri	LDC

### The following projects reviewed / discussed:

Title: **A linkable survey for zero-dose and under-immunized children in low-performing districts of Pakistan: Innovative quantification of zero-dose drivers.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1249	<b>Mr. Imtiaz Hussain</b> Department of Paediatrics and Child Health Aga Khan University Karachi.	<ul style="list-style-type: none"> <li>Study Approved.</li> </ul>

Title: **Identifying Innovative Solutions to Scale Up Self-Testing for Hepatitis C in Pakistani population.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1250	<b>Dr. Kashif Asghar</b> Pakistan Kidney and Liver Institute and Research Center (PKLI&RC), One PKLI Avenue, DHA, Phase-6, Lahore, Pakistan	<ul style="list-style-type: none"> <li>Please provide more details about the kit being used in this study. How sensitive and specific are the results? Has this kit been approved by DRAP? Is it available in the market? Will it be available in future if currently it is not marketed yet?</li> <li>How will study participants be approached and recruited? What incentives are there to be a part of the study?</li> <li>Who is the co-investigator from KPK? How will further testing and treatment be provided in KPK?</li> <li>Is there any alignment with the Hepatitis control program running in the country? What will happen if someone tests positive on the kit?</li> </ul>

**Title: Trial: Comparison of Treatment of Severe Acute Malnutrition (SAM) in Children 6-59 months old with standard Ready-to-use therapeutic food (RUTF) and newly formulated Lipid Optimized Ready-to-use-Therapeutic food (LO-RUTF): An Individual Randomized, Double-Blind, Controlled Trial.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1251</b>	<b>Dr. Gul Nawaz Khan</b> Department of Paediatrics and Child Health, Aga Khan University, National Stadium Road, Karachi	<ul style="list-style-type: none"> <li>• Please explain why this study needs to be done in Baluchistan. Severe malnutrition is present in most areas of Sindh where AKUH has its footprints. Is the trial site registered with DRAP?</li> <li>• Is there a potential of adverse events due to allergy etc. If yes, how and where will they be managed?</li> <li>• Please provide the information about Satya Food Company. Where is it based? From where will the RUTF be supplied to the trial site? Has this company been approved by our national food agency?</li> <li>• Satya Nutrition is based in India. Is it the same being supplied in Baluchistan? This could have strategic implications for the country.</li> </ul>

**Next meeting:**

The next zoom meeting will be held at 02:00 pm on 3<sup>rd</sup> June, 2025. The following projects will be reviewed: **NBCR-1252, NBCR-1253 and NBCR-1254.**




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**Chairperson NBC-R**

## Minutes of the NBC-R meeting held on 03-06-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on June 3<sup>rd</sup>, 2025. The following members of NBC-R attended the meeting:

1. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2. Prof. Dr. Munir Akhtar Saleemi	Member
3. Prof. Dr. Jamshed Akhtar	Member
4. Prof. Dr. Nazli Hossain	Member
5. Prof. Dr. Saqib Mehmood	Member
6. Prof. Dr. Marie Andrades	Member
7. Prof. Dr. Sualeha Siddiq Shekhani	Member
8. Dr. Farkhanda Ghafoor	Member
9. Mr. Waryal Ali Daheri	LDC (NBC-R)

**The following projects reviewed / discussed:**

Title: **Calcified Tissue generation using stem cells from human dental pulp: an in-vivo model.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1252</b>	<b>Dr. Tashfeen Ahmad</b> Department of Surgery, Aga Khan University, PO Box 3500 Stadium Road, Karachi	<ul style="list-style-type: none"> <li>With a co-PI from DUHS, we would like to see the IRB approval from DUHS as well</li> </ul>

Title: **Trial: Efficacy of probiotic supplementation in preterm and small for gestational age infants. A multi-centre, placebo- controlled, individually-randomised trial (Probiotics in preterm and small for gestational infants, PROPS trial).**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1253</b>	<b>Dr. Fyezah Jehan</b> Department of Pediatrics and Child Health, Aga Khan University, Karachi.	<ul style="list-style-type: none"> <li>Why is main AKUH not a trial site for this project? Selective use of patient population specifically from public sector hospitals is an ethical issue in our opinion.</li> <li>Please list the collaborators from each trial site. What is the sample expected from each site?</li> <li>JPMC neonatology ward does not provide comprehensive care of preterm infants. Where these babies will be referred out and get treatment?  <ul style="list-style-type: none"> <li>Mother appear to be the primary person to give consent. In our culture this does not always apply. She can get into trouble with her in laws.</li> <li><b>We will not be able to pay for additional hospital investigations or treatment.</b> This is not right if the baby develops an infection the cost of treatment should be borne by the study.</li> <li>Will red flags be taught to the mother?</li> <li>What supportive advice for infant care be given to the mother/family during the month the child is being treated.</li> </ul> </li> </ul> <p>Please mention the composition of the DSMB.</p> <p>The placebo consists of maltodextrin. Is it safe to use in this age group?</p>

Title: **Using metagenomic sequencing to evaluate the relationship between enteropathogens and microbial diversity with preterm birth in the Pregnancy Risk, Infant Surveillance, Measurement Alliance (PRISMA).**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1254	Dr. Fyezah Jehan Department of Pediatrics and Child Health, Aga Khan University, Karachi.	<ul style="list-style-type: none"> <li>The investigators have not mentioned about the settings of the study, where it will be conducted? Even if the study has enrolled participants from any other running trial, it should be mentioned in the NBC form. Went through the protocol as well, and could not find it there as well.</li> <li>There are other etiological factors for preterm birth, how they will be ruled out?</li> <li>What if ultrasound shows abnormalities what process of care will be guided to patient? <ul style="list-style-type: none"> <li><b>Your information will be included in a de-identified public-use database managed by the Bill &amp; Melinda Gates Foundation and shared with current and future research partners or affiliates for research, product development, or other commercial purposes, which will later be used to improve the lives of women and children in poor countries. <u>Needs further clarity in terms of use of their genomic information, DNA testing etc</u></b></li> </ul> </li> <li>Will biological samples be sent abroad? This is not clear. If so, please provide an MTA.</li> </ul>

**Next meeting:**

The next zoom meeting will be held at 02:00 pm on 17<sup>th</sup> June, 2025. The following projects will be reviewed:

**NBCR-1255, NBCR-1258 and NBCR-1129.**



## Minutes of the NBC-R meeting held on 17-06-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on June 17<sup>th</sup>, 2025. The following members of NBC-R attended the meeting:

1. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2. Prof. Dr. Munir Akhtar Saleemi	Member
3. Prof. Dr. Jamshed Akhtar	Member
4. Prof. Dr. Nazli Hossain	Member
5. Prof. Dr. Saqib Mehmood	Member
6. Prof. Dr. Marie Andrades	Member
7. Prof. Dr. Amjad Mehboob	Member
8. Prof. Dr. Sualeha Siddiq Shekhani	Member
9. Dr. Farkhanda Ghafoor	Member
10. Mrs. Tayyaba Rahat	National Coordinator (NBC-R)
11. Mrs. Ayesha Abid	Assistant (NBC-R)
12. Mr. Waryal Ali Daheri	LDC (NBC-R)

**The following projects reviewed / discussed:**

Title: **Intelligent Pregnancy Products Platform (13P): Implementation of digital intrapartum monitoring in LMIC.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1255</b>	<b>Dr. Zahra Hoodbhoy</b> National Stadium Rd, Aga Khan University Hospital, Karachi	<ul style="list-style-type: none"> <li>Please give the rationale for doing this project in Koohi Goth rather than in a more central part of the city?</li> <li>The high-risk cases will be transferred to JPMC which is more than a 100 km away. Why not use the AKUH satellite centers for this study?</li> <li>What about the cost of the equipment? Would it be justified if found to be effective but increase health care cost and if these centers would be able to afford them? Is there any post-trial access or potential benefit to our population?</li> <li>What is the likelihood of a machine fault? How would that be detected if it occurs and how would it be rectified?</li> <li>What is the data sharing agreement in place?</li> <li>IRB approval from Koohi Goth Hospital would be required.</li> </ul>

Title: **Physical Activity Intervention to Reduce Health Risks Associated with Problematic Internet Use in Adolescents With and Without Learning Disabilities.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1258</b>	<b>Ms. Samrah Saeed</b> Lithuanian Sports University Sporto g. 6, Kaunas 44221, Lithuania	<ul style="list-style-type: none"> <li>This proposal has several methodological flaws. We do not know what is the intervention that is being proposed. Please give operational definitions. Where does disability fall into this? What type of disability? Learning disabilities are of several kinds. How can they be grouped as one?</li> <li>Is there any psychologist on board? How will participants be recruited, using what criteria?</li> <li>How will the schools be approached? Which schools is the PI targeting? Public or private? Is there an understanding with any school or government educational department?</li> <li>Considering the online methodology and engagement of participants it seems that there will be a high attrition rate and the study's objectives may not be</li> </ul>

		fulfilled. • Why could this study not be done in Lithuania? • What is the collaboration with Iqra University? How is the University involved in this project?
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Title: **Lu-177 based Synovectomy in the Management of Chronic Inflammatory Joint Diseases.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1129</b>	<b>Dr. Aakif Ullah Khan</b> Director & Chief Medical Officer, Institute of Radiotherapy and Nuclear Medicine (IRNUM), Peshawar, Pakistan	• Kindly send the attached response with track changes back to the PI so that he may improve upon this project.

**Next meeting:**

The next zoom meeting will be held at 02:00 pm on 24<sup>th</sup> June, 2025. The following projects will be reviewed:

**NBCR-1259, NBCR-1261 and 1271.**

## Minutes of the NBC-R meeting held on 24-06-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on June 24<sup>th</sup>, 2025. The following members of NBC-R attended the meeting:

1. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2. Prof. Dr. Munir Akhtar Saleemi	Member
3. Prof. Dr. Jamshed Akhtar	Member
4. Prof. Dr. Saqib Mehmood	Member
5. Prof. Dr. Marie Andrades	Member
6. Dr. Farkhanda Ghafoor	Member
7. Mrs. Tayyaba Rahat	National Coordinator (NBC-R)
8. Mrs. Ayesha Abid	Assistant (NBC-R)

The following projects reviewed / discussed:

Title: **Translating evidence for early intervention in psychosis (TRANSLATE): Protocol for an effectiveness and implementation study in low and lower-middle income countries (LMICs).**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1259	<b>Prof. Saeed Farooq</b> School for Primary, Community and Social Care Keele University, Staffordshire, ST5 5BG, UK	<ul style="list-style-type: none"><li>• Please clarify the methodology of doing the TRANSLATE study. Is it a trial? Will there be a control arm? How is this a quasi-experimental study?</li><li>• Is there a possibility of financial burden on families? Where will any psychiatric emergency be dealt with?</li><li>• Is there a DSMB in place? What is its composition?</li><li>• How long is this project to last? The budget is of five years but protocol mentions two.</li></ul>

Title: **Wellbeing Initiative for Nurturing Generations through Schools (WINGS).**

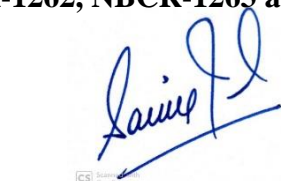
Project #	PI Name & Address	Final NBC-R Comments
NBCR-1261	<b>Dr. Taha Sabri Taskeen</b> Health Initiative, Pakistan 3rd Floor, Plot # 73C, Jami Commercial, 8th Commercial Street, D.H.A. Phase 7, Karachi	<ul style="list-style-type: none"><li>• Study Approved.</li></ul>

Title: **Pakistan Vaccine Demand Survey 2025.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1271	<b>Susan Rae Mackay</b> Acasus Consultancy (SMC-Pvt.) Ltd. 1st Floor, MA Tabba Foundation Building, Gizri Road, Block 9, Clifton, Karachi	<ul style="list-style-type: none"><li>• Please clarify how this study will add to the local literature? This issue has been studied extensively for the last several years in Pakistan. The PI of this project has not given any reference to our local studies.</li><li>• How will veracity of the data be ensured considering that this study will also be conducted in hard to reach areas of Baluchistan and KP?</li></ul>

**Next meeting:**

The next zoom meeting will be held at 02:00 pm on 1<sup>st</sup> July, 2025. The following projects will be reviewed: **NBCR-1262, NBCR-1263 and 1281.**



**Chairperson NBC-R**

## Minutes of the NBC-R meeting held on 01-07-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on July 1<sup>st</sup>, 2025. The following members of NBC-R attended the meeting:

1. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2. Prof. Dr. Munir Akhtar Saleemi	Member
3. Prof. Dr. Jamshed Akhtar	Member
4. Prof. Dr. Nazli Hossain	Member
5. Prof. Dr. Saqib Mehmood	Member
6. Prof. Dr. Amjad Mehboob	Member
7. Dr. Farkhanda Ghafoor	Member
8. Dr. Faiza Bashir	Research Director/Focal Person (NBC-R)
9. Mrs. Tayyaba Rahat	National Coordinator (NBC-R)
10. Mr. Waryal Ali Daheri	LDC (NBC-R)

**The following projects reviewed / discussed:**

Title: **Trial: Health Communication Campaign for Prevention and Early Identification of Breast Cancer in Pakistan: Study Protocol.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1262	<b>Prof. Nasim Chaudhry</b> Pakistan Institute of Living and Learning Suite No. 201, 2nd Floor, The Plaza, Karachi	<ul style="list-style-type: none"> <li>Study Approved.</li> </ul>

Title: **Identification and Molecular Characterization of Genes Involved in Human Diseases in Consanguineous Pakistani Families.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1263	<b>Dr. Asim Ali</b> Department of Biotechnology, COMSATS University Islamabad, Abbottabad Campus, University Road, Tobe Camp, Postal Code 22060 Abbottabad	<ul style="list-style-type: none"> <li>This study is very vague in presenting its methodology. What is the sampling method, sample size, duration of study, inclusion/exclusion criteria, recruitment process etc. Please provide these details clearly. Ethical approval cannot be granted for an indefinite period or unspecified sample size.</li> <li>The questionnaire attached to the proposal lacks critical information necessary for the proper recruitment of families. There is no section addressing relevant clinical information or detailed family history both of which are essential for genetic studies. Furthermore, the inclusion of questions related to addiction habits appears irrelevant with a potential for stigmatization. A pedigree should be drawn for each recruited family as part of a standard documentation for genetic studies.</li> <li>The proposal does not address whether the genetic testing results will be shared with the participants and their families. This is a significant omission. Transparency regarding the return of results is an important ethical consideration and must be clearly outlined in the protocol. This information should be explicitly included in the patient/family information sheets to ensure informed consent.</li> <li>The proposal suggests that sequencing will be</li> </ul>

		performed in China, however, Next Generation Sequencing (NGS) is no longer considered a highly complex procedure and several NGS platforms are available in Pakistan. It is advisable that funding be utilized for conducting NGS in collaboration with local, well equipped NGS facilities. Only the more advanced and specialized downstream research activities such as genetically modified animal models may be justified for collaboration with China.
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Title: **Trial: A Global, Randomized, Open-label, Multicenter, Phase 2b/3 Trial Evaluating BJT-778 vs Delayed Treatment for the Treatment of Chronic Hepatitis Delta Infection (AZURE-1).**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1281	Dr. Saeed Sadiq Hamid The Aga Khan University (AKU) National Stadium Rd, Aga Khan University, Karachi	<ul style="list-style-type: none"> <li>• Please elaborate the post-trial benefits if any to our Pakistani population. Will the drug be available at an affordable cost?</li> <li>• is there any potential conflict of interest with the pharmaceutical company involved?</li> <li>• The study has three arms. However, the Informed consent form is generic. Different protocols are designed for each arm. Should the ICF not be tailored to the different groups?</li> </ul>

**Next meeting:**

The next zoom meeting will be held at 02:00 pm on 8<sup>th</sup> July, 2025. The following projects will be reviewed:

**NBCR-1264, NBCR-1265 and NBCR-1266.**

## Minutes of the NBC-R meeting held on 08-07-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on July 8<sup>th</sup>, 2025. The following members of NBC-R attended the meeting:

1. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2. Prof. Dr. Munir Akhtar Saleemi	Member
3. Prof. Dr. Jamshed Akhtar	Member
4. Prof. Dr. Saqib Mehmood	Member
5. Prof. Dr. Sualeha Siddiq Shekhani	Member
6. Dr. Farkhanda Ghafoor	Member
7. Mrs. Tayyaba Rahat	National Coordinator (NBC-R)
8. Mr. Waryal Ali Daheri	LDC (NBC-R)

**The following projects reviewed / discussed:**

Title: **An evaluation of new TB diagnostic tests (NATs) for Active case finding for TB in Pakistan.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1264</b>	<b>Abdullah Latif</b> Mercy Corps, 189/190, Street 6, I-9/2 Islamabad	<ol style="list-style-type: none"> <li>1. Is this study aligned with or in collaboration with National TB program? Please clarify</li> <li>2. Will any data or DNA samples be sent abroad? If yes, please provide details and MTA.</li> <li>3. An assent form is required for minors less than the legal age.</li> <li>4. What is the estimated cost of the new tests in comparison to the standard tests? Will it be available for our country later on if proven to be cost-effective?</li> <li>5. Who is the main funding agency of this project?</li> </ol>

Title: **Goat Milk-Derived Formula Alternatives vs. Undiluted Goat Milk in Babies Unable to Exclusively Breastfeed: Analysis of Growth Metrics and Biological Markers.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1265</b>	<b>Dr. Junaid Iqbal</b> Department of Paediatrics and Child Health Aga Khan University Karachi	<ol style="list-style-type: none"> <li>1. Please clarify the rationale for using the breast feeding or mixed feeding arm. Will it not contaminate the study itself? Will it not be less than ideal for the child?</li> <li>2. Is goat milk normally consumed in this population? What is the feeding practice of this community?</li> <li>3. The ICF mentions that blood and stool samples may be sent abroad for further tests/studies. Please clarify this statement as to why this is required.</li> <li>4. MTA to be on legal paper.</li> <li>5. The questions asked from this study is similar to another study by the PI on gut microbiome in mothers and their infants. Is there a connection between the studies?</li> </ol>

Title: **Assessing the Feasibility of Multimedia Interventions to Reduce Blood Pressure in Marginalized Hypertensive Communities of Karachi, Pakistan.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1166</b>	<b>Dr. Hina Sharif</b> SINA Health Education & Welfare Trust,	<ol style="list-style-type: none"> <li>1. Please clarify the need for this project to come to NBC? Is it being funded by the govt. or from abroad?</li> <li>2. The methodology of this study is poorly designed. Please give us a detailed account of how and where</li> </ol>

	Karachi-Pakistan	<p>this study will be conducted in the SINA centers. It is suggested that the PI have the project vetted by an experienced researcher.</p> <ol style="list-style-type: none"> <li>3. The informed consent form is lacking in terms of giving complete information and determining voluntariness to be recruited into the project.</li> <li>4. The age range is too broad and needs to be trimmed for practical execution of the project.</li> <li>5. Please be clear on what is meant by a "marginalized" community.</li> <li>6. The budget mentions "diagnostics". Please clarify as to what this means.</li> </ol>
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**Next meeting:**

The next zoom meeting will be held at 02:00 pm on 15<sup>th</sup>July, 2025. The following projects will be reviewed:

**NBCR-1267, NBCR-1268 and 1269.**

## Minutes of the NBC-R meeting held on 15-07-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on July 15<sup>th</sup>, 2025. The following members of NBC-R attended the meeting:

1. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2. Prof. Dr. Munir Akhtar Saleemi	Member
3. Prof. Dr. Jamshed Akhtar	Member
4. Prof. Dr. Saqib Mehmood	Member
5. Prof. Dr. Marie Andrades	Member
6. Dr. Farkhanda Ghafoor	Member
7. Prof. Dr. Sualeha Siddiq Shekhani	Member
8. Mrs. Tayyaba Rahat	National Coordinator (NBC-R)
9. Mr. Waryal Ali Daheri	LDC (NBC-R)

**The following projects reviewed / discussed:**

Title: **Enhancing Emotional Safety and Family-Centered Care in Pediatric Emergency Departments in Low- and Middle-Income Countries through Simulation-Based Training..**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1267	<b>Dr. Noor ul ain Farooq</b> Department of Emergency Medicine Aga Khan University Karachi	<ol style="list-style-type: none"><li>1. Would one observation of pre and post intervention be justified to determine if the simulation training was successful or not? Should there not be at least 3-4 observations to validate the usefulness of the intervention?</li><li>2. Why not involve staff from public sector hospitals to be involved in this endeavour? In this way this would be a true representation of LMIC involvement as suggested in the project title.</li><li>3. The budget submitted mentions a high cost of the certificate and more than \$2,000/- for office supplies. Is this rational?</li></ol>

Title: **Mapping of Pediatric Cancer Care Centers across Pakistan: A survey-based study.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1268	<b>Dr. Asim F. Belgaumi</b> Department of Oncology Aga Khan University Karachi	<ol style="list-style-type: none"><li>1. The AKUH IRB letter mentions the name of Dr. Sadaf Altaf and the NBC form mentions Dr. Asim Belgaumi. Please clarify who is the PI.</li><li>2. Data collection from each center should ensure that the stakeholders are aware that their data is being shared. Is the institutional Head enough to give this consent or should it not be routed through their IRBs or IRB chairs?</li></ol>

Title: **Effects on cardiometabolic diseases in adolescents and young adults residing in food streets in Karachi, Pakistan: A mixed methods study.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1269	<b>Dr. SANA SHEIKH</b> Department of Medicine Aga Khan University Karachi	<ol style="list-style-type: none"><li>1. What is the operational definition of food being "unhealthy"? Please clarify for us.</li><li>2. Is there a likelihood of stigmatizing food vendors? How will this be addressed?</li><li>3. Data collectors will be visiting homes of the young adults. How is their safety ensured?</li><li>4. Who are the gatekeepers of these food streets? Should not government approval be sought first to make easier to access the community?</li></ol>

**Next meeting:**

The next zoom meeting will be held at 02:00 pm on 22<sup>nd</sup> July, 2025. The following projects will be reviewed:



## Minutes of the NBC-R meeting held on 22-07-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on July 22<sup>nd</sup>, 2025. The following members of NBC-R attended the meeting:

1. Prof. Dr. Jamshed Akhtar	Chairperson
2. Prof. Dr. Nazli Hossain	Member
3. Prof. Dr. Saqib Mehmood	Member
4. Prof. Dr. Marie Andrades	Member
5. Dr. Farkhanda Ghafoor	Member
6. Prof. Dr. Sualeha Siddiq Shekhani	Member
7. Mrs. Tayyaba Rahat	National Coordinator (NBC-R)
8. Mr. Waryal Ali Daheri	LDC (NBC-R)

**Regret received from the following members:**

1. Prof. Dr. Saima Pervaiz Iqbal
2. Prof. Dr. Munir AKhtar Saleemi

**The following projects reviewed / discussed:**

Title: **Climate change and its impact on dengue and malaria transmission in Sindh, Pakistan.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1270	<b>Dr. Abdul Momin Kazi</b> Dept of Paediatrics and Child Health Aga Khan University Karachi	<ol style="list-style-type: none"> <li>1. This is a project apparently of a scholar at Stanford Amna Tariq whose name is found as a footer on each page of synopsis. Kindly clarify this observation.</li> <li>2. The methodology is not clear. Many aspects of the study are ill-defined.</li> <li>3. There is no mention of sites at Thatta and Karachi from where the data shall be collected.</li> <li>4. How two study sites are identified in context of "climate change"?</li> <li>5. Which tests shall be performed on "any child with high grade fever" ?This criteria is ambiguous in itself. It needs to be refined in context of Dengue fever and Malaria.</li> <li>6. Who will pay for the tests?</li> <li>7. Will participants shall be informed about the results of the tests?</li> <li>8. Where these children shall be treated and who will pay for that?</li> <li>9. In case of complications where such children shall be treated?</li> <li>10. What will be the source of data and how its authenticity shall be ensured?</li> <li>11. The government of Sindh collects data on both the diseases. Is there any plan to access that? Same data is also collected at national level.</li> <li>12. How 100 children prospectively identified shall provide a "robust data" about a condition?</li> <li>13. Why adult population is excluded?</li> <li>14. Is the duration of retrospective data collection from 2014 or 2017? It is written differently as places.</li> <li>15. The data which is being collected and transferred outside Pakistan has many aspects that are not related to the title of the study and research</li> </ol>

		<p>question. Why PI has decided to collect significant information about Pakistani population which is not directly related to the study? Information like 79 number, have you breast fed your child?</p> <p>16. Data transfer agreement is not found.</p> <p>17. What is the purpose of biological data storage for a very long period of time? Will there be an option for opt out?</p> <p>18. Will biological samples be transferred to outside Pakistan? If yes send MTA.</p> <p>19. How Rs. 500 is justified in context of significant contribution of the study participants?</p>
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Title: **Characterization of Occupational Heat Exposure and Its Association with Health and Productivity Among Construction Workers in Karachi: A Cross- Sectional Study.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1272</b>	<b>Dr. Asaad Nafees</b> Department of Community Health Sciences Aga Khan University Karachi	<p>1. What shall PI do if construction company environment is found unsuitable for the workers? Will owners be updated, educated or guided?</p> <p>2. How will PI ensure that laborers are not harmed if they disclose adverse conditions in which they work?</p> <p>3. How such potential harm may be addressed?</p> <p>4. Pictures shall be taken is mentioned. It needs clarity.</p> <p>5. Will PI report to the relevant governmental authorities if any violation of environment related SOPs are found during the survey?</p> <p>6. Is the study ongoing as duration mentioned is June to August?</p>

Title: **Breaking barriers on two wheels: Socio-Cultural implications for rising women's mobility in Pakistan.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1294</b>	<b>Aeron O' Connor (supervisor)</b> University College London (UCL), Department of Risk and Disaster Reduction Gower St, London WC1E 6AE United Kingdom	<p>1. Is this research design truly ethnographic?</p> <p>2. Is the sample truly representative of all segments of the society or tilted towards a particular socioeconomic group? Apparently it is biased towards affluent class who might not face challenges as those from other socioeconomic strata.</p> <p>3. What if psychological and health related questions may be incorporated.</p> <p>4. Is sample size enough to captures all the themes?</p> <p>5. It appears that this data will be transferred outside Pakistan? Data transfer agreement is required for this purpose.</p> <p>6. Interview sites are mentioned differently. DHA and Gulberg.</p> <p>7. Contact number from Pakistan, a cell phone number to the study participants will be appreciated rather than E mail address from outside country.</p> <p>8. The discrepancy is found in the amount of the budget for this study. It needs clarity.</p> <p>9. The project is still not approved yet by the UK University.</p>

#### **Next meeting:**

The next zoom meeting will be held at 02:00 pm on 29<sup>th</sup> July, 2025. The following projects will be reviewed:

**NBCR-1273, NBCR-1274 and 1284.**

## Minutes of the NBC-R meeting held on 29-07-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on July 29<sup>th</sup>, 2025. 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. Munir Akhtar Saleemi	Member
4. Prof. Dr. Nazli Hossain	Member
5. Prof. Dr. Saqib Mehmood	Member
6. Prof. Dr. Marie Andrades	Member
7. Dr. Farkhanda Ghafoor	Member
8. Mrs. Tayyaba Rahat	National Coordinator (NBC-R)
9. Mr. Waryal Ali Daheri	LDC (NBC-R)

**Regret received from the following members:**

1. Prof. Dr. Sualeha Siddique Shekhani	Member
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**The following projects reviewed / discussed:**

Title: **Birthing at Burning Places: An ethnographic study of intersections among climate- linked risks, maternal nutritional health, and cultural practices in Sindh Pakistan.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1273	<b>Dr. Zahid Memon</b> Department of Community Health Sciences Aga Khan University Karachi	<ol style="list-style-type: none"> <li>1. Please explain how this study qualifies as an ethnographic study? Is the PI going to reside in the communities for long periods of time?</li> <li>2. Will any data be transferred to the UK?</li> <li>3. What will be the utility of this study after data collection? How does the PI foresee that the lives of the community dwellers be changed?</li> </ol>

Title: **Global Outreach Study of Methylation-based Classification Tools for CNS Tumors and Sarcomas (MNP Outreach Study).**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1274	<b>Dr. Syed Ather Enam</b> Department of Centre of Oncological Research in Surgery The Aga Khan University Karachi	<ol style="list-style-type: none"> <li>1. Please clarify the methodology of this study. Is it prospective or retrospective? what is the utility of this study in future? How will it benefit our country or population? This was unclear to us.</li> <li>2. There are two IRB letters in the package with two different study titles.</li> <li>3. Why are samples being sent abroad if the lab is being developed here in Pakistan?</li> <li>4. The informed consent form needs to be simplified for better understanding of participants who are laymen.</li> <li>5. How long will this study last? Is it currently ongoing?</li> <li>6. For patients who have already died, would it not be traumatic for family members to revisit the deaths of their loved ones for data collection?</li> </ol>

Title: **Trial: "Randomized, Multicenter, Multinational, Double-Blind Study to Compare the Pharmacokinetics, Efficacy, Safety and Immunogenicity of MB12 (Proposed Pembrolizumab Biosimilar) versus Keytruda® in Combination with Chemotherapy for the Treatment of Patients with Advanced Stage IV Non-Squamous Non-Small Cell Lung Cancer (NSCLC) (BENITO Study)".**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1284	<b>Dr. Adnan Abdul Jabbar</b> Ziauddin University	<ol style="list-style-type: none"> <li>1. Please give us a brief and simplified account of the BENITO study. What exactly does it entail?</li> <li>2. What are the results of Phase 1 and Phase 2 trials</li> </ol>

	4-B Shahrah-e-Ghalib, Block-6, Clifton Karachi.	<p>with the new biosimilar?</p> <p>3. What is the standard of care being employed in this cohort of patients with Stage IV disease? Is Keytruda the gold standard or not or is it ambiguous?</p> <p>4. Both Keytruda and the MB12 are expensive medications and not freely available in Pakistan. How will our country or our population benefit by being involved in this study? Are there any post trial benefits?</p> <p>5. Is there a possibility of our patients being burdened in case the funds relapse?</p> <p>6. Please provide details of the DSMB.</p>
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**Next meeting:**

The next zoom meeting will be held at 02:00 pm on 5<sup>th</sup> August, 2025. The following projects will be reviewed:

**NBCR-1275, NBCR-1277 and 1278.**



**Chairperson NBC-R**

## Minutes of the NBC-R meeting held on 05-08-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on August 5<sup>th</sup>, 2025. The following members of NBC-R attended the meeting:

1. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2. Prof. Dr. Munir Akhtar Saleemi	Member
3. Prof. Dr. Jamshed Akhtar	Member
4. Prof. Dr. Nazli Hossain	Member
5. Dr. Farkhanda Ghafoor	Member
6. Prof. Sualeha Siddique Shekhani	Member
7. Mrs. Tayyaba Rahat	National Coordinator (NBC-R)
8. Mr. Waryal Ali Daheri	LDC (NBC-R)

**The following projects reviewed / discussed:**

Title: **NBCR-1275: Immunization Gaps Assessment in Pakistan (IGAP)- Data collection and surveys-related activities in Pakistan's immunization programme.**

PI Name & Address	Final NBC-R Comments
<b>Dr. Sajid Bashir Soofi</b> Dept of Paediatrics and Child Health Aga Khan University Karachi	<ol style="list-style-type: none"><li>1. Considering the law and order situation of the areas targeted what protective measures are available for the data collectors and researchers?</li><li>2. Considering the unfortunate events in the past with immunization programs is there any likelihood of safety concerns at the national level?</li></ol>

Title: **NBCR-1277: Menstrual Hygiene Management Practice and Associated Factors Among Adolescent Girls (10-18 Years) Living in A Semi-Urban Area: An Analytical Cross-Sectional Study in Karachi, Pakistan.**

PI Name & Address	Final NBC-R Comments
<b>Dr. Fareeha Shaikh</b> Dept of Community Health Sciences Aga Khan University Karachi.	<ol style="list-style-type: none"><li>1. Once data is collected is there anything being offered to participants like an awareness session? Tampons?</li></ol>

Title: **NBCR-1278: Development and field testing of an e-learning antimicrobial resistance (AMR) stewardship training platform and clinical decision support system for healthcare workers in Kasur (Punjab Province) Pakistan.**

PI Name & Address	Final NBC-R Comments
<b>M. Imran Khan</b> Precision Health Consultants (PHC) Global (Private) Limited Office No.415, 4th Floor, Al-Hafeez Executive, Ali Zaib Road, Gulberg-III Lahore	<ol style="list-style-type: none"><li>1. Please clarify the methodology for us that is simple and easy to understand. We still were not able to appreciate what the training activity entails.</li><li>2. Please justify Kasur as the research site as the PI is from Karachi.</li><li>3. Who are the other co-PIs in this project?</li></ol>

### **Next meeting:**

The next zoom meeting will be held at 02:00 pm on 12<sup>th</sup> August, 2025. The following projects will be reviewed:

**NBCR-1279, NBCR-1280 and NBCR-1282.**

## Minutes of the NBC-R meeting held on 12-08-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on August 12<sup>th</sup>, 2025. The following members of NBC-R attended the meeting:

1. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2. Prof. Dr. Munir Akhtar Saleemi	Member
3. Prof. Dr. Jamshed Akhtar	Member
4. Prof. Dr. Nazli Hossain	Member
5. Prof. Dr. Saqib Mehmood	Member
6. Prof. Dr. Marie Andrades	Member
7. Prof. Dr. Sualeha Siddiq Shekhani	Member
8. Dr. Farkhanda Ghafoor	Member
9. Mrs. Tayyaba Rahat	National Coordinator (NBC-R)
10. Mr. Waryal Ali Daheri	LDC (NBC-R)

**The following projects reviewed / discussed:**

Title: **NBCR: 1279: Trial: Immunogenicity and Safety of two dosages of Rabies Vaccine (Serum-free Vero Cell), Freeze-dried in Comparison with Verorab®, in a Simulated Post-exposure Prophylaxis Regimen in Healthy Adults: A Randomized, Double-Blind, Active-controlled Phase II Clinical Trial.**

PI Name & Address	Final NBC-R Comments
<b>Dr. Ali Saleem</b> Department of Paediatrics and Child Health Aga Khan University Karachi	<ol style="list-style-type: none"><li>1. There seems to be a Phase 3 trial going on as well as there is discrepancy in the forms. Sample sizes mentioned are different.</li><li>2. What is the insurance coverage given to participants? Where will any adverse events be treated? What is remuneration given to participants? Please clarify.</li><li>3. Please mention on the Informed consent forms that samples will be sent abroad.</li></ol>

Title: **NBCR-1280: Trial: Caffeine for Hypoxic Ischemic Encephalopathy (CHIME Trial).**

PI Name & Address	Final NBC-R Comments
<b>Dr. Sarah Saleem</b> Department of Community Health Sciences Aga Khan University Karachi	<ol style="list-style-type: none"><li>1. Please justify using patients from a public sector hospital when patients can be recruited from AKUH and its subsidiaries.</li><li>2. What benefit or capacity building be done for the co-PIs of DUHS?</li><li>3. Who are the co-PIs from DUHS. What is their intellectual contribution in this study?</li><li>4. What is the standard of care for infants with HIE? How can that be denied to any arm of the trial?</li><li>5. We would like to see IRB approvals from AKUH and DUHS.</li><li>6. Has the Hyperfine machine been used before in infants? Will this machine be donated to DUHS once the project is over?</li><li>7. Please give composition of DSMB for this project.</li><li>8. Is there any Data Transfer Agreement or MTA? Please provide details.</li></ol>

Title: **NBCR-1282: Exploring Stakeholder Perceptions of the Early Warning System for Flood Prediction and Preparedness in Hunza Pakistan. A Qualitative Study.**

PI Name & Address	Final NBC-R Comments
<b>Dr. Uzma Rahim Khan</b> National Stadium Rd, Aga Khan University Hospital, Karachi Pakistan	<ul style="list-style-type: none"><li>• Study Approved.</li></ul>

**Next meeting:**

The next zoom meeting will be held at 02:00 pm on 19<sup>th</sup> August, 2025. The following projects will be reviewed:

**NBCR-1285, NBCR-1286 and 1287.**

## Minutes of the NBC-R meeting held on 19-08-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on August 19<sup>th</sup>, 2025. The following members of NBC-R attended the meeting:

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

### The following projects reviewed / discussed:

Title: **NBCR-1285: Gender disparities in quality of life of stroke survivors in a tertiary care hospital, Karachi. A cross sectional study.**

PI Name & Address	Final NBC-R Comments
<b>Dr. Zahra Hoodbhoy</b> Department of Paediatrics and Child Health Aga Khan University Karachi	1. Study Approved

Title: **NBCR-1286: Trial: Integration of mHealth Applications and Real-World Evidence for Diabetes Management: A Study on the Efficacy, Adherence, and Quality of Life Improvements in Pakistan.**

PI Name & Address	Final NBC-R Comments
<b>Dr Muhammad Daoud Butt</b> School of Pharmaceutical Sciences, Universiti Sains Malaysia, 11800 Universiti Sains Malaysia, Pulau Pinang, Malaysia.	<ol style="list-style-type: none"> <li>1. This proposal needs to be re-written and resubmitted. The methodology is not clear for an interventional study or RCT. There is no mention of randomisation.</li> <li>2. It is ambiguous whether the study will enroll treatment-naive patients or patients already on other anti diabetic therapy who will be switched to semaglutide.</li> <li>3. The primary objective is stated as evaluating the efficacy of bio synthetic semaglutide. However the study design is a comparative effectiveness trial between an mHealth group and a standard care group not an efficacy trial for semaglutide itself. Since both groups receive semaglutide the study cannot isolate the drug's efficacy. Instead it measures the additional benefit of the mHealth app when used alongside semaglutide.</li> <li>4. Objective 5 of the secondary objectives "compare efficacy, adherence and quality of life improvements between Patients in Pakistan is redundant.</li> <li>5. The informed consent form needs to be revised stating clearly the study objectives, amount of blood collected, any insurance and health coverage provided, focal person who may be contacted within the country etc.</li> <li>6. Please clarify the role of Northwest Hospital and Bahauddin Zakariya University. Their IRB approvals are required. Who are the co-PIs from this site? Why have these sites been selected?</li> </ol>



Title: **NBCR-1287: Exploring Menstrual Health & Sexual Violence Protection for Girls with Intellectual Developmental Disability in Pakistan: Primary Caretaker's Perspective.**

PI Name & Address	Final NBC-R Comments
<b>Dr. Sarah Saleem</b> Department of Community Health Sciences Aga Khan University Karachi	<div>1. Please clarify for us who is the PI on one hand it seems to be Sarah Saleem on the other hand letters are addressed to Safana Shahid.</div> <div>2. Will any psychosocial support be provided to the caretakers?</div>

**Next meeting:**

The next zoom meeting will be held at 02:00 pm on August 26, 2025. The following projects will be reviewed:

**NBCR-1289, NBCR-1290 and 1291.**

## Minutes of the NBC-R meeting held on 26-08-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on August 26<sup>th</sup>, 2025. The following members of NBC-R attended the meeting:

1. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2. Prof. Dr. Jamshed Akhtar	Member
3. Prof. Munir Akhtar Saleemi	Member
4. Prof. Dr. Nazli Hossain	Member
5. Prof. Dr. Saqib Mehmood	Member
6. Prof. Dr. Marie Andrades	Member
7. Prof. Dr. Amjad Mehboob	Member
8. Dr. Farkhanda Ghafoor	Member
9. Mr. Waryal Ali Daheri	LDC (NBC-R)

### Regret received from the following members:

1. Prof. Sualeha Siddique Shekhani	Member
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### The following projects reviewed / discussed:

Title: **NBCR-1289: Frequency of Functional Gastrointestinal Disorders and their association with occupational stress among nurses at a tertiary care hospital in Karachi, Pakistan: an analytical cross-sectional study.**

PI Name & Address	Final NBC-R Comments
Dr. Asaad Nafees Dept of Community Health Sciences AKU, Karachi	1. Study Approved.

Title: **NBCR-1290: Exploring Clinicians Perspectives Towards AI-Assisted Diagnostic Radiology in Clinical Practices of Karachi, Pakistan- A Qualitative Study.**

PI Name & Address	Final NBC-R Comments
Dr. Shiyam Sunder Dept of Community Health Sciences AKU, Karachi	1. Please specify from where data will be collected. If collected from DUHS then their IRB approval is required.

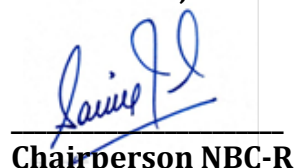
Title: **NBCR-1291: Breaking the Silence: Improving Educational Access and Technology for Deaf Learners in Pakistan.**

PI Name & Address	Final NBC-R Comments
Dr. Sana Shams Engineering (CLE), Al-Khawarizmi Institute of Computer Science (KICS), University of Engineering and Technology (UET), Lahore	1. Study Approved.

### Next meeting:

The next zoom meeting will be held at 02:00 pm on 2<sup>nd</sup> September, 2025. The following projects will be reviewed:

**NBCR-1292, NBCR-1293 and 1311.**



Chairperson NBC-R

## Minutes of the NBC-R meeting held on 02-09-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on September 2<sup>nd</sup>, 2025. The following members of NBC-R attended the meeting:

1. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2. Prof. Dr. Munir Akhtar Saleemi	Member
3. Prof. Dr. Jamshed Akhtar	Member
4. Prof. Dr. Nazli Hossain	Member
5. Prof. Dr. Saqib Mehmood	Member
6. Prof. Dr. Marie Andradess	Member
7. Prof. Dr. Amjad Mehboob	Member
8. Dr. Farkhanda Ghafoor	Member
9. Mr. Waryal Ali Daheri	LDC (NBC-R)

**Regret received from the following members:**

1. Prof. Sualeha Siddique Shekhani	Member
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**The following projects reviewed / discussed:**

Title: **Study on Newer Regimens for Multi-drug Resistant/Rifampicin- Resistant Tuberculosis Treatment: Evaluating Effectiveness, Safety, and Feasibility.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1292</b>	<b>Dr. Uzma Khan</b> Interactive Research & Development (IRD) 4th Floor, Woodcraft Building, Plot 3 & 3-A Sector 47, Korangi Creek Road, Karachi	<ol style="list-style-type: none"> <li>1. Please clarify the study design being observational. Is it not comparing different regimens with a standard of care?</li> <li>2. There is no mention of how focus group will be formulated and what questions will be asked?</li> <li>3. How will feasibility be assessed in this study?</li> <li>4. Is this a study embedded in the trials taking place? Please clarify.</li> </ol>

Title: **Strengthening Postpartum Family Planning (PPFP) in Sindh, Pakistan.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1293</b>	<b>Dr. Nausheen Naz</b> Senior Technical Lead Programs Vital Pakistan Trust Office No. 301-904, 9th Floor, Al Tijarah Center, Shahrah-e-Faisal, PECHS Building No.6, Karachi.	<ol style="list-style-type: none"> <li>1. Please clarify methodology of this study. What is the research question and how is it being addressed?</li> <li>2. Who will insert IUCDs and how will its consent be taken from the participants? As IUCD insertion is technically demanding what are the provisions of its training, monitoring and adverse effects management, for example in remote areas. Can there be a provision of performing such procedures only at RHC with presence of all facilities including doctors?</li> <li>3. Is this study in alignment with the National Family Planning Policy of Pakistan?</li> <li>4. IRB approval letters from participating centers would be required.</li> </ol>

Title: **Trial: An Evaluation of Bemnifosbuvir-Ruzasvir (BEM/RZR) Versus Sofosbuvir-Velpatasvir (SOF/VEL) for the Treatment of Chronic Hepatitis C Virus (HCV) Infection in a Phase 3 Randomized, Controlled, Open-label Study.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1311</b>	<b>Prof. Saeed Hamid</b> Department of Medicine Aga Khan University Karachi	<ol style="list-style-type: none"> <li>1. Study Approved.</li> </ol>

**Next meeting:**

The next zoom meeting will be held at 02:00 pm on 9<sup>th</sup>September, 2025. The following projects will be reviewed:

**NBCR-1295, NBCR-1296 and NBCR-1298.**

## Minutes of the NBC-R meeting held on 09-09-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on September 9<sup>th</sup>, 2025. 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. Nazli Hossain	Member
4. Prof. Dr. Marie Andrades	Member
5. Prof. Dr. Amjad Mehboob	Member
6. Dr. Farkhanda Ghafoor	Member
7. Mrs. Tayyaba Rahat	National Coordinator (NBC-R)
8. Mr. Waryal Ali Daheri	LDC (NBC-R)

### Regret received from the following members:

1. Prof. Dr. Munir Akhtar Saleemi,	Member
2. Prof. Dr. Saqib Mehmood	Member
3. Prof. Sualeha Siddique Shekhani	Member

### The following projects reviewed / discussed:

Title: **Tracing Child Migrants' Education Access Amidst Climate-Induced Disruptions in Pakistan.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1295</b>	<b>Mrs. Fatima Mehmood</b> Centre for Human Rights (CFHR) Address of PI Institute/Organization: 1.5 km from Thokar Niaz Baig, Raiwind Road, Lahore.	<ol style="list-style-type: none"> <li>1. Please clarify the rationale of this study if any government body is not on board. Has the govt. of Pakistan outsourced this study to DARE-RC? Who will use this data for implementing the policy(s) generated?</li> <li>2. Is this data being shared with any agency abroad? If so why?</li> <li>3. Is there a possibility to pick up child trafficking rackets as these are vulnerable children? If so, how would that be addressed?</li> <li>4. The floods are still going on. What sites in KP and Sindh will be accessed by the PI and how? Will there be transitions to make-shift schools in these camps? How will teachers be recruited for these sites as they themselves would be affected by these disasters?</li> <li>5. Why is there a mention of sales tax and withholding tax in the budget?</li> </ol>

Title: **Introducing Hormonal Intrauterine Device (HIUD) in Pakistan: A Feasibility and Acceptability Assessment.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1296</b>	<b>Dr. Sana Durvesh</b> Greenstar Social Marketing Pakistan 8th Floor, Ocean Tower, Main Clifton Road, Karachi.	<ol style="list-style-type: none"> <li>1. Please clarify for the NBC if the PI is using Mirena or introducing a new hormonal IUD?</li> <li>2. The cost of Mirena is PKR 18,000/-. Will this be provided to the research participants free of cost or subsidized cost?</li> <li>3. Please clarify the high volume clinics mentioned in the proposal. How have they been selected? Are they private clinics owned by GPs or Greenstar clinics?</li> <li>4. Please mention the study sites. Fig 2 which claims to do so is missing in the document.</li> </ol>

		5. Is there a possibility of coercion to women being part of this study to get the hormonal IUD inserted by the Family Planning counsellors? How will this be addressed?
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Title: **Age related Macular Degeneration (AMD) Benchmark Imaging Dataset- A cross sectional observational study.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1298	<b>Dr. Haroon Tayyab</b> Department of Ophthalmology and Visual Sciences Aga Khan University Karachi	<ul style="list-style-type: none"> <li>Study Approved.</li> </ul>

**Next meeting:**

The next zoom meeting will be held at 02:00 pm on 16<sup>th</sup>September, 2025. The following projects will be reviewed:

**NBCR-1299, NBCR-1300 and 1301.**

## Minutes of the NBC-R meeting held on 16-09-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on September 16<sup>th</sup>, 2025. The following members of NBC-R attended the meeting:

1. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2. Prof. Dr. Munir Akhtar Saleemi	Member
3. Prof. Dr. Jamshed Akhtar	Member
4. Prof. Dr. Marie Andrades	Member
5. Prof. Dr. Amjad Mehboob	Member
6. Dr. Farkhanda Ghafoor	Member
7. Mrs. Tayyaba Rahat	National Coordinator (NBC-R)
8. Mr. Waryal Ali Daheri	LDC (NBC-R)

### **Regret received from the following members:**

1. Prof. Sualeha Siddique Shekhani	Member
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### **The following projects reviewed / discussed:**

Title: **Endline Assessment – Advancing the Leadership of Women and Girls Towards Better Health and Climate Change Resilience in Sindh and Khyber Pakhtunkhwa.**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1299</b>	<b>Dr. Sadiq Bhanbhro</b> Integrated Research Solutions Global – Pakistan, Karachi.	<ol style="list-style-type: none"> <li>1. Please clarify the title of this study about Advancement of Leadership of Women and Girls towards Climate Change resilience and its relevance to the methodology written in the proposal. The document highlights questions on sexual and reproductive health mostly but does not address how that will build leadership or climate change resistance among the participants.</li> <li>2. There should be a formal informed consent form as the PI is asking for sensitive data from the participants.</li> <li>3. Are there any competing interests? Please enlighten us about the previously approved Ujala project, its results and how it ties in with the current project?</li> <li>4. Why is data being transferred abroad? Should it not be disseminated for the benefit of our own population among our health care own authorities?</li> <li>5. There are 5 sites from Sindh and 1 from KP. Is this not quite disproportionate?</li> </ol>

Title: **Determining Diagnostic Accuracy of a Non-Invasive Hemoglobin monitor for Anemia Screening Among Pregnant Women in Rural Pakistan (SEHAT Study).**

Project #	PI Name & Address	Final NBC-R Comments
<b>NBCR-1300</b>	<b>Dr Fareeha Shaikh</b> The Aga Khan University Hospital The Department of Community Health Sciences, AKU. Karachi.	<ol style="list-style-type: none"> <li>1. Who is the manufacturer of this device that is being tested? Will it be provided to our population if found useful or as good as venous sampling? Please explain benefit sharing for the community if any.</li> <li>2. Why is there a need to go to Thatta for this study? This study may be done in AKUH or its secondary clinics as anemia in pregnancy is a common problem. Furthermore, why can this device not be checked for diagnostic accuracy in the lab where patients frequently come to get their hemoglobin checked?</li> <li>3. Why are patients/research subjects being referred to Civil Hospital? Should there not be some provision for treating their anemia in the community with iron therapy?</li> </ol>

		4. Why is there a need to transfer our country's data abroad? The results can be analyzed within the country.
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Title: **Trial: An open-label, single-dose, randomized, two-period, 2x2 crossover bioequivalence study of Norvasc 10 mg Tablet (Amlodipine).**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1301	<b>Prof. Dr. Muhammad Tariq Farman</b> Dow Institute of Cardiology, Dow University of Health Sciences, (DUHS) Ojha Campus, Karachi, Pakistan	<ol style="list-style-type: none"> <li>1. Please clarify the source from where the raw materials for amlodipine for Pfizer and AGP are coming from? Is it the same source and are the list of impurities similar to each other?</li> <li>2. Where will adverse events be treated as amlodipine can cause problems in normotensive adults?</li> <li>3. Is there a DSMB for this study? Please give details.</li> <li>4. Please clarify health insurance and remuneration package for the participants.</li> </ol>

**Next meeting:**

The next zoom meeting will be held at 02:00 pm on September 30, 2025. The following projects will be reviewed:

**NBCR-1304, 1305,1308, 1313,1315 & 1317.**



## Minutes of the NBC-R meeting held on 30-09-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on September 30<sup>th</sup>, 2025. The following members of NBC-R attended the meeting:

1. Prof. Saima Pervaiz Iqbal	Chairperson
2. Prof. Nazli Hossain	Member
3. Prof. Jamshed Akhtar	Member
4. Prof. Munir Akhtar Saleemi	Member
5. Prof. Saqib Mehmood	Member
6. Prof. Marie Andrades	Member
7. Prof. Amjad Mehboob	Member
8. Prof. Sualeha Siddique Shekhani	Member
9. Dr. Farkhanda Ghafoor	Member
10. Prof. Shahid Mehmood Baig	Member
11. Prof. Ejaz Ahmad Khan	Member
12. Prof. Ejaz Ahmad Khan	Member
13. Prof. Akhtar Sherin	Member
14. Prof. Sarosh Saleem	Member
15. Dr. Faheem Ashraf Khan	Member
16. Prof. Shaper Mirza	Member
17. Dr. Rameeza Kaleem	Member
18. Prof. Agha Riaz Ahmad	Member
19. Dr. Natasha Anwar	Member
20. Mrs. Tayyaba Rahat	National Coordinator (NBC-R)
21. Mr. Waryal Ali Daheri	LDC (NBC-R)

**Regret received from the following members:**

**The following projects reviewed / discussed:**

Title: **NBCR-1305: A Comparison of the Accuracy and Efficiency of Artificial Intelligence (AI)-Assisted Diabetic Retinopathy Screening Using Handheld Fundus Cameras Versus Usual Care in Primary Care Clinics.**

PI Name & Address	Final NBC-R Comments
<b>Dr. Haroon Tayyab</b> Dept of Ophthalmology and Visual Sciences Aga Khan University Karachi.	<ol style="list-style-type: none"> <li>1. Please clarify selection of the sample of patients with diabetes. For how long should they be having the disease to classify into this project or will they be a part of the routine screening program in the clinics?</li> <li>2. As patients will be making multiple visits (3 months/6months) to clinics is there any transportation allowance?</li> <li>3. As the standard of care is routine screening by an ophthalmologist should this not be present in both arms? In primary care, the physicians do not do eye exams in diabetic patients as a routine.</li> <li>4. Participants should be informed explicitly that the AI tool is under evaluation and not yet a replacement for routine screening.</li> <li>5. Who will be filling the proformas with all the technical information that is required?</li> <li>6. Are there any plans of post-study access to the AI tools if they prove to be useful?</li> </ol>

Title: **NBCR-1305: Typhoid Risk factors and Intervention for Prevention in Pakistan (TRIPP).**

PI Name & Address	Final NBC-R Comments
<b>Dr. M. Tahir Yousafzai</b> Department of Paediatrics and Child Health Aga Khan University Karachi	<ol style="list-style-type: none"> <li>1. Please clarify who are the stakeholders mentioned in the study as there could be several types.</li> <li>2. How will safety of data collectors be ensured as they would be going into the households?</li> <li>3. There is a possibility of getting biased responses to appease the data collectors. How will this be addressed?</li> <li>4. The benefit sharing with community is largely confined to education materials.</li> <li>5. Could there be more tangible community benefits eg. Linkages for</li> </ol>

	WASH initiatives, support for local health workers etc. 6. Sindhi consent form is needed.
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Title: **NBCR-1308: PGI Accelerating Pathogen Detection through Wastewater Surveillance.**

PI Name & Address	Final NBC-R Comments
<b>Dr. Imran Nisar</b> Dept of Paediatrics and Child Health Aga Khan University Karachi	<ol style="list-style-type: none"> <li>1. Please clarify what kind of biological materials are being collected and where will they be shared and with whom.</li> <li>2. Who is doing the bioinformatics part of the project and the next gen sequencing?</li> <li>3. Is the Pakistan Council of Research and Water Resources involved in this project as it would be in their area of interest and expertise?</li> <li>4. The reliance on generic information sessions may not be sufficient to ensure trust and buy-in from the community.</li> <li>5. Benefits of this research are described in broad national terms (pandemic preparedness, early detection etc.) but there is limited explanation of direct benefits for the communities from where samples will be collected.</li> <li>6. It is not clear how equity will be ensured</li> <li>7. There is no explanation of whether vulnerable or underserved areas (squatter settlements, peri-urban slums etc) will be included which may carry greater infectious disease burdens.</li> <li>8. The proposal mentions capacity development workshops but does not clearly specify how this capacity will be institutionalized in public health systems beyond the study period.</li> <li>9. Adverse events are marked as "Not applicable" however even in environmental surveillance adverse events can occur (Laboratory accidents, community reaction, breach of confidentiality)</li> </ol>

Title: **NBCR-1313: Feasibility of a Virtual Integrated Multidisciplinary Tele Stroke Approach for Secondary Prevention and Rehabilitation in a Lower-Middle-Income Country" (VISTA).**

PI Name & Address	Final NBC-R Comments
<b>Dr. Ayeesha Kamal</b> Department of Medicine Aga Khan University Karachi	<ol style="list-style-type: none"> <li>1. Is this a student project? It is noted that Dr. Zainab Samad is also involved in it. Her role is not described.</li> <li>2. As there are no collaborators, so with whom data can be shared. Journals do not require raw data as such.</li> <li>3. How huge sum of money mentioned against computer software and cloud. How it can be justified?</li> <li>4. How the cost for national and international travel is calculated?</li> <li>5. What is the interest of international funder for this project? Is this project is based upon a sub grant of some other funding received by any other person at AKU?</li> <li>6. In the primary objective it is mentioned that it is a feasibility study but no feasibility benchmarks are found.</li> <li>7. Describe the waiting list and intervention groups in which the patients will be grouped. Also give the duration of waiting list.</li> <li>8. Explain how outcomes will be compared between waitlist-control groups.</li> <li>9. Include a brief summary for the post-stroke care algorithm, the standard approach and this intervention may differ?</li> <li>10. Clarify what standard care the waitlist group will receive.</li> <li>11. Clarify the contradiction between the exclusion criteria that says "Patients with severe cognitive impairment will be excluded" and that in the consent form that say "In case of stroke survivors having compromised decision-making capacity, consent will be obtained from the caregiver"</li> <li>12. Clarify that participation involves 4 virtual consultations over 3 months and completion of follow-up questionnaires, and mention approximate total time commitment.</li> <li>13. State whether participants can have caregivers present during sessions and if sessions will be recorded or not.</li> </ol>

14. Organize the questionnaire into clear sections for understanding.
15. Include medications at the time of discharge in the questionnaire.
16. Add a question on caregiver experience in the Qualitative Interviews with Patients.
17. Describe the Clinical condition of the patient in each virtual session in the questionnaire.
18. There should be some provision for those who are found gravely sick on telecommunication.
19. The researchers have mentioned potential risks of harm and benefits in detail. However, do the researchers anticipate any psychological harms (or benefits) from this research? If yes, share details of anticipated psychological risks and steps that will be taken to mitigate them
20. Details of the participant recruitment process needed (if done while in-patient, is there a certain time, like around the time of discharge, or immediately after admission, etc., when the patient/family will be approached for consent?)
21. When will the wait-list group be enrolled? The protocol (Page 4 of protocol under Cohort Recruitment Strategy) mentions that the wait-list group will be enrolled after 6 months. Is it 6 months after the stroke?
22. Section 1.2 of NBC Application; page 5 of Protocol) The details of Focus Group Discussions (FGDs) are required. Will each FGD include family members and healthcare providers of one patient? When will these discussions take place (how long after the four sessions are complete)? Will these discussions be recorded (audio or video?)
23. If FGDs will be held with the patient, family, and healthcare providers altogether, is it justified to ask for feedback in a FGD? Wouldn't separate FGDs (one with each patient and family and one with their relevant healthcare providers) be better? Or having 1-2 FGDs separately, with all HCPs and researchers involved, may be an option because the required information isn't about individual patients' care, rather it's **about the feasibility of using a virtual platform.**
24. If healthcare providers are also interviewed, aren't they the research participants as well? What about family members?
25. The research is sponsored. Is it justified to make the research participants pay for internet access for the virtual sessions? The study participants are also a vulnerable group. A reasonable data package should be offered to all research participants.
26. CONSENT:
  - a. The consent forms mention (in the Procedures section), "You may also be asked to complete short questionnaires about your health, recovery progress, and quality of life during the study." Details are required for review.
  - b. Information about two groups (the immediate and the wait-list group) should be in the consent form, as that is the study design, and the potential research participants should have that information before making a decision.
  - c. Details of FGDs at the end of study (including all the information about recording of interviews) must be included in the consent form.
27. Questionnaire: rephrasing few questions, as some are leading

	<p>questions, while some are closed-ended questions.</p> <p>28. In secondary objective, what does system mean?</p> <p>29. For the fortnight clinic visit, who will pay the compensation for the participant and for the caregiver, for traveling and wage of the caregiver? This needs to be included in the consent form.</p> <p>30. Incase during the virtual consultation, if physical presence is required, who will pay for the transportation and compensation.</p> <p>31. Since the strength cannot be measured on tele-medicine, and also limitation of study, how this will be justified for the outcome.</p> <p>32. Ill the participants be charged for tele- medicine, after the study is concluded.</p> <p>33. It is a trial as well. Trial Registration may be required.</p>
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Title: **NBCR-1315: Trial: An open-label, single-dose, randomized, two-period, 2x2 crossover bioequivalence study of Accethrom (Clarithromycin) 125mg/5ml suspension.**

PI Name & Address	Final NBC-R Comments
<p><b>Dr. Saba Afshan</b> DUHS, Ojha Campus Admin Block, Sindh Infectious Diseases Hospital &amp; Research Centre (SIDH &amp; RC); Institute of Biological, Biochemical &amp; Pharmaceutical Sciences, Karachi</p>	<ol style="list-style-type: none"> <li>1. IRB approval is awaited.</li> <li>2. How Rs. 12,000 is justified as a travelling allowance but no monetary gain of participating "voluntarily" in this study. Volunteers shall stay for two days in the facility.</li> <li>3. Share flyer for this study for public to know about it.</li> <li>4. How news shall be disseminated?</li> <li>5. Provide insurance document.</li> <li>6. Provide budget related documents for this study.</li> <li>7. In case of adverse events where subjects shall receive treatment.</li> <li>8. Will data be shared with the sponsor from Philippines? If yes provide data transfer agreement.</li> <li>9. Is the site currently approved by the DRAP? Provide letter issued by DRAP.</li> <li>10. The word <b>confinement</b> is problematic, if they can leave at any time why will you confine them.</li> <li>11. More information is required about this 'confinement' facility, will there be a medical team present, who will be the leading physician, will they be on duty for the entire period of monitoring and sampling?</li> <li>12. Informed consent is very technical and expects the participant to be able to understand terms like 'washout period'.</li> <li>13. Will all participants be tested together at the same time?</li> <li>14. It is mentioned that 16 pricks will be done for blood sampling. Why not use a branula?</li> <li>15. If you detect something in the chemical/drug screen, what will you do?</li> <li>16. Medical screening form (In consent form &amp; questionnaire) issue date Nov. 2023 and effective date Dec. 2023. How this medical screening form validated?</li> <li>17. For this study, the gender is not specified, the study participants will be from which gender?</li> <li>18. Which biochemical and serological tests will be done, at the time of screening and on each bleed. The tests need to be detailed in methodology as well as in consent form, also where these tests will be done.</li> <li>19. Where the samples will be stored and for how long?</li> <li>20. Who will verify data collected? Any DSMB?</li> <li>21. Please provide the Registration of trial with DRAP.</li> <li>22. After 48 hours at the time of discharge, in case any abnormality is seen in blood, urine tests or ECG, how that</li> </ol>

	<p>will be dealt with and who will pay the cost of treatment / hospitalization.</p> <p>23. The study budget is missing.</p> <p>24. The washout period should be clearly justified using relevant pharmacokinetic data (e.g., half-life, clearance) to support its adequacy.</p> <p>25. The dosing regimen and washout period require clearer explanation to ensure the study design is scientifically sound.</p> <p>26. The randomization process must be described in detail, including method &amp; allocation.</p> <p>27. The inclusion and exclusion criteria are incomplete — only BMI and age range are provided.</p> <p>28. The adverse event and serious adverse event reporting process needs to be presented more clearly.</p> <p>29. A flowchart showing timelines, responsible personnel, escalation steps, and contact points should be included.</p> <p>30. The statement regarding initial abnormal laboratory screening results is too general. A specific referral pathway should be described for participants with abnormal findings, rather than simply advising consultation with a physician.</p> <p>31. The ICF should include a lay summary of the study purpose and procedures to enhance participant understanding.</p> <p>32. A lay summary of potential risks, including rare but serious adverse events, should be added to the ICF.</p> <p>33. Clarify whether the Institute of Biological, Biochemical &amp; Pharmaceutical Sciences (IBBPS), Dow University of Health Sciences is functioning as a Contract Research Organization (CRO) in this study.</p> <p>34. The study monitor's qualifications and experience do not conform with the role he has to play.</p> <p>35. Include a detailed conflict of interest statement, particularly addressing the sponsor's involvement in protocol design, data analysis, or publication.</p> <p>36. Clearly mention in the NBC form and IC that there is 'no direct benefit' to study participants.</p> <p>37. Will all data be shared and kept with the sponsor? Justification is required.</p> <p>38. IC requires further details about how many days the study participants will be required to stay at the research facility, what other specifications will be (like sitting upright for 4 hours after drug administration, and other restrictions).</p> <p>39. What will be the recruitment process of healthy volunteers? How will the study be advertised to recruit participants?</p> <p>40. What is the justification for asking about ethnicity in the screening questionnaire?</p> <p>41. In the sponsor-CRO agreement, an explanation of section 6.5</p> <p>42. Protocol section 43. The data will be a property of sponsor</p> <p>43. In the sponsor-CRO agreement, Appendix 3 says Cefixime!?</p> <p>44. Details of duration of blood and urine sample storage are required.</p>
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Title: **NBCR-1317: Strengthening Immunization Services in High-Risk Union Councils of the Southern districts of Khyber Pakhtunkhwa.**

PI Name & Address	Final NBC-R Comments
<b>Dr. Sajid Soofi</b> Department of Centre of Excellence in Women and	<p>1. PI is already involved in 13 grants related projects. How this 14<sup>th</sup> project may be justified?</p> <p>2. It will be of interest to know how many similar projects</p>

related to the vaccination coverage has been conducted by the researchers and at their university?

3. This is an implementation study. How previous strategies with almost approach failed to provide desired results? In this project communities are involved in a similar pattern, use of mosques as a place, local elders and other plans.
4. What new this project might add to the already known facts?
5. How fool proof security may be guaranteed for the staff in the high risk areas. In some of these military operation is ongoing. How will PI ensure that through this targeted approach, desired outcome shall be achieved? Will PI be a part of the team working along with the communities?
6. Define 'Low-risk' and 'High-risk' areas. How is that ascertained and details of how the risks will be mitigated or managed. (There are details about what strategies will be used in these two types of areas, however, specific measures for the safety and security of not only research teams but also of research participants must be described in detail.)
7. Section 2.1 of NBC form says that this is a minimal risk study.
8. Considering the risks to both research participants and research implementation team, this research falls into the category of "more than minimal research". Considering the research participants, children and women are vulnerable populations, this statement needs revision and strategies must be clearly defined to reduce risks and promote protection of both participants and researchers.
9. The Research benefits section (and IC) state that decrease in zero-dose children and vaccination to children are research benefits. However, these may not be described as direct benefits of research, as a) EPI vaccinations are free anyway, and b) if decreasing zero-dose children is an expected outcome of the research, it cannot be a direct benefit to research participants.
10. In a more than verbal risk study, with children, is verbal consent justified?
11. Section 1.3 of NBC Form mentions both children and women as target population of study but later, I did not find any details of including women and data collection, etc. No relevant IC is available.
12. Details of how research participants will be recruited?
13. The proposal should clarify how this project builds on and differs from previous health camp initiatives.
14. The sample size justification is missing — while a range of 2,600–2,800 children is mentioned, no rationale, effect size assumptions, or power calculations are provided based on the population of the selected area.
15. No co-investigator or collaborator from KPK is included in the research team.
16. Furthermore, no MOU or NOC from the KPK Health Department or EPI Directorate is attached.
17. Although the proposal identifies zero-dose, partially

	<p>immunized, and defaulter children as key target groups, it does not outline differentiated immunization strategies for each. The plan should detail how each group will be identified, tracked, and managed according to EPI guidelines.</p> <p>18. The proposal lacks a comprehensive immunization plan.</p> <p>19. There are inconsistencies regarding the age group — some sections refer to “under 2 years” while others refer to “under 5 years.” This must be standardized and clearly justified.</p> <p>20. The use of verbal consent must be clearly justified.</p> <p>21. Is any survey available where the number and type of pharmacies as per governmental standards are available on ground being supervised by the pharmacists exist at study sites? If yes provide details. This is a different step incorporated. Do you think such pharmacies may be a target for those against vaccination? How they shall be secured?</p> <p>22. How PI will reply to the non-compliance to vaccination when it is provided at door-step to people by EPI people? Why would people themselves reach out to the pharmacies voluntarily for vaccination?</p> <p>23. If that may be the hypothesis then why governmental health facilities are not the suitable place?</p> <p>24. Where women receive reproductive health services in these high risk facilities? What is the current status of neonatal tetanus in these communities?</p> <p>25. In the introduction of the ICF, include a brief explanation of the importance of immunization in lay terms to help participants understand the study context.</p> <p>26. Although consent forms are provided in English and Urdu, translations into regional languages (e.g., Pashto) are essential.</p> <p>27. Similarly, information materials and brochures should be available in local languages to ensure community understanding and participation.</p> <p>28. Since fathers are often primary decision-makers in these communities, the consent process should consider obtaining consent from both parents.</p> <p>29. Clearly define referral pathways and specify designated health facilities for AE/SAE management.</p> <p>30. The verbal consent will be taken from different stakeholders, the draft required what will be explained for taking consent. The only consent attached is for mothers.</p> <p>31. -Performance-based incentives will be offered to community gatekeepers based on the number of eligible children mobilized for immunization. What will be the incentives?</p> <p>32. -For outreach sessions, the houses will be designated as outreach points, equipped with Information, Education, and Communication (IEC) materials, please provide the communication materials, also who will conduct these sessions and who and how many will be the participants per session and who will conduct these sessions.</p> <p>33. The consent form does not make it clear that this is a research project, says AKU is helping with the EPI program, does not mention the questions/questionnaire that needs to be completed.</p>
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	<p>34. Provide itemized budget not as lump sum under one head. It involves crores of rupees.</p> <p>35. How much of this will go to KPK?</p> <p>36. Will data be sent outside Pakistan? If yes send data sharing document.</p>
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**Next meeting:**

The next zoom meeting will be held at 02:00 pm on 7<sup>th</sup>October, 2025. The following projects will be reviewed:

**NBCR-1318, 1319, 1320, 1321, 1324 & 1327.**



**Chairperson NBC-R**