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 7th, 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	**Dr. Naseem Salahuddin,** The Indus Hospital, Opposite Darussalam Society, Korangi Crossing, Karachi	• Please specify which anti-rabies vaccine is being tested? • 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 flourescent 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. • Which cytokines are being measured? Can any of these tests be done in Pakistan? If not, is there any capacity development in the pipeline?

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	**Dr. Zainab Latif** Oxford Policy Management, Pakistan Plot 271, St No.1, Sector I-9/3, Islamabad	• Why in particular has district Khushaab been selected? • Has permission been taken from the school Principals or Education department for this study? • Please mention who is doing the school and class observation. • There is no mention of duration required for focus group sessions. • The proposal also states asking for contact numbers of students. Would that be culturally appropriate especially where girls are concerned?

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.	• Study Approved.

Next meeting:

The next zoom meeting will be held at 02:30 pm on 14th 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 14th, 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 Supplimentation Affect the Outcome in Neonate with Hypoxic Ischemic Encephalopathy?**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1197	**Dr. Bushra Fatima,** Department of Neonatology, University of Child Health Sciences and Children's Hospital , Lahore	• 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. • 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. • Will baseline folinic acid levels be conducted on all CSF samples? • 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? • Who is paying for all the tests being conducted? • Is the site approved by DRAP? • 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?

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

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1198	**Dr. Zahid Memon** Department of Community Health Sciences Aga Khan University Karachi"	• Study Approved.

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	**Prof. Dr. Saleem Ahmed Khan** National University of Medical Sciences, The Mall, Rawalpindi, Pakistan	• Please provide information about the local tool kit that is being tested for diagnostic accuracy. With what tool is it being compared against? • From where will samples be collected? Who are the volunteers for giving samples? Please specify. • What is the Data Management Agreement with the CRO that is involved? Why will they be storing samples and for what purpose? • Does this study really require a DSMB? This is more of a validation study.

Next meeting:

The next zoom meeting will be held at 02:30 pm on 21st 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 21st, 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
NBCR-1201	**Dr. Rehana Rehman** Dept of Biological & Biomedical Science Aga Khan University at Stadium Road Karachi	• Why has this trial been presented to the NBC now when it was initiated several years ago? • Are the participants being tested for Vitamin D toxicity? Has it been reported in any of the cohorts? • How will therapeutic misconception be addressed as these women would be desperate to get pregnant? • Some of the questions are not culturally appropriate like "Have you received a suntan in the last 12 months?" • How much blood is being drawn...5 ml or 10 ml? It should be specified in the informed consent form. • Who is paying for the tests and ultrasound? This should be mentioned in the informed consent form.

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
NBCR-1202	**Dr. Hina Sharif** SINA Health Education & Welfare Trust Plot No.1 D-21, Sector 30 Karachi.	• Study Approved.

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

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1203	**Dr. Muhammad Ansar** Dow University of Heath Sciences, Karachi, Pakistan	• 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. • 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

		sensitivity and this may create more problems for the people being involved. • 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. • 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? • There is no MTA. Approval from the IRB of DUHS is required.

Next meeting:

The next zoom meeting will be held at 02:30 pm on 28th 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 28th, 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	**Dr. Naeem Majeed** SPHERE Consulting 2-Justice Sardar Iqbal Rd, Gulberg 5, Lahore	• 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? • All four provinces have different PHC set ups and SOPs. How such differences shall be addressed? • 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. • There is no document found that shows a permission by the relevant health department. • It is very convenient to assess PHC services in major cities but that leaves the rural areas most vulnerable. This does not seem appropriate. • Details related to KPK and Baluchistan are not found. • 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? • 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? • Data transfer to another funder from US is an issue not addressed. • AKU IRB approval is suggested. • What is the conflict of interest of the university who has outsourced the process to a CRO? • Who is going to monitor or have an oversight on this project. • How much time they are expected to spend in the PHC? • Data collection tools mentions putting names of the participants. This is not appropriate. • In maternal health data, male is also mentioned. • Verbal consent is not appropriate strategy. A formal consent form is suggested as part of study from all stakeholders.

		• 2.3 is not satisfactory. Only publication is a purpose mentioned in this section. • It is expected that there should be a clear statement mentioning that BGMF is actually the funder. • The time of interaction is mentioned as 10 - 15 minutes in ICF. This is not possible. • 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.

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	**Dr. Wasim Mirza** Contech International 2-G Model Town, Lahore, Pakistan	• BGMF is the actual funder. This must be mentioned in the ICF. • Why would any PHC allow the researchers from outside for this study? • There is no formal letter from concerned ministries / departments about the study and permission granted. • Many studies already done on the subject from Pakistan. What new is expected out of another data collection? • The client interviews require privacy and confidentiality and we hope the investigators are equipped to deal with such delicate questions with appropriate responses. • 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? • Data transfer to another funder from US is an issue not addressed. • AKU IRB approval is suggested.

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	**Prof Nasim Chaudhry** Pakistan Institute of Living and Learning Suite No. 201, 2nd Floor, The Plaza, Karachi	• More information is required about CEI. For how long it has been working, how many members are there? What are their ongoing agendas? • Country specific protocols are not present. • 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. • What benefits are there for study participants? • Will obstetricians / gynecologist be involved in this? • What are the interests of funders and PI from outside Pakistan? • Is there a data transfer agreement available? • What shall be done when study is completed? • Do you have any framework in mind to facilitate psychological well-being of the participants?

Next meeting:

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

Data Sharing document will be discussed.

Member Secretary NBC-R

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 4th, 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 11th 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 11th, 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
NBCR-1129	**DR. Aakif Ullah Khan** Director & Chief Medical Officer, Institute of Radiotherapy and Nuclear Medicine (IRNUM), Peshawar, Pakistan	• **Rationale:** 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? • **Objective:** Please mention what clinical end points the PI is determining to prove. Which subsets of patients are these? • **Methodology:** 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? • We suggest the PI to attend a workshop or collaborate with an experienced researcher to get clarity on the science of this study.

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

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1207	**Prof. Abdul Basit** Health Promotion Foundation Suit # 102, 1st Floor, Al-Ameera Center, Near Passport Office, Saddar, Karachi-Pakistan	• 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. • Please identify the co-PIs who are collaborating in this project and from which institutions along with their support letters. • Why can this study not be done in the big cities like Karachi where the patient pool would be easier to collect? • Is there any pharmaceutical funding involved? • What is the Data Transfer Agreement in place? • We would like to see the country specific protocol for this study.

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
NBCR-1208	**Dr. Sarah Saleem** Department of Community Health Sciences Aga Khan University National Stadium Road Karachi	• What will be options for women whose hemoglobin do not show any rise with MMNS? • The investigators assume there is similarity between population of Burkino Faso and Thatta? How can this be justified? • 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? • Investigators should write explicitly whether they will store biospecimen or not? If yes, then there should be MTA for it. • WHO is already providing this supplement to women in powder form, for women living in coastal belt?

Next meeting:

The next zoom meeting will be held at 02:30 pm on 18th 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 February18th, 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
NBCR-1209	**Dr. Syed Abbas Raza** National Hospital and National Medical Center DHA Lahore	• A pharmaceutical company is a sponsor. Is their conflict of interest? • Why the study design is written as trial? A clarification is needed as it is an observational study. • 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

		contacted in future as well and their data will be re visited. • AE and SAE reporting is meant for a trial. What are these? How it relates to this follow up study? • The monitoring of this study is for what purpose? • In what capacity Mr. Syed Abbas is sponsor of the study? This is funded by the Highnoon company? • Why data is the property of the funder? • IRB approval letters are required from other institutions and consent of the GPs. • List all the tests that shall be done and who will pay for it? Echocardiography is an important test, will it be included. • How PI has decided to finally include a number nearly 350 of the total subjects enrolled previously. • The present study does not include the previous investigators. How it will be ensured that same subjects are enrolled. • The budget does not include the costs for tests which is mentioned in the proposal that it will be covered by the study sponsor. • The name of the study is misleading since this is not a trial but rather a cross-sectional study. • A general physician can also be a consultant- this is vague in the questionnaire • There is a mention of an agreement but it is not clear.

Title: **Trial: MULTI-CENTER, RANDOMIZED, DOUBLE BLIND AND PLACEBO CONTROLLED CLINICAL TRIAL ON THEEFFICACY AND SAFETY OF JINHUA QINGGAN (JHQG) GRANULES FOR THE TREATMENT OF ACUTE UPPERRESPIRATORY INFECTION (WIND-HEAT PATTERN).**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1210	**Prof. Dr. M. Raza Shah** Center for Bioequivalence Studies and Clinical Research (CBSCR), International Center for Chemical and Biological Sciences (ICCBS) ICCBS, University of Karachi, Karachi	• The inclusion of two CO PI is to be justified. One is simple MBBS and other is an anesthesia person. • The project is about a respiratory disease. • 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? • Provide DRAP approval certificate for the two hospitals that shall be the site for THIS TRIAL. COVID 19 related permission is no more valid. • Chinese IRB certificate translation in English is required. • Why competing interests of funding agency not matter? The product is about traditional Chinese medicine and is experimented of Pakistani and Jordanian peopleand simultaneously at China. It is of interest to know why there is a hurry in conducting this trial in Pakistan. • Data of usefulness mentioned is in context of influenza. Provide details of Phase I II and III trials conducted in China. • Why it is a placebo control trial? What is the standard of care?

		• What these granules re expected to do? Mode of action. • Age group is too wide. What if patient does not improve? • There is a mention of simulation in the project. This is not clear. • Why chest radiograph is needed for URTI? Is not done as a routine. • No insurance document found? • Data transfer agreement is not found. • 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. • Informed consent form must mention that the drug is not approved in Pakistan. Reference to year 2016 is deceptive. • Acetaminophen is also allowed in this trial in a particular situation. Does this mean failure of the intervention? This need clarity. • 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. • How much blood shall be drawn? Where tests shall be performed? Will reports given to the study participants? • Amount to be paid to the participants is not mentioned. • Will patient remain hospitalized during the course of treatment? • AE SAE related document is not found. • What were the results of previous studies conducted particularly during Covid-19? • How the participants be recruited? This is unclear • The informed consent form is too long, and provides unnecessary details • 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 • The exclusion criteria is huge, who will be paying for all these tests? • Will the Co-PI from Southcity Hospital include his patients? • Batool General Hospital is a small clinic, who will be monitoring at Batool General Hospital, which basically provides maternity services.

Title: **IMAGING THE STRUCTURAL CORRELATES OF COGNITION IN PARKINSON'S DISEASE USING PORTABLE MRI.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1211	**Dr. Kiran Aftab** Lecturer, Department of Surgery, Aga Khan University, Karachi	• The PI is a lecturer in GS. How this may affect the conduct of study. • What are the conflict of interests of the UK institution where PI is probably enrolled? • 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? • Why data will not be accessible to the patients? Will they be told the outcome? • What PI expect to gather from this interventional study that may help patients and their families plus volunteers? • What if new nervous system related condition is detected? • With whom this data shall be shared? Is any data sharing agreement done? • 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 • Is use portable MRI in other places indicated for same reason? • How data security will be ensured. This is an era of AI and patient's data is used for making algorithms.

Next meeting:

The next zoom meeting will be held at 02:30 pm on 25th 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 February25th, 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
NBCR-1212	**Dr. Muhammad Irfan** Department of Medicine Aga Khan University Karachi	• Budget is mentioned as provisional. It may be elaborated. • There is no mention of how pregnant women shall be x rayed? Any protocol for shielding will be done. • The software if included in processing the x rays then mention how confidentiality shall be addressed. • What is the cost of this gadget? How it compares in cost effectiveness with already existing available x ray chest machine? • Provide satisfaction survey form. Also share feedback forms to be used.

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

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1213	**Dr. Farheena Iqbal Awan** DNA Core Facility, Center for Applied Molecular Biology (CAMB), University of the Punjab Lahore	• 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. • Mention the details about the staff trained for this study. • Ethical approval is still awaited from the universities. Mention name of the universities and share it with NBC. • 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. • Elaborate which part of the research shall be done in Pakistan? What steps shall taken for capacity building? • IRB approval letter of Punjab university is not on IRB letterhead. • There is no MTA.

		• There is no data sharing agreement document. • There is no mention of study sites from where samples shall be collected with IRB approval in ERC form. • There is no mention of clinical site Co PIs. Clearly mention all the sites as it is written from all over Pakistan. • Budget is not at hand. It is an essential requirement. • Number of samples to be collected is also not mentioned. • 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. • 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. • 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. • The consent form is ambiguous, needs to bere written, explaining what is being done in easy language. • 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. • Psychological counseling may be required but there is no mention of it. There is no mention of how these women shall be treated. • Which of the mutations PI is particularly interested in? • It is also mentioned, there may be change of institution if funding is not secured. • The PI should is suggested to resubmit in light of above comments as at present essential requirements for the evaluation of the proposal are not met.

Title: **AN OPEN LABEL CLINICAL STUDY BCD 248. RELAPSE AND REFRACTORY MULTIPLE MYELOMA.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1214	**Dr. Munira Borhany** Zia Uddin University Hospital, 4/B, Sharah-e-Ghalib, Block 6, Clifton, Karachi	• It is a phase II trial to be conducted at Four sites. Russian Drug. • 21 bullet in IFC is incorrect. The project is being reviewed and not approved yet. • 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

		how the treatment affects the body". • 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. • 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? • AKU IRB approval letter is not found. • MTA should be on a legal paper. • DSMB from Pakistan is not found. • Is insurance cover valid for Pakistan? • Data transfer agreement is not found. • Head wise budget and how much amount to be paid to each Co PI is not found. • How much money shall be transferred to KEMU treasury account is also not found. • What is the probable cost of this drug? • Will it be available in future in Pakistan once the study is completed? • What alternate treatment patients shall receive once study is completed? • Is the trial registered in international registry? • What are the other countries in which this trial is currently being carried out? • Share brief results of Phase I trial. • 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. • 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?

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 4th, 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
NBCR-1215	**Prof. Salman Kirmani** Department of Pediatris and Child Health, Aga Khan University**, Karachi**	• Please explain the rationale for having more samples from the peri-urban sites rather than the urban site. • The questionnaire has been taken directly from the Indian Longitudinal Ageing Survey with terms used commonly in India. It needs a Pakistani context. • If a participant screens positive for anxiety or depression or dementia or there is an abnormal MRI to whom will the patient be referred? • There is no Urdu informed consent, in addition there is no informed consent for the caregiver. • The MTA needs to be drafted onto a legal paper.

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

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1217	**Dr Raheela Ali** Hussaini Blood Bank, Head Office PLOT # ST 02, BLOCK T, QALANDARIA CHOWK, opposite Talib Chaman Park, North Nazimabad Town,**Karachi**	• Please explain why this had to come to NBC as this is not a research study but just a transfer of platelet products abroad. • 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? • A Material Transfer Agreement needs to be developed on a legal paper.

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
NBCR-1218	**Dr Shahbaz Ahmed Zakki** The University of Haripur near swat chowk **Haripur 22620, KPK,**	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." • Informed consent needs to be rewritten. No mention of RCT, duration of study and intervention in detail.

		Complete rewrite required • For participants in both groups , if severe depression is found what measures will be taken?? Where will they be treated • Some of the questions in the questionnaire do not make sense like asking them the following. They may not know the answers o What are your most recent physiological measurements? (Please provide values for the following) o Blood Pressure: mmHg o HDL (Good Cholesterol): mg/dL o LDL (Bad Cholesterol): mg/dL o Weight: kg o Height: cm o Blood Glucose mg/dL o Other relevant measurements (e.g. BMI, Waist Circumference): • Another question in the questionnaire: Do any of your family members provide you: Social Support Psychological Support No Support. **This question if open for interpretation and inappropriate as puts the person in a defensive position** • For weight we use KG NOT pounds as mentioned in questionnaire • **The questions need to be culturally appropriate. We don't use Shake off the Blues**: I felt that I could not shake off the blues even with help from my family or friends.

Next meeting:

The next zoom meeting will be held at 02:30 pm on 18th 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 18th, 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	**DR. Aakif Ullah Khan** Director & Chief Medical Officer, Institute of Radiotherapy and Nuclear Medicine (IRNUM), **Peshawar, Pakistan**	• 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. • Study Design: To achieve a proper comparison, the study should include two distinct patient groups: o One group treated with established isotopes (Yttrium-90 or Rhenium-188). o Another group treated with the indigenous Lu-177. This comparative approach will provide credible data on efficacy and safety. • 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. • 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. • What is the cost of Lu-177 based RIO? • How will efficacy, safety and feasibility be measured? Please clarify your clinical end points. • How will side effects be managed? Who will pay for them? Are there any radiation hazards? • The aims and objectives read more like a wish list rather than actual measurable objectives. • How will patients be recruited? • The rationale for radioisotope therapy for hemophilia needs more convincing. Hemophilia is a condition that

		will persist throughout life. Synovectomy will treat the consequence of the disease but not the disease itself.

Title: **Nutritional Supplementation in Pregnancy to Neutralize Heat Stress.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1220	**Dr. Junaid Iqbal** Department of Paediatrics and Child Health Aga Khan University **Karachi**	• 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? • Informed consent form needs to mention that even the non-supplementation group will have to provide their samples. • Where patients would be referred if they have mental health issues. Is there a mental health expert on board? • What is the exact recipe of the nutritional supplement? Will it be socially and culturally acceptable and feasible? • Participants in the non-supplemental group may feel disadvantaged. Should they not be provided a standard meal? • We would like to see an itemized budget of this project.

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

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1221	**Dr. Abbas Raza:** National Hospital, Lahore **Dr. Mohammad Ali Arif:** Pakistan Institute of Medical Sciences, Islamabad **Dr. Amna Subhan:** Aga Khan University Hospital, **Karachi** **Dr. Bilal Afzal:** Mukhtar A. Sheikh Hospital,Multan **Dr. Azizul Hassan Aamir:** Peshawar General Hospital, Peshawar	• Study Approved.

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

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1222	**Prof. Imran Bashir Chaudhry** Suit 201, 2nd floor, Dr. Plaza, do talwar, Clifton, **Karachi**	• 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. • What is the role of Ziauddin University? Its IRB approval would be required. • Please submit an itemized budget with funding source.

Next meeting:

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

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

Member Secretary NBC-R

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 8th, 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 Tobevibart + Elebsiran Combination Therapy in Participants with Chronic HDV Infection (ECLIPSE 1)".**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1223	**Dr. Saeed Hamid** Dept of Medicine Aga Khan University, Karachi	• Study Approved.

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	**Dr. Mueen Abid** Pakistan Institute of Living and Learning (PILL) Karachi	• Please elaborate on the rationale of this study. What will this study hope to achieve for the participants? • The project mentions that this study is an RCT but it is not in actuality. • Please explain the methodology of this study. How will the participants be contacted without feeling that their privacy has been breached? • Why has Qambar Shahdad Kot been selected as a study site whereas the study can be completed in any of the big cities? • Is there an MoU with PILL and the associated hospitals where data will be collected? • Where will the interviews be conducted? • Any compensation or token of appreciation to be offered to the participants? • Assent form has to be attached.

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

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1226	**Dr. Sajid Bashir Soofi** Dept of Paediatrics, Associate Director Centre of Excellence in Women and Child Health (CoE-WCH), Aga Khan University (AKU), Karachi.	• Please clarify the operational definition of a High Risk District. • 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? • What about safety and security of the investigators especially if they have to collect data from conflict areas like Baluchistan?

Next meeting:

The next zoom meeting will be held at 02:30 pm on 15th 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 15th, 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	**Dr. Saima Afaq** Institute of Public health and Social Sciences, Khyber Medical University, Peshawar, Pakistan	• 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. • 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? • 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. • 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 &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. • Is PI currently employed in two different institutions? This is mentioned in CV. This may be explained. • Remove NBC address from whom to contact in informed consent form. • 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. • What are the responsibilities of PI in UK and Co PI in Peshawar in context of this study? How on ground they will work?

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	**Dr. Ali Faisal Saleem** Department of Paediatrics and Child Health, Centre of Excellence – Women & Child Health, 2nd floor Aga Khan University, Stadium Road, Karachi	• 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 c conflict of interest and by-passing government departments, EPI program lead, may be counterproductive. • What is the cost of vaccine? Who will provide it if found useful? • 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. • Share AKU IRB approval letter. • Share the names of DSMB members. • Provide funding approval letter. • What shall be amount paid as imbursement for the parents? • At least provide a rough number of participants in IRB form that shall be enrolled and from each study site. • How PI will tell the communities that they are not part of EPI program and are conducting study on their own? • What impact it might cause? • Will parents be informed about the results of the study? • It is mentioned at a place that shall be shared. Provide details of a need of data sharing and for what purpose. • Provide details of how biological samples shall be collected from study sites, stored and transferred to NIH? Who will pay for it? • Will results of the study be shared with the parents?

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

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1229	**Prof. Dr. Iram Murtaza** Department of Biochemistry, Quaid-i-Azam University, 45320 Islamabad	• Share the results of previous study done by the PI group and was NBC R approval obtained for that study. • 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. • 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? • Why women are excluded? They suffer from large number of cardiometabolic disorders too. • Settings are unclear, tertiary hospitals of only KPK? Or will it also include other provinces? • The PI has not justified the importance of the diagnostic test. The protocol only has 4 references,

		which are a decade old. • 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. • 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? • There are a number of flaws in the questionnaire. Even gender is mentioned while women are not included. Diseases are also not clearly defined. • Methods of harvesting blood samples are also incorrect. • Will patients know about the results of the test? • Why RMI is chosen as a study site? • What is included in the management of the patients? Where this management shall be done? • Why study cannot be done in general population? Why it is a hospital based data collection. • How shall results be validated in subjects who are not suffering from any cardiac ailments? • What if positive results are reported? What shall be the strategy from this point onwards? • 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? • What shall be done with the instrument when study ends? • Will biological samples shall be used for any other purpose?

Next meeting:

The next zoom meeting will be held at 02:30 pm on 22nd 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 22nd, 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	• These are 5 different projects grouped into one protocol. Each project has a different dimension and needs to be evaluated separately. • 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. • With whom will the biological samples be shared with? Are they being sent abroad? If so. data sharing agreement will need to be attached. • Why are pregnant women excluded? • Point 3.5 in informed consent form needs elaboration. Why will the results not be given to the participants?

Title: **xploring 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	• Study Approved.

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	• Study Approved.

Next meeting:

The next zoom meeting will be held at 02:30 pm on 29th 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 29th, 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	**Dr Ashraf Ali Lakho,** FELTP Fellow 15th Cohort, NIH Islamabad	• Please clarify for us the rationale of this proposal. What are the gaps in knowledge and how will this study help in filing these gaps? • Will HDV positive subjects be given treatment? If yes, by whom? • What is the role of Abbot Pharmaceuticals in this study? • Why is the sample being collected from one district in Sindh? • The informed consent form needs to be in Sindhi. • How is this study aligned with National hepatitis programs?

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	**Dr. Abbas Raza** National Hospital & Medical Center, Street 123, Sector L Dha Phase 1, Lahore **Dr Ayesha Nageen** Creek General Hospital, Sector 48-H, Creek Road, Sector 48 H Korangi Creek, Karachi,	• This study is not a cohort study; it is an interventional study and should be designed as such. • Please mention the interventional product and its composition? Have previous studies been done on this product? • Please resubmit the project according to its methodology.

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	**Dr. Mariyam Sarfraz,** Associate Professor, Health Services Academy, Islamabad	• 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. • If a child is determined to have high lead levels, how will this be dealt with? • The questionnaire talks about imported canned food, imported toys whereas in our society there are multifactorial causes of lead poisoning. • 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?

Next meeting:

The next zoom meeting will be held at 02:30 pm on 6th 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 6th, 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	**Dr. Muhammad Imran Nisar** Department of Paediatrics and Child Health, The Aga Khan University, Karachi.	• Study Approved.

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	**Dr. Shelina Bhamani** Dept of Obstetrics and Gynecology Aga Khan University Karachi	• The survey instrument does not seem to answer the research question identified. A lot seems to be out of the cultural context of Pakistan. • Do we have antenatal classes in the context that is being studied? • What classes or literature will be given to the antenatal mothers and fathers?

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

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1240	**Kris Ann Schultz** Children's Minnesota 910 East 26th Street., Suite 40-LL08 Minneapolis, MN 55404 USA **Dr. Alina Sadaf** Head of Department of Pediatric Oncology Shaukat Khanum Memorial Cancer Hospital & Research Centre, 7A, Block R3, Johar Town, Lahore	• 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?

Next meeting:

The next zoom meeting will be held at 02:30 pm on 13th 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 May13th, 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	**Dr. Shiyam Sunder** Dept of Community Health Sciences Aga Khan University Karachi	• Has this trial been registered with clinical.gov? • 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. • Why is the intervention drug only Nitrofuratoin? • 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? • If a child is born premature, where will that child receive health services? • What is the data sharing agreement with the funders and collaborators? • Please clarify the need to follow these patients postpartum and doing additional tests like placental growth factor.

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

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1243	**Prof. Dr. Ume Sughra** AI-Shira Research Centre, AI-Shira Trust Eye Hospital, Rawalpindi	• Please clarify what is meant by a simulated post exposure prophylaxis? Will the rabies virus be inoculated into healthy subjects to determine a response? • Why could this study not be done in China? • What are results of Phase 1 and Phase 2 trials? • 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? • Will there be any indemnity insurance? • 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? • Is the trial site registered with DRAP for this trial?

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

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1244	**Dr. Zahid Memon** Department of Community Health Sciences Aga Khan University Karachi	• Study Approved.

Next meeting:

The next zoom meeting will be held at 02:00 pm on 20th 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 20th, 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	**Dr. Fozia Parveen** AKU-IED 1-5/b-VII, 1-5/B Street 7, Federal B Area Karimabad Block 7 Gulberg Town, Karachi	• Study Approved.

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	**Prof Nasim Chaudhry** Pakistan Institute of Living and Learning Suite No. 201, 2nd Floor, The Plaza, Karachi	• 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. • Please mention the local collaborators from each of the sites. Will they be the ones delivering the interventions? • Is this trial being registered with clinical.gov? • What is the data sharing agreement between the sponsors and the collaborating institutes?

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

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1248	**Mr. Imtiaz Hussain** Department of Paediatrics and Child Health Aga Khan University Karachi	• 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. • It will be of interest, working in a same setup how a

		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. • 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. **Under objectives it is mentioned that.** **The primary objectives of the intervention include:** • **Strengthening Immunization Services and Enhancing Coverage:** 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. • **Creating Demand for Routine Vaccination:** Mobilize communities and raise awareness about the importance of routine immunization by engaging health counsellors and Lady Health Workers (LHWs). • **Supporting Governance and Accountability:** 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). • 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. • 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.

Next meeting:

The next zoom meeting will be held at 02:00 pm on 27th 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 27th, 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	**Mr. Imtiaz Hussain** Department of Paediatrics and Child Health Aga Khan University Karachi.	• Study Approved.

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	**Dr. Kashif Asghar** Pakistan Kidney and Liver Institute and Research Center (PKLI&RC), One PKLI Avenue, DHA, Phase-6, Lahore, Pakistan	• 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? • How will study participants be approached and recruited? What incentives are there to be a part of the study? • Who is the co-investigator from KPK? How will further testing and treatment be provided in KPK? • Is there any alignment with the Hepatitis control program running in the country? What will happen if someone tests positive on the kit?

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
NBCR-1251	**Dr. Gul Nawaz Khan** Department of Paediatrics and Child Health, Aga Khan University, National Stadium Road,Karachi	• 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? • Is there a potential of adverse events due to allergy etc. If yes, how and where will they be managed? • 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? • Satya Nutrition is based in India. Is it the same being supplied in Baluchistan? This could have strategic implications for the country.

Next meeting:

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

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 3rd, 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
NBCR-1252	**Dr. Tashfeen Ahmad** Department of Surgery, Aga Khan University, PO Box 3500 Stadium Road,Karachi	• With a co-PI from DUHS, we would like to see the IRB approval from DUHS as well

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
NBCR-1253	**Dr. Fyezah Jehan** Department of Pediatrics and Child Health, Aga Khan University, Karachi.	• 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. • Please list the collaborators from each trial site. What is the sample expected from each site? • JPMC neonatology ward does not provide comprehensive care of preterm infants. Where these babies will be referred out and get treatment? 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. ▪ **We will not be able to pay for additional hospital investigations or treatment.** This is not right if the baby develops an infection the cost of treatment should be borne by the study. ▪ Will red flags be taught to the mother? ▪ What supportive advice for infant care be given to the mother/family during the month the child is being treated. Please mention the composition of the DSMB. The placebo consists of maltodextrin. Is it safe to use in this age group?

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.	• 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. • There are other etiological factors for preterm birth, how they will be ruled out? • What if ultrasound shows abnormalities what process of care will be guided to patient? ▪ **Your information will be included in a de-identified public-use database managed by the Bill & 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>** • Will biological samples be sent abroad? This is not clear. If so, please provide an MTA.

<u>Next meeting:</u>

The next zoom meeting will be held at 02:00 pm on 17th 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 17th, 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
NBCR-1255	**Dr. Zahra Hoodbhoy** National Stadium Rd, Aga Khan University Hospital, Karachi	• Please give the rationale for doing this project in Koohi Goth rather than in a more central part of the city? • 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? • 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? • What is the likelihood of a machine fault? How would that be detected if it occurs and how would it be rectified? • What is the data sharing agreement in place? • IRB approval from Koohi Goth Hospital would be required.

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
NBCR-1258	**Ms. Samrah Saeed** Lithuanian Sports University Sporto g. 6, Kaunas 44221, Lithuania	• 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? • Is there any psychologist on board? How will participants be recruited, using what criteria? • 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? • 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

		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?

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

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1129	**Dr. Aakif Ullah Khan** 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 24th 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 24th, 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	**Prof. Saeed Farooq** School for Primary, Community and Social Care Keele University, Staffordshire, ST5 5BG, UK	• 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? • Is there a possibility of financial burden on families? Where will any psychiatric emergency be dealt with? • Is there a DSMB in place? What is its composition? • How long is this project to last? The budget is of five years but protocol mentions two.

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

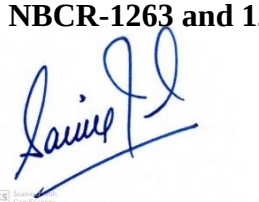
Project #	PI Name & Address	Final NBC-R Comments
NBCR-1261	**Dr. Taha Sabri Taskeen** Health Initiative, Pakistan 3rd Floor, Plot # 73C, Jami Commercial, 8th Commercial Street, D.H.A. Phase 7, Karachi	• Study Approved.

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

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1271	**Susan Rae Mackay** Acasus Consultancy (SMC-Pvt.) Ltd. 1st Floor, MA Tabba Foundation Building, Gizri Road, Block 9, Clifton, Karachi	• 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. • 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?

Next meeting:

The next zoom meeting will be held at 02:00 pm on 1st 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 1st, 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	**Prof. Nasim Chaudhry** Pakistan Institute of Living and Learning Suite No. 201, 2nd Floor, The Plaza, Karachi	• Study Approved.

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	**Dr. Asim Ali** Department of Biotechnology, COMSATS University Islamabad, Abbottabad Campus, University Road, Tobe Camp, Postal Code 22060 Abbottabad	• 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. • 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. • 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. • The proposal suggests that sequencing will be

		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.

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	• Please elaborate the post-trial benefits if any to our Pakistani population. Will the drug be available at an affordable cost? • is there any potential conflict of interest with the pharmaceutical company involved? • 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?

Next meeting:

The next zoom meeting will be held at 02:00 pm on 8thJuly, 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 July8th, 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
NBCR-1264	**Abdullah Latif** Mercy Corps, 189/190, Street 6, I-9/2 Islamabad	1. Is this study aligned with or in collaboration with National TB program? Please clarify 2. Will any data or DNA samples be sent abroad? If yes, please provide details and MTA. 3. An assent form is required for minors less than the legal age. 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? 5. Who is the main funding agency of this project?

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
NBCR-1265	**Dr. Junaid Iqbal** Department of Paediatrics and Child Health Aga Khan University Karachi	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? 2. Is goat milk normally consumed in this population? What is the feeding practice of this community? 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. 4. MTA to be on legal paper. 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?

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
NBCR-1166	**Dr. Hina Sharif** SINA Health Education & Welfare Trust,	1. Please clarify the need for this project to come to NBC? Is it being funded by the govt. or from abroad? 2. The methodology of this study is poorly designed. Please give us a detailed account of how and where

	Karachi-Pakistan	this study will be conducted in the SINA centers. It is suggested that the PI have the project vetted by an experienced researcher. 3. The informed consent form is lacking in terms of giving complete information and determining voluntariness to be recruited into the project. 4. The age range is too broad and needs to be trimmed for practical execution of the project. 5. Please be clear on what is meant by a "marginalized" community. 6. The budget mentions "diagnostics". Please clarify as to what this means.

Next meeting:

The next zoom meeting will be held at 02:00 pm on 15thJuly, 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 15th, 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	**Dr. Noor ul ain Farooq** Department of Emergency Medicine Aga Khan University Karachi	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? 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. 3. The budget submitted mentions a high cost of the certificate and more than $2,000/- for office supplies. Is this rational?

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

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1268	**Dr. Asim F. Belgaumi** Department of Oncology Aga Khan University Karachi	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. 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?

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	**Dr. SANA SHEIKH** Department of Medicine Aga Khan University Karachi	1. What is the operational definition of food being "unhealthy"? Please clarify for us. 2. Is there a likelihood of stigmatizing food vendors? How will this be addressed? 3. Data collectors will be visiting homes of the young adults. How is their safety ensured? 4. Who are the gatekeepers of these food streets? Should not government approval be sought first to make easier to access the community?

Next meeting:

The next zoom meeting will be held at 02:00 pm on 22nd 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 22nd, 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	**Dr. Abdul Momin Kazi** Dept of Paediatrics and Child Health Aga Khan University Karachi	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. 2. The methodology is not clear. Many aspects of the study are ill-defined. 3. There is no mention of sites at Thatta and Karachi from where the data shall be collected. 4. How two study sites are identified in context of "climate change"? 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. 6. Who will pay for the tests? 7. Will participants shall be informed about the results of the tests? 8. Where these children shall be treated and who will pay for that? 9. In case of complications where such children shall be treated? 10. What will be the source of data and how its authenticity shall be ensured? 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. 12. How 100 children prospectively identified shall provide a "robust data" about a condition? 13. Why adult population is excluded? 14. Is the duration of retrospective data collection from 2014 or 2017? It is written differently as places. 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

		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? 16. Data transfer agreement is not found. 17. What is the purpose of biological data storage for a very long period of time? Will there be an option for opt out? 18. Will biological samples be transferred to outside Pakistan? If yes send MTA. 19. How Rs. 500 is justified in context of significant contribution of the study participants?

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

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

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

Next meeting:

The next zoom meeting will be held at 02:00 pm on 29th 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 29th, 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

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	**Dr. Zahid Memon** Department of Community Health Sciences Aga Khan University Karachi	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? 2. Will any data be transferred to the UK? 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?

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	**Dr. Syed Ather Enam** Department of Centre of Oncological Research in Surgery The Aga Khan University Karachi	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. 2. There are two IRB letters in the package with two different study titles. 3. Why are samples being sent abroad if the lab is being developed here in Pakistan? 4. The informed consent form needs to be simplified for better understanding of participants who are laymen. 5. How long will this study last? Is it currently ongoing? 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?

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	**Dr. Adnan Abdul Jabbar** Ziauddin University	1. Please give us a brief and simplified account of the BENITO study. What exactly does it entail? 2. What are the results of Phase 1 and Phase 2 trials

	4-B Shahrah-e-Ghalib, Block-6, Clifton Karachi.	with the new biosimilar? 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? 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? 5. Is there a possibility of our patients being burdened in case the funds relapse? 6. Please provide details of the DSMB.

Next meeting:

The next zoom meeting will be held at 02:00 pm on 5th 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 5th, 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
Dr. Sajid Bashir Soofi Dept of Paediatrics and Child Health Aga Khan University Karachi	1. Considering the law and order situation of the areas targeted what protective measures are available for the data collectors and researchers? 2. Considering the unfortunate events in the past with immunization programs is there any likelihood of safety concerns at the national level?

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
Dr. Fareeha Shaikh Dept of Community Health Sciences Aga Khan University Karachi.	1. Once data is collected is there anything being offered to participants like an awareness session? Tampons?

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
M. Imran Khan Precision Health Consultants (PHC) Global (Private) Limited Office No.415, 4th Floor, Al-Hafeez Executive, Ali Zaib Road, Gulberg-III Lahore	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. 2. Please justify Kasur as the research site as the PI is from Karachi. 3. Who are the other co-PIs in this project?

Next meeting:

The next zoom meeting will be held at 02:00 pm on 12th 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 12th, 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
Dr. Ali Saleem Department of Paediatrics and Child Health Aga Khan University Karachi	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. 2. What is the insurance coverage given to participants? Where will any adverse events be treated? What is remuneration given to participants? Please clarify. 3. Please mention on the Informed consent forms that samples will be sent abroad.

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

PI Name & Address	Final NBC-R Comments
Dr. Sarah Saleem Department of Community Health Sciences Aga Khan University Karachi	1. Please justify using patients from a public sector hospital when patients can be recruited from AKUH and its subsidiaries. 2. What benefit or capacity building be done for the co-PIs of DUHS? 3. Who are the co-PIs from DUHS. What is their intellectual contribution in this study? 4. What is the standard of care for infants with HIE? How can that be denied to any arm of the trial? 5. We would like to see IRB approvals from AKUH and DUHS. 6. Has the Hyperfine machine been used before in infants? Will this machine be donated to DUHS once the project is over? 7. Please give composition of DSMB for this project. 8. Is there any Data Transfer Agreement or MTA? Please provide details.

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
Dr. Uzma Rahim Khan National Stadium Rd, Aga Khan University Hospital, Karachi Pakistan	• Study Approved.

Next meeting:

The next zoom meeting will be held at 02:00 pm on 19th 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 19th, 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
Dr. Zahra Hoodbhoy 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
Dr Muhammad Daoud Butt School of Pharmaceutical Sciences, Universiti Sains Malaysia, 11800 Universiti Sains Malaysia, Pulau Pinang, Malaysia.	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. 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. 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. 4. Objective 5 of the secondary objectives "compare efficacy, adherence and quality of life improvements between Patients in Pakistan is redundant. 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. 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?

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
Dr. Sarah Saleem Department of Community Health Sciences Aga Khan University Karachi	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. 2. Will any psychosocial support be provided to the caretakers?

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 26th, 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

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 analyticalcross-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.

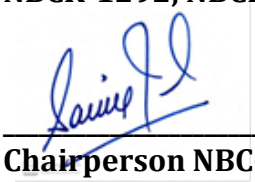
Title: **NBCR-1291: Breaking the Silence: Improving Educational Access and Technology for Deaf Learners in Pakistan.**

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 2nd 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 2nd, 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

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
NBCR-1292	**Dr. Uzma Khan** Interactive Research & Development (IRD) 4th Floor, Woodcraft Building, Plot 3 & 3-A Sector 47, Korangi Creek Road, Karachi	1. Please clarify the study design being observational. Is it not comparing different regimens with a standard of care? 2. There is no mention of how focus group will be formulated and what questions will be asked? 3. How will feasibility be assessed in this study? 4. Is this a study embedded in the trials taking place? Please clarify.

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

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1293	**Dr. Nausheen Naz** Senior Technical Lead Programs Vital Pakistan Trust Office No. 301-904, 9th Floor, Al Tijarah Center, Shahrah-e-Faisal, PECHS Building No.6, Karachi.	1. Please clarify methodology of this study. What is the research question and how is it being addressed? 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? 3. Is this study in alignment with the National Family Planning Policy of Pakistan? 4. IRB approval letters from participating centers would be required.

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
NBCR-1311	**Prof. Saeed Hamid** Department of Medicine Aga Khan University Karachi	1. Study Approved.

Next meeting:

The next zoom meeting will be held at 02:00 pm on 9th 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 September9th, 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
NBCR-1295	**Mrs. Fatima Mehmood** Centre for Human Rights (CFHR) Address of PI Institute/Organization: 1.5 km from Thokar Niaz Baig, Raiwind Road, Lahore.	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? 2. Is this data being shared with any agency abroad? If so why? 3. Is there a possibility to pick up child trafficking rackets as these are vulnerable children? If so, how would that be addressed? 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? 5. Why is there a mention of sales tax and withholding tax in the budget?

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

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1296	**Dr. Sana Durvesh** Greenstar Social Marketing Pakistan 8th Floor, Ocean Tower, Main Clifton Road, Karachi.	1. Please clarify for the NBC if the PI is using Mirena or introducing a new hormonal IUD? 2. The cost of Mirena is PKR 18,000/-. Will this be provided to the research participants free of cost or subsidized cost? 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? 4. Please mention the study sites. Fig 2 which claims to do so is missing in the document.

		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?

Title: **Age related Macular Degeneration (AMD) Benchmark Imaging Dataset- A cross sectional observational study.**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1298	**Dr. Haroon Tayyab** Department of Ophthalmology and Visual Sciences Aga Khan University Karachi	• Study Approved.

Next meeting:

The next zoom meeting will be held at 02:00 pm on 16thSeptember, 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 16th, 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

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
NBCR-1299	**Dr. Sadiq Bhanbhro** Integrated Research Solutions Global – Pakistan, Karachi.	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. 2. There should be a formal informed consent form as the PI is asking for sensitive data from the participants. 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? 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? 5. There are 5 sites from Sindh and 1 from KP. Is this not quite disproportionate?

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
NBCR-1300	**Dr Fareeha Shaikh** The Aga Khan University Hospital The Department of Community Health Sciences, AKU. Karachi.	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 good as venous sampling? Please explain benefit sharing for the community if any. 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? 3. Why are patents/research subjects being being referred to Civil Hospital? Should there not be some provision for treating their anemia in the community with iron therapy?

		4. Why is there a need to transfer our country's data abroad? The results can be analyzed within the country.

Title: **Trial: An open-label, single-dose, randomized, two-period, 2x2 crossover bioequivatence study of Norvasc 10 mg Tablet (Amlodipine).**

Project #	PI Name & Address	Final NBC-R Comments
NBCR-1301	**Prof. Dr. Muhammad Tariq Farman** Dow Institute of Cardiology, Dow University of Health Sciences, (DUHS) Ojha Campus, Karachi, Pakistan	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? 2. Where will adverse events be treated as amlodipine can cause problems in normotensive adults? 3. Is there a DSMB for this study? Please give details. 4. Please clarify health insurance and remuneration package for the participants.

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 30th, 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
Dr. Haroon Tayyab Dept of Ophthalmology and Visual Sciences Aga Khan University Karachi.	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? 2. As patients will be making multiple visits (3 months/6months) to clinics is there any transportation allowance? 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. 4. Participants should be informed explicitly that the AI tool is under evaluation and not yet a replacement for routine screening. 5. Who will be filling the proformas with all the technical information that is required? 6. Are there any plans of post-study access to the AI tools if they prove to be useful?

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

PI Name & Address	Final NBC-R Comments
Dr. M. Tahir Yousafzai Department of Paediatrics and Child Health Aga Khan University Karachi	1. Please clarify who are the stakeholders mentioned in the study as there could be several types. 2. How will safety of data collectors be ensured as they would be going into the households? 3. There is a possibility of getting biased responses to appease the data collectors. How will this be addressed? 4. The benefit sharing with community is largely confined to education materials. 5. Could there be more tangible community benefits eg. Linkages for

	WASH initiatives, support for local health workers etc. 6. Sindhi consent form is needed.

Title: **NBCR-1308: PGI Accelerating Pathogen Detection through Wastewater Surveillance.**

PI Name & Address	Final NBC-R Comments
Dr. Imran Nisar Dept of Paediatrics and Child Health Aga Khan University Karachi	1. Please clarify what kind of biological materials are being collected and where will they be shared and with whom. 2. Who is doing the bioinformatics part of the project and the next gen sequencing? 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? 4. The reliance on generic information sessions may not be sufficient to ensure trust and buy-in from the community. 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. 6. It is not clear how equity will be ensured 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. 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. 9. Adverse events are marked as "Not applicable" however even in environmental surveillance adverse events can occur (Laboratory accidents, community reaction, breach of confidentiality)

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
Dr. Ayeesha Kamal Department of Medicine Aga Khan University Karachi	1. Is this a student project? It is noted that Dr. Zainab Samad is also involved in it. Her role is not described. 2. As there are no collaborators, so with whom data can be shared. Journals do not require raw data as such. 3. How huge sum of money mentioned against computer software and cloud. How it can be justified? 4. How the cost for national and international travel is calculated? 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? 6. In the primary objective it is mentioned that it is a feasibility study but no feasibility benchmarks are found. 7. Describe the waiting list and intervention groups in which the patients will be grouped. Also give the duration of waiting list. 8. Explain how outcomes will be compared between waitlist-control groups. 9. Include a brief summary for the post-stroke care algorithm, the standard approach and this intervention may differ? 10. Clarify what standard care the waitlist group will receive. 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" 12. Clarify that participation involves 4 virtual consultations over 3 months and completion of follow-up questionnaires, and mention approximate total time commitment. 13. State whether participants can have caregivers present during sessions and if sessions will be recorded or not.

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

	questions, while some are closed-ended questions. 28. In secondary objective, what does system mean? 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. 30. Incase during the virtual consultation, if physical presence is required, who will pay for the transportation and compensation. 31. Since the strength cannot be measured on tele-medicine, and also limitation of study, how this will be justified for the outcome. 32. Ill the participants be charged for tele- medicine, after the study is concluded. 33. It is a trial as well. Trial Registration may be required.

Title: **NBCR-1315: Trial: An open-label, single-dose, randomized, two-period, 2x2 crossover bioequivalence study ofAccethrom (Clarithromycin) 125mf!/5ml suspension.**

PI Name & Address	Final NBC-R Comments
Dr. Saba Afshan DUHS, Ojha Campus Admin Block, Sindh Infectious Diseases Hospital & Research Centre (SIDH & RC); Institute of Biological, Biochemical & Pharmaceutical Sciences, Karachi	1. IRB approval is awaited. 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. 3. Share flyer for this study for public to know about it. 4. How news shall be disseminated? 5. Provide insurance document. 6. Provide budget related documents for this study. 7. In case of adverse events where subjects shall receive treatment. 8. Will data be shared with the sponsor from Philippines? If yes provide data transfer agreement. 9. Is the site currently approved by the DRAP? Provide letter issued by DRAP. 10. The word ***confinement*** is problematic, if they can leave at any time why will you confine them. 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? 12. Informed consent is very technical and expects the participant to be able to understand terms like 'washout period'. 13. Will all participants be tested together at the same time? 14. It is mentioned that 16 pricks will be done for blood sampling. Why not use a branula? 15. If you detect something in the chemical/drug screen, what will you do? 16. Medical screening form (In consent form & questionnaire) issue date Nov. 2023 and effective date Dec. 2023. How this medical screening form validated? 17. For this study, the gender is not specified, the study participants will be from which gender? 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. 19. Where the samples will be stored and for how long? 20. Who will verify data collected? Any DSMB? 21. Please provide the Registration of trial with DRAP. 22. After 48 hours at the time of discharge, in case any abnormality is seen in blood, urine tests or ECG, how that

	will be dealt with and who will pay the cost of treatment / hospitalization. 23. The study budget is missing. 24. The washout period should be clearly justified using relevant pharmacokinetic data (e.g., half-life, clearance) to support its adequacy. 25. The dosing regimen and washout period require clearer explanation to ensure the study design is scientifically sound. 26. The randomization process must be described in detail, including method & allocation. 27. The inclusion and exclusion criteria are incomplete — only BMI and age range are provided. 28. The adverse event and serious adverse event reporting process needs to be presented more clearly. 29. A flowchart showing timelines, responsible personnel, escalation steps, and contact points should be included. 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. 31. The ICF should include a lay summary of the study purpose and procedures to enhance participant understanding. 32. A lay summary of potential risks, including rare but serious adverse events, should be added to the ICF. 33. Clarify whether the Institute of Biological, Biochemical & Pharmaceutical Sciences (IBBPS), Dow University of Health Sciences is functioning as a Contract Research Organization (CRO) in this study. 34. The study monitor's qualifications and experience do not conform with the role he has to play. 35. Include a detailed conflict of interest statement, particularly addressing the sponsor's involvement in protocol design, data analysis, or publication. 36. Clearly mention in the NBC form and IC that there is 'no direct benefit' to study participants. 37. Will all data be shared and kept with the sponsor? Justification is required. 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). 39. What will be the recruitment process of healthy volunteers? How will the study be advertised to recruit participants? 40. What is the justification for asking about ethnicity in the screening questionnaire? 41. In the sponsor-CRO agreement, an explanation of section 6.5 42. Protocol section 43. The data will be a property of sponsor 43. In the sponsor-CRO agreement, Appendix 3 says Cefixime!? 44. Details of duration of blood and urine sample storage are required.

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
Dr. Sajid Soofi Department of Centre of Excellence in Women and	1. PI is already involved in 13 grants related projects. How this 14th project may be justified? 2. It will be of interest to know how many similar projects

Child Health Aga Khan University Karachi	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 desire 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

	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. 18. The proposal lacks a comprehensive immunization plan. 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. 20. The use of verbal consent must be clearly justified. 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? 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? 23. If that may be the hypothesis then why governmental health facilities are not the suitable place? 24. Where women receive reproductive health services in these high risk facilities? What is the current status of neonatal tetanus in these communities? 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. 26. Although consent forms are provided in English and Urdu, translations into regional languages (e.g., Pashto) are essential. 27. Similarly, information materials and brochures should be available in local languages to ensure community understanding and participation. 28. Since fathers are often primary decision-makers in these communities, the consent process should consider obtaining consent from both parents. 29. Clearly define referral pathways and specify designated health facilities for AE/SAE management. 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. 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? 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. 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.

	34. Provide itemized budget not as lump sum under one head. It involves crores of rupees. 35. How much of this will go to KPK? 36. Will data be sent outside Pakistan? If yes send data sharing document.

Next meeting:

The next zoom meeting will be held at 02:00 pm on 7thOctober, 2025. The following projects will be reviewed:

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

Chairperson NBC-R

Minutes of the NBC-R meeting held on 07-10-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on October 7th, 2025. The following members of NBC-R attended the meeting:

Sr.#	Group-I		Sr. #	Group-II	
1.	Prof. Saima Pervaiz Iqbal	Chairperson	1.	Prof. Jamshed Akhtar	Chairperson
2.	Prof. Munir Akhtar Saleemi	Member	2.	Prof. Saqib Mehmood	Member
3.	Prof. Marie Andradess	Member	3.	Dr. Farkhanda Ghafoor	Member
4.	Prof. Amjad Mehboob	Member	4.	Prof. Shahid Mehmood Baig	Member
5.	Prof. Sualeha Siddique Shekhani	Member	5.	Prof. Akhtar Sherin	Member
6.	Prof. Ejaz Ahmed Khan	Member	6.	Dr. Natasha Anwar	Member
7.	Prof. Rameeza Kaleem	Member	7.	Prof. Shaper Mirza	Member
8.	Prof. Agha Riaz	Member	8.	Mrs. Tayyaba Rahat	National Coordinator
9.	Prof. Faheem Ashraf Khan	Member			
10.	Dr. Farah Asif	Member			
11.	Prof. Abubakar Ali Saad	Member			
12.	Mr. Waryal Ali Daheri	NBC Secretariat			

The following projects reviewed / discussed:

Title: **<u>Monitoring & Evaluation of GenAI and Human-Staffed HPV Hotlines in Pakistan.</u>**

Project #	PI Name & Address
NBCR-1318	**Dr. Zahid Memon** Department of Community Health Sciences Aga Khan University Karachi

Final NBC-R Comments

1. Please expand on the role of VIAMO in this study.
2. MoH has been mentioned as a collaborator but no investigators have been named from this institute.
3. There is insufficient clarity in the protocol regarding how participants will be identified and recruited, particularly:
    - Who will be contacted for participation?
    - Who provides the contact information and on what basis?
    - How is initial consent or interest in participation obtained?
4. This lack of detail raises concerns about privacy, especially since some individuals may not have directly consented to be contacted.
5. The consent form shared for parents of girls lacks specific reference to the use of GenAI in the project.
6. This omission is ethically problematic, as participants must be clearly informed that:
    - A consent form is Sindhi is recommended
    - Their conversations may be processed or analyzed by AI systems,
    - These systems may not function the same as human responders,
    - There may be risks associated with automated decision-making or data processing.
7. Transparent communication about the use of GenAI is essential for meaningful informed consent.
8. The project proposes to use all calls to the government-supported HPV hotline as part of the research dataset. This raises multiple ethical concerns:
    - No apparent mechanism exists to notify regular hotline users that their calls might be used for research purposes.
    - No opt-in or opt-out mechanism is described.
    - Individuals using the hotline for routine, confidential health advice may unknowingly become research subjects, violating principles of autonomy and informed consent.
9. At a minimum, regular users of the hotline should be prompted at the beginning of the call to

consent (or decline) the use of their anonymized data for research purposes.
10. What specific safeguards are in place to protect caller identity and confidentiality, particularly when AI systems are involved?
11. With the new interest in HPV vaccination could there be an element of mistrust as was seen in polio?
12. Could this potentially undermine the HPV vaccine drive?

Title: **Extended Data Analysis of Typhoid Conjugate Vaccine (TCV) in Pakistan.**

Project #	PI Name & Address
NBCR-1319	**Dr. Farah Qamar** Department of Paediatrics and Child Health Aga Khan University Karachi

Final NBC-R Comments

1. How has Socioeconomic status been operationally defined in this project?
2. How will information on partially verified vaccination be handled as this was unclear to us.
3. The consent process lacks clarity on how comprehension will be confirmed among the participants with limited literacy or poor recall of the original study.
4. The community engagement looks passive rather than participatory. Along with Typhoid vaccination is there any addressal of WASH facilities in the study site?
5. Please clarify the need for external analytical support. What is the capacity building approach for Pakistan?
6. Which university owns the data? AKU or Oxford?
7. What Data agreement is there?

Title: **School based vision screening program in Skardu, Pakistan-A clear and bright future.**

Project #	PI Name & Address
NBCR-1320	**Dr. Khadijah Abid** Department of Ophthalmology, The Aga Khan University Hospital, Stadium Road, Karachi

Final NBC-R Comments

1. If this study is quasi-experimental then there should be a control group consisting of schools not receiving the intervention.
2. It may be a pre-post design study in which compliance should be measured as to how many children are wearing glasses at 3 mths/6 mths?
3. Long-term outcomes should be measured in this study.
4. What is the criteria for selecting teachers as they would be getting additional payment for this?
5. Identify the referral centres around Skardu or have some MoU with them if further evaluation is required.

Title: **Developing Standardized Trauma Algorithms in Limited Resource Countries: A Public-Private Partnership.**

Project #	PI Name & Address
NBCR-1321	**Dr. Shaneela Khowaja** Liaquat University of Medical and Health Sciences, Jamshoro People‟s Nursing School, Liaquat University of Medical and Health Sciences, Jamshoro

Final NBC-R Comments

1. 1.4 Existing guidelines (e.g., ATLS) are often difficult to implement fully in Pakistani healthcare settings due to constraints in manpower, infrastructure, and training.
2. This statement is not sound. How PI came to the above conclusion?
3. ATLS trauma algorithms are equally applicable to LMIC. No hi fi gadgets are required for taking care of a trauma victim in ER. ABCDE of primary survey is extremely straight forward. All equipments are available in ERs.
4. The PI is a nurse in LUMHS. Can she describe who and how trauma is treated in her institute? Is she a part of first responders team? Usually the trauma team leader is a doctor. However, Nurses may be involved.
5. ATLS certificate is a mandatory requirement for all the surgical faculty who are involved in teaching and training of undergraduate and postgraduate students in Pakistan. Both FCPS and MS curricula include this approach.
6. From AKU few ED consultants and a large number of faculty members of AKU are involved as instructors of ATLS courses at CPSP. They have first-hand knowledge and skill for care of trauma victims. It will be of interest to know why they are not included in this project.
7. ATCN courses are also available for nurses in line with ATLS as well prehospital EMT courses. All speak the same language. Rescue 1122 personnel are also trained on ATLS pattern and are rendering effective services throughout Pakistan.
8. In context of Pakistan there is a question mark against the inclusion of so called “experts” in the Delphi process.
9. There is a significant funding of 1.5 million rupees for this project while premise is not based upon scientific evidence in context of Pakistan. People involved in developing algorithm have not provided any evidence that current trauma care programs in their countries as to why they are not applicable to LMIC.
10. The budget document does not match with the cost to be incurred. The ERC form states a funding of 5,000 US dollars but synopsis mentions it is not applied as of yet. This need clarification.
11. Consent form in Urdu is incomprehensible. Why Sindhi ICF is required? Are the participants not well versed with English language. How shall they communicate with participants from other countries?
12. Provide data from Pakistan where ATLS algorithm implementations found impractical.
13. Recruiting experts from the same organization which has operations in different countries will not provide the diversity required for a Delphi study. One public hospital in Pakistan and AKU is a private hospital in Karachi, Kenya and Tanzania how representative is this of public and private experience of LMICs?
14. What are the anticipated harms and benefits for both individual research participants and for communities?
    a. When clinicians, nurses, or paramedics discuss trauma-management cases or decision-making, they may question their competence or past clinical actions, particularly if adverse outcomes are mentioned.
    b. Experience guilt, shame, or self-blame.
15. If the core team is identifying people for the survey, there might be an element of selection bias in addition if someone is selected that might feel pressured to participate – how will the researchers mitigate these issues?
16. The inclusion criteria for experts are briefly described (>5 years’ experience), but there is no detail on the total expected number of panelists, the diversity of specialties (e.g., surgeons, anesthetists, emergency physicians, nurses), and strategies to minimize bias (e.g., geographic diversity, gender balance).
17. “Consensus” is defined as >70% agreement, but how this threshold was chosen is not justified. Additionally, no plan is described for handling persistent disagreement after multiple Delphi rounds.
18. The proposal stops at algorithm development and awareness sessions. A pilot implementation and clinical validation (e.g., impact on time-to-treatment or patient outcomes) would make the study far more valuable.
19. Only descriptive statistics and consensus proportions are planned. No qualitative analysis plan is

mentioned for open-ended responses from experts.

20. The information sheet contains minor inconsistencies — e.g., There is a section stating "this research may bring positive outcomes in the life of people living with cancer in Pakistan" which is unrelated to this study.
21. The PI mentioned reviewing literature and international guidelines like ATLAS, WHO etc. However, there is no mention of reviewing existing guidelines or algorithms in Pakistan, and how they match-up to current international algorithms. Identification of shortcomings in our ER-SOPs and how they could be improved with this exercise.
22. Dissemination of results is mentioned by there is no mention of implementation of the new algorithms (or at-least testing of new algorithm) in real-life scenarios. Also, no monitoring or evaluation process for the
23. Statistical methods.
24. Not clear how data will be analyzed for the development of standard of care plan or the trauma algorithm. Few points are mentioned in data analysis plan, but they are ambiguous.
25. The team includes all trauma physicians they need an expert statistician to compile results and perform rigorous, scientifically sound reliable analysis for development of effective algorithm.
26. There is a need to evaluate performance of the algorithm. Some kind of primary outcome for risk stratification for trauma patients.
27. The possibility of Generaliz ability of algorithms to different patient population in different parts of Pakistan is also not found as only two institutions are identified for the process.
28. What will be the review of charts time period (retrospectively) for the clinical conditions for making Algorithms?
29. In section 2.5 of NBC form, during the Study:
30. Capacity Building: Healthcare providers (physicians and nurses) involved in the project will receive training and participate in awareness sessions on trauma care algorithms, strengthening local clinical capacity in trauma management. Where these trainings will be held and who will be trainers.

Title: **Technical Role of the Aga Khan University in Enhancing Diagnostic Accuracy of the Soil-Transmitted Helminths (STH) Impact Assessment Survey.**

Project #	PI Name & Address
NBCR-1324	**Dr. M. Asim Beg** Department of Pathology and Laboratory Medicine Aga Khan University, Karachi

Final NBC-R Comments

1. How long the stored samples be kept in the lab. Do PI plan to do any additional tests on these samples, PCR is mentioned.
2. Do PI plan to educate children and families as well a school authorities as to the hygiene and safe disposal of waste? This may help in decreasing the burden of STH.
3. Data sharing document is required.
4. How school children shall be accessed at home visit and when stool samples shall be collected?
5. How communities shall be accessed? Any involvement of local leaders, elders, health facilities staff?
6. Will prior information be circulated in the area?
7. What shall be done for out of school children? Will their parents be educated about it?
8. Mention clearly the districts and place of in towns and villages from where samples shall be collected.
9. Is it fair to take notes about home and other facilities without informing the study participants?
10. Is it fair to take picture of school? Why to identify the particular area?
11. If government of particular geographical location is on board, more relevant would be to ask them why basic water, food and disposal of sewage facilities are not present in the area and schools?
12. Rather than distributing anthelminthic drugs provision of basic facilities should be a priority. This is not found in this project.
13. The funding is nearly 5 crores rupees which could have been utilized for the targeted population (sample selected – the numbers) for this study. Address the main issue rather than its side effects. Prevention and provision of public health measures are nowhere to be seen in this project.
14. It is more of a researcher centered / funding agency centered project rather than community focused.

Questionnaire

15. *Section on Hand-washing.* There is only one question on hand washing practices Disposal of waste- if possible, can this be autoclaved before incineration?
16. **Section 2.5-** Will schools be provided with the prevalence rate of infection in their institute. Will parents receive results of their child's stool test.

17. Need to add some questions on
    - How frequently they play in playgrounds and are there any open drains near those play-grounds ?
    - Do they wear close toe shoes while playing or slippers
    - Do they wear slippers to schools or close toe shoes.
    - Do they find feces on the floor of school/home/community toilets?
18. Few questions on food preparation and food purchasing practices
    - Do they have a kitchen garden (vegetables growing in their backyard)
    - Preparation of meal from these veggies.
19. Kids eating them raw, washing or not washing them before eating.
20. Sample transport- How will the technical team ensure 2-8ºC – icepacks dry ice???
21. Will this information be shared with schools and households that are participating in survey and sampling. They should get something, IRD has been performing these exercises for quite some time, what evidence did they or did they not generate in the past. The current study do not even refer to the work done by them or lessons learned from that exercise and how this particular study will move the field forward except for using a new kit for diagnosis.

Budget-Number of senior techs does 10 refer to number of techs or Effort of 1 tech. 17,477 USD is almost 5 million PKR.

- The title does not accurately reflect the study methodology. While the title highlights the technical role of Aga Khan University in enhancing diagnostic accuracy, the described methods mainly involve stool sample collection, laboratory detection of STH, and assessment of hygiene practices. Unless there is a clear focus on novel diagnostic techniques or accuracy improvement by AKU, the title should be revised to align with the actual scope of the research. "Enhancing diagnostic accuracy" implies measurable improvement, but the proposal does not specify baseline vs. expected accuracy, sensitivity, or specificity targets.
- There is no external validation or EQA participation to benchmark diagnostic performance.
- The inclusion of the entire KPT, AJK, and ICT regions covers a very large geographical area and population base. However, the proposal does not provide sufficient evidence or recent epidemiological data to justify a high burden of STH in these areas. However, if these regions are to be included, the study should define specific target populations or sampling sites located within a feasible distance from AKU-affiliated laboratories to ensure that stool samples can be transported and processed within the required timeframe for accurate results
- The proposal provides a target sample size but lacks a statistical justification.
- It is unclear why school students are being used as the first point of contact in most of the sample size for the study. Expecting them to provide assent, guide the interviewer to their home, and facilitate parental consent before initiating the research raises practical concerns. This approach may place undue responsibility on minors and could compromise the consent process. A more appropriate strategy would be to engage parents or guardians directly as the initial point of contact.
- While MBG is mentioned, the description of how schools and households will be selected (randomization procedure, stratification, clustering) is insufficiently detailed.

22. How will stool be collected – in school or will they take containers home and bring them back? If it is in school the children may feel uncomfortable and embarrassed, this needs to be addressed.
23. So, these samples are going to be sent to AKU Karachi from KPK, wouldn't this be a good opportunity to collaborate with an institute in KPK to improve their capacity for STH diagnostics? Set up a camp and have AKU team present for the microscopy analysis?
24. How do you plan to access, store and distribute any collected biological material? They will store samples for future genetic analysis they need to specify that this will be helminth DNA or human genomic DNA that is stored.

Consent form:

- If you allow your child to participate in this study, he/she will be asked some general questions about his/her eating habits and daily routine and asked to submit stool sample for STH microscopy. Will they understand what microscopy is? This should be rewritten so that it is easier to understand.
- We will keep a small portion of sample for PCR confirmation of STH. Will they understand what PCR is? How long will it be kept for and will it be used for anything else not mentioned?

25. Note: Schools are safe places where parents send their children because they trust that they are cared for and protected. There are lots of studies involving schools and I wonder how this will translate and be understood by the public.
26. It is a follow up survey, what was the outcome of previous surveys? And how this will be different.
27. How will be assessed that the children treated previously, are still having the problem, how they will be dealt.

28. Where the Study investigators will conduct Training for laboratory personnel to ensure high-quality diagnostics?
29. For collection and transportation of stool sample from collection to designated laboratory facility in cold chain, needs clarification, it is not consistent in project write-up.
30. The sample collection time is Sept. and Oct. 2025 the whole timeline needs to be changed.
31. Children are being asked to bring the stools from home. To transport the morning stool sample from home to designated area will be different without cold chain, how it effect the results.
32. For how long and where a small portion of stool will be stored at -20C for future studies?
33. Will the participants be provided with results and those who are found positive, will they be provided treatment.
34. Parental/guardian consent and child assent procedures should be clearly defined and obtained in culturally appropriate ways.
35. Children's participation is voluntary, and refusal does not affect their school attendance or access to health services.
36. Privacy and dignity of child participants will be protected during stool collection.
37. Informed Consent Process, the project mentions "parental/guardian consent" but lacks details on:
38. The content and language of the consent form (should be in Urdu/local language).
39. How consent will be obtained in school and household settings?
40. Child assent process for those old enough to understand.
41. Whether teachers or local authorities will facilitate consent (risk of coercion).
42. Clarity that participation is not linked to any academic or medical benefit.
43. The project involves stool sample collection, lab testing, and data handling across multiple sites.
44. Data storage procedures and access control for both biological samples and records, Whether any data will be shared internationally (e.g., with Evidence Action)?
45. DNA analysis of helminths or human biological samples related clarity is required.
46. Future Use of Biological Samples: The project mentions "A small quantity of samples will be stored for potential future molecular analysis of pathogens (additional funding will be applied)."
47. The duration and location of storage, as well as ownership of samples, must be stated.
48. NBC typically requires that future use be clearly justified and subject to fresh ethical review before analysis.

Title: **Classroom, Family and Community-related Experiences of Children with Disabilities in Mainstream Schools in Pakistan.**

Project #	PI Name & Address
NBCR-1327	**Dr. Nasima Shakeel** Aga Khan University, Institute for Educational Development 1-5/B-VII, Gate no. 10, Federal B. Area, Karimabad, Kara

Final NBC-R Comments

1. There are multiple versions of research proposals given.
2. Lacks updated statistics, prevalence data, and relevant policy context to justify site and population selection.
3. Details about collaborators — Sightsavers and Oxford Policy Management — are not provided.
4. Sample size is too small to produce valid or generalizable results.
5. Sample size justification, criteria for saturation, and details of the analytical framework are missing.
6. The intensity or severity of disability among participants is not identified, limiting the interpretability of results.
7. Because Sightsavers primarily works with visually impaired children, the sample may be heavily skewed toward this group, reducing diversity and representativeness.
8. Disability-specific experiences, unmet support needs, and type/severity of disability are not explored deeply enough.
9. Socio-economic questions may include intrusive or irrelevant items.
10. Tools are overly long and detailed, risking participant fatigue and compromising data quality.
11. Several questions are repetitive or overlapping without adding value.
12. Language in children's tools may be too complex for younger participants.
13. No direct questions about institutional policies, training gaps, or resource limitations, which are often key barriers.
14. Procedures for consent and assent, especially for children with cognitive impairments, require clearer explanation.
15. No plan for psychosocial support or referral pathways if sensitive issues (e.g., abuse, stigma) are disclosed.
16. Procedures for handling sensitive disclosures are not adequately described.
17. Privacy and ethical safeguards for photo-elicitation and other sensitive data collection activities are insufficiently addressed.
18. Permissions from provincial authorities (e.g., KPK) and other required approvals are still pending.
19. Funding source details are not clearly stated.
20. The PI mention multiple disabilities, what is confusing is how are they going to determine needs of students with multiple disabilities. Autistic kids will have different needs compared to physically challenged students. This is not clear in the protocol. While I understand that study protocol is not our concern by "inclusion and equity" is an important component of their protocol and unless they highlight how they will define experiences of children with multiple disabilities, it will be difficult to develop policies and interventions.
21. The proposal aims to investigate the classroom, family and community related experience of children, however, the study seems to be looking at only school experiences there were ONLY two questions about community.
22. Some of the questions will be difficult for the children with mental disabilities like Downs or Autism.
23. *Data collection schedule* The PI will communicate with local networks to identify study sites, but criteria of study sites to be eligible for study is not mentioned in the application.
24. Children with mental disabilities will feel intimidated how will the team provide an environment that is relaxing for them. What if they had a panic attach, do they have a child psychologist on team to address these issues.
25. The proposal intro says that they will be collecting data from KP and Sindh, but most of the institutes listed in the study sites are again schools in Ibrahim Hyderi, Bin Qasim, Malir and Korangi.
26. **Budget**
27. Dates on budget are from May 2025 – March 2026 so is the study in process. If yes than what do they need approval for.

Next meeting:

The next zoom meeting will be held at 02:00 pm on 28th October, 2025. The following projects will be reviewed:

NBCR-1328,1330,1332,1334,1335 & 1336.

Minutes of the NBC-R meeting held on 28-10-2025

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

Sr.#	Group-I		Sr. #	Group-II	
1.	Prof. Saima Pervaiz Iqbal	Chairperson	1.	Prof. Jamshed Akhtar	Chairperson
2.	Prof. Munir Akhtar Saleemi	Member	2.	Prof. Nazli Hossain	
3.	Prof. Marie Andradess	Member	3.	Prof. Saqib Mehmood	Member
4.	Prof. Amjad Mehboob	Member	4.	Dr. Farkhanda Ghafoor	Member
5.	Prof. Sualeha Siddique Shekhani	Member	5.	Prof. Akhtar Sherin	Member
6.	Prof. Agha Riaz	Member	6.	Dr. Natasha Anwar	Member
7.	Prof. Faheem Ashraf Khan	Member	7.	Dr. Sarosh Saleem	Member
8.	Prof. Rameeza Kaleem (Regret to join)	Member	8.	Mrs. Tayyaba Rahat	National Coordinator
9.	Mr. Waryal Ali Daheri	NBC Secretariat			

The following projects reviewed / discussed:

Title: **Implementation Research to Scale-up and Evaluate the Impact of Antenatal Corticosteroids on Preterm Newborn Outcomes.**

Project #	PI Name & Address
NBCR-1328	**Dr. Mariyam Sarfraz** Health Services Academy, Islamabad
Final NBC-R Comments	
1. We need clarity as to how this project will be conducted in Pakistan. Is there a Pakistan specific protocol? 2. How will clusters in Pakistan be identified? How will the PI ensure that control clusters are not receiving the intervention? 3. Is the intervention of ACS, not a standard of care? 4. The consent form does not mention any follow-up of the child whereas the protocol says the neonate will be followed for 28 days. 5. Who will be in the focus group for the qualitative arm? Please provide details and focus group guide. We could not see any consent form for it. 6. What is the Data transfer agreement with the sponsors of this study?	

Title: **Trial: Glycemic Control with Triple Pathway Approach through Empagliflozin Linagliptin Metformin Combination (Glyco-3P).**

Project #	PI Name & Address
NBCR-1330	**Dr. Javed Akram** Apka Clinic 49 Justice Akram Road, MozangChungi, Lahore
Final NBC-R Comments	
1. This proposal needs to be resubmitted and evaluated for scientific rigor. The rationale was not clear as this drug is already in use. What is the PI aiming to achieve or determine by doing this study? The NBC form and the protocol attached are not consistent about the methodology being applied. Observational? Experimental? 2. Please declare any potential conflict of interest. 3. Who/ which entity is funding the study? Is the drug being provided by the Pharmaceutical industry? What are their stakes in this research? Is there not a potential for therapeutic misconception? 4. What burden will the study participants have to bear? Cost of investigations? Visits to doctor? Transport costs? What will happen in case of adverse events?	

Title: **A Protocol for Sugar-sweetened Beverages Packaging and Labelling Interventions in Five South Asian Countries: Bridging Policy, Perception, and Co-Creation.**

Project #	PI Name & Address
NBCR-1332	**Dr. Romaina Iqbal** Department of Community Health Sciences Aga Khan University, Karachi

Final NBC-R Comments

1. Why are only private schools being selected? Schools from lower income areas or public schools may have higher intake of sugary beverages and less health awareness.
2. KAP questionnaire does not have options of the answers. Also the question are very leading, which will result in over positive responses
3. Protocol says classes 8-10 and consent mention 9 to 12
4. Educational leaflet needs to be in urdu as well
5. Given that students and teachers will spend time on this, there should be targeted interventions/workshops for all schools involved rather than the subset of participants from qualitative component.

Title: **Monitoring & Evaluation of GenAI and Human-Staffed HPV Hotlines in Pakistan.**

Project #	PI Name & Address
NBCR-1334	**Dr. Sohail Naseem** Maroof International Hospital 10th Avenue, F-10 Markaz, Islamabad

Final NBC-R Comments

1. The study description is unclear and conflicting. Some sections mention a control group, while Section 3.2 says all participants will receive PBMT, with no randomization.
2. A sample size of only 5 patients (2 control, 3 treatment) is too small to provide meaningful results, even for a pilot study, and no justification is provided.
3. It is also mentioned that Treating physicianshall take the decision on his own. This is too subjective.
4. No definition of the "standard care" protocol (type of antibiotics, oxygen strategies, steroid use, other anti-inflammatories) is given.
5. Mechanistic justification relies heavily on COVID-19 studies rather than pneumonia induced ARDS more broadly.
6. Treatment lasts 4 days while follow-up extends to Day 9. However, long-term ARDS outcomes often require longer evaluation periods.
7. The patient information sheet/consent form uses technical terms like "PBMT," "cytokine storm," and "ARDS," which may be difficult for patients to understand unless they are explained in simpler language.
8. The protocol/consent form does not clearly describe what the patient will physically experience during the therapy sessions, what instrument will be used, how the light will be applied, positioning, sensations, or duration-related procedures.
9. The description of potential benefits may give patients the impression that the treatment will help them, without clearly stating that it is experimental and its effectiveness is not yet proven. In fact the proposal language overstates PBMT effectiveness (highly effective) despite enrolling a vulnerable, hypoxemic population, which may bias informed consent.
10. Acute lung injury VS "pneumonia transitioning to ARDS"The protocol uses both **Acute lung injury** and **"pneumonia transitioning to ARDS"**to describe the target condition. However, patients on ventilation are excluded, and the Berlin ARDS criteria (P/FO_2 ratio with PEEP≥5 cmH_2O) are not applied. This creates confusion about the actual study population and may lead to incorrect outcome classification.
11. APACHE II - Protocol mentioned to track PF ratio and use CURB-65/APACHE II, but the scheduled labs/vitals do not reliably collect all variables required.
12. Serum electrolytes, Urea creatinine are required for APACHE II score, which are not mentioned in the protocol.

13. The high compensation and payment linked to continued participation may pressure patients to stay in the study, affecting their ability to freely choose or withdraw.

14. Does a non-phase study mean a Phase 0 clinical trial? In any case the project does not fall in either of the categories. It is an INTERVENTION.
15. Section 1.3 (Eligibility Criteria): What "positive findings on CXR" and CT scan chest? Provide objective criteria.
16. Section 1.3 (Eligibility Criteria): What Age group is being included? How that decision shall be taken if enrollment is of only five patients?
17. Section 1.3 (Eligibility Criteria): Exclusion of "Subjects with a positive pregnancy test or confirmed pregnancy." How and when do the researchers plan to screen?
18. Section 1.4 (Study Procedure): The equipment is specifically designed for this study. What are the details, and how will the patient/Participant's safety be ensured? (Some details found in protocol).
19. Is the equipment to be used has been approved for Pakistan? Provide details.
20. Will patients with cardiac conditions and other chronic diseases will be enrolled?
21. Is there a potential risk of photosensitivity with this intervention? Just for the clarification.
22. What is the cost of the treatment?
23. What is the experience of the PI in using this equipment? One of the Co PI is a biochemist?
24. Can intervention itself increase the inflammation?
25. What if the intervention does not produce the desired results, both clinical and biochemical?
26. Can there be other biomarkers in addition to those mentioned in the project that may be considered more specific?
27. What is being done to mitigate the risks mentioned in section 2.1?
28. The study participants are a vulnerable population because of their illness, and hence, some measures should be suggested to ensure that there is no therapeutic misconception and researcher bias?
29. Will it be possible for the subjects to give consent when their condition is progressing to ARDS?
30. How surrogate consent is applicable in this condition?
31. Any justification of including patients with dementia in this study?
32. It is mentioned that in case of medical complications, directly related to the study (not mentioned), appropriate care will be provided at no cost. Compensation (if applicable) will be provided in accordance with local regulations and ethical guidelines (Not found).
33. Where these patients will be treated when admitted again? This needs to be clearly mentioned in the consent form.
34. The tests IL-6 and CRP will be done as part of study, needs to be mentioned in consent form, also, who will pay, how much blood will be drawn, where the tests will be done and will the patients get the reports?
35. From day 5 onward to day 9 (a total of 5 days), patients will be monitored daily via telephone. (Is it possible to discharge patients with acute pneumonia transitioning to ARDS to be discharged so early?)
36. They will be inquired about their health condition, and if needed, may be called to the site for diagnostic tests. Who will pay for the travel and diagnostic tests?
37. Where patients will be admitted if face any adverse events?
38. Though it is written in methodology about the variables to be recorded from files, also the tests to be carried out. The template to be used as study tool, needs to attached?
39. What is the role of the Sponsor?
40. Provide evidence that same therapy is used in the country that has provided funding for

this project.

41. Please refer to WoS, Scopus based journals in context of pneumonia progressing to ARDS by researcher from abroad. Kindly do not add COVID 19 related studies.
42. Provide itemized budget, not just some broad categories.
43. MTA should be on a legal page.
44. Data transfer agreement is also required including all the details.

Title: **London-Pakistan Parkinson`s Project (LP-3).**

Project #	PI Name & Address
NBCR-1335	**Prof. Alastair Noyce,** Wolfson Institute of Population Health, Queen Mary University of London.

Final NBC-R Comments

1. The title is too broad and vague. It does not communicate the scope, depth, or scientific nature of the work.
2. The recruitment of controls primarily from spouses or clinic attendees may introduce socio-environmental bias, as they may share lifestyle exposures with cases.
3. The selection criteria for the subset of 60 participants undergoing CSF collection are not clearly justified. The basis for inclusion in this invasive subset should be clarified.
4. CSF collection involves invasive procedures with potential risks, but the protocol does not sufficiently explain how participants will be informed of risks, monitored afterward, or provided care if adverse effects occur.
5. Environmental and nutritional factors such as magnesium and B12 deficiencies are included, but the methodology for quantifying exposures and integrating these variables analytically is not fully explained.
6. The process of obtaining broad consent for genomic data to be used indefinitely, including in future research unrelated to PD, must ensure that participants fully understand the scope of data sharing and implications.
7. The protocol does not address whether clinically actionable genetic findings (e.g., LRRK2 or GBA variants) will be returned to participants or whether incidental findings policy exists.
8. There is a conflict between the Consent Form and the MTA. The Consent Form allows samples and data to be shared with commercial partners, but the MTA clearly states that commercial use is not allowed. This needs clarification.
9. MTA is not on a legal page.
10. Patient information sheet is not provided
11. Financial outline says that money has been set aside for the patients' mobility etc. but the amount to be paid to each recruited patient is not given.
12. Provide itemized budget, not just broad categories.
13. Can genomic test to be done abroad done in Pakistan? Or any capacity building cooperation be involved?
14. Which type of genomic tests shall be done?
15. The researchers sort of downplay the risks associated with the genetic information (breach of confidentiality in terms of information regarding other family members).
16. What will be the procedure for informing any accidental findings among the control group?
17. What is the role of the Sponsor? Will they have access to data/samples?
18. Informed Consent documents are missing
19. The questionnaires are all about Dementia.
20. CSF sampling is not a standard approach in PD. Provide justification.
21. In questionnaire the questions which are UK based needs to be transformed according to local culture e.g. address, calculation etc., and other questions which do not relate to this culture from where the participants will be recruited.
22. All questions need to be translated into local language, and made culturally specific.
23. It is detailed "Patients will be identified as potential candidates for the study by

neurologists during routine outpatient appointments at participating healthcare centers." Which are these participating centers, who are the Co-PIs, ethical approval and support letter from these institutions is required.

24. Venous blood sample and will be collected for blood-based biomarker analysis and CSF biomarker analysis. How much blood and cerebrospinal fluid will be drawn, where and which markers will be done, will the patients get reports.
25. When people with PD from Black or Asian backgrounds are present in UK, why there is need to do this study, in Pakistan, if the main goal of this study is to better understand how the severity and frequency of Parkinson's Disease (PD) symptoms are linked to genes. What has the studies have identified so far?
26. Where and how the samples will be stored before shipping, and for how long these samples will be stored, and these will be destroyed.
27. All together there will be 475 blood samples and 60 CSF samples, which will be these 60 participants and on what basis they were selected for CSF., wherethese will be processed before sending?
28. In the event of adverse event due to sampling (blood for 475 participants and CSF for 60 participants the participant will be referred to medical specialist/neurologist for further treatment. Who will pay for the treatment and where they will be treated?
29. In MTA receiving party name and signatures are missing.
30. Who will be responsible to train the team.
31. Section 1.5 is copy pasted from NBCR1334
32. PI (Dr Saboora) is trained as a biochemist. She is the second and the fourth author on the two papers that she has published on genomics and molecular biology. The senior author is either Dr King or Dr Jacqueline A Wilce.
33. Are they doing Lumbar puncture only for the study or is this part of routine protocol for diagnosis of PD and/or for determining progression.
34. The protocol is basically for DNA, sample and clinical data collection which will be sent to UK for further processing, storage and analysis.
35. Co-principal investigator has experience in surgery stroke prevention etc. but neither PI nor Co-PI are eligible to execute this study which is purely genomics
36. Data confidentiality needs to be addressed. Section 2.3 makes two conflicting statements. In one they say that data will be stored using Redcap data collection tool at Queen Mary university of London. In the very next paragraph, the PI states that the data from samples will be primarily stored locally in Pakistan with a "back up copy" in UK. This needs clarification.
37. Will they store DNA as well or just the demographic and clinical data. If they are storing DNA where will that be stored and for how long, Pakistan or UK. Nothing is mentioned in the consent form. How long will they store blood and CSF for and where?
38. Will they share clinical/biological analysis of CSF for free with the patient?
39. Similarly, with they share genomics results with the participants.

Title: **Salmonella Paratyphi A Controlled Human Infection Model in an Endemic Setting: Determining Safety, Dose Escalation, and Correlates of Protection.**

Project #	PI Name & Address
NBCR-1336	**Dr. Farah Qamar** Department of Paediatrics and Child Health, Aga Khan University, Karachi.

Final NBC-R Comments

1. The proposal needs clearer ethical justification for deliberately infecting healthy individuals and demonstrating why no safer alternative exists.
2. The protocol states inclusion of "healthy adults aged 18–55 years" but does not specify whether both males and females will be enrolled or whether there are gender-based exclusions. It does mention pregnancy testing and contraception requirements, which implies inclusion of women, but this is not explicitly clarified.
3. While the protocol indicates that participants retain the right to withdraw even after infection, it does not clearly address how withdrawal will be ethically managed in situations where early discontinuation may pose a risk to public health
4. Reimbursement structure is not specified. It is unclear if compensation may unduly influence economically vulnerable participants.
5. In MTA the ownership and IP rights favor the recipient institution with no clear benefit-sharing framework for source participants or community.
6. This is a Human Challenge study. The risks are being downplayed especially in the informed consent
7. Keeping samples for future use, is vague statement.
8. All above mentioned concerns question how the risks and (potential) benefits of the research for the possible development of a vaccine can be justified.
9. Investigators should explicitly write how much blood will be collected during the study.
10. There are case reports of abscess formation in Paratyphi infection, investigators have only mentioned ileal perforation. Similarly, they have only mentioned medical treatment if affected. Who will bear the cost of surgical complications in both immediate and post trial observation period?
11. The study can have undesirable psychiatric effects, considering the study participant remains in isolation. There should be involvement of a psychiatrist, instead of simple HADS charting.
12. Is the trial registered?
13. Screening investigations will be paid by whom?
14. There is still a lingering concern of an outbreak in the hospital and how will they protect patient who are severely ill.
15. Will the study participants remain in a contained environment? Will the food be brought to them in their wards or rooms?
16. How will the PI ensure that cultures are appropriately made, will they do a plate count before they provide a dose for ingestion.
17. Considering the ethical framework, risks are far higher than any potential benefits to the study participants. The strain of the organisms to be used and its related details are also required.
18. Informed consent form is too long and difficult for the participants to read and understand.

Chairperson NBC-R

Minutes of the NBC-R meeting held on 04-11-2025

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

Sr.#	Group-I	
1.	Prof. Saima Pervaiz Iqbal	Chairperson
2.	Prof. Munir Akhtar Saleemi	Member
3.	Prof. Marie Andradess	Member
4.	Prof. Amjad Mehboob	Member
5.	Prof. Sualeha Siddique Shekhani	Member
6.	Prof. Ejaz Ahmed Khan	Member
7.	Prof. Rameeza Kaleem	Member
8.	Prof. Agha Riaz	Member
9.	Prof. Faheem Ashraf Khan	Member
10.	Dr. Farah Asif	Member
11.	Prof. Abubakar Ali Saad	Member
12.	Mrs. Tayyab Rahat	National Coordinator

The following projects reviewed / discussed:

Title: **Trial: Ambroxol in Type III Gaucher Disease (GD3): A Prospective 6-Month Single-Center Open-Label Study with an optional 12-month extension phase.**

Project #	PI Name & Address
NBCR-1337	**Prof. Hurna Cheema** The Children's Hospital, University of Child Health Sciences Ferozepur Rd. Nishter Town, Lahore.
Final NBC-R Comments	
1. Please clarify if this study is a Phase 1 or Phase 2 study. Please ensure that in whatever phase this study is, there is adequate information provided to the research participants along with indemnity insurance to ensure that participants are protected from any harm that may befall on them by being involved in the study. 2. Has this drug been tested in other countries? If so, please provide details about its safety and efficacy. 3. The consent form should document the potential side-effects that may occur with use of Ambroxol so that subjects are aware of what to expect. 4. What is the data sharing agreement with the sponsors of this study? 5. Would Pakistani patients have post-trial access if the drug is found effective?	

Title: **Transforming and Strengthening Childcare Workforce in Pakistan..**

Project #	PI Name & Address
NBCR-1338	**Dr. Seema Zainulabdin LASI** Department of Human Development Program Aga Khan University, Karachi
Final NBC-R Comments	
1. Please clarify the methodology for us about data collection. The title mentions "Pakistan" so how will other provinces be represented? 2. The title also mentions "strengthening the workforce" but there were no details in the proposal as to how that will be addressed.	

Title: **Parenting in Poverty and Role of Social Agencies: Perspectives of Housekeepers and Households.**

Project #	PI Name & Address
NBCR-1339	**Dr. Shelina Bhamani** Dept of Obstetrics and Gynecology Aga Khan University, Karachi

Final NBC-R Comments

1. Please elaborate on the rationale for "parenting in poverty". Explain as to why only poverty stricken people should be studied on their parenting skills and not well endowed parents. Please also clarify the "social agencies" involved.
2. Which are the community settings in which this study will be done?
3. How will the research participants be protected? Are there any additional safeguards for them?
4. The attached questionnaire needs to be re-looked at for appropriateness. It asks questions about accepting your body appearance etc. which would not be related to parenting.
5. If the purpose is to identify mental health illness among the participants then what will the study team do the address any underlying anxiety or depression?
6. Please clarify the role of the collaborator and funder of this study.

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

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on November 11th, 2025. The following members of NBC-R attended the meeting:

Sr.#	Group-II	
1.	Prof. Jamshed Akhtar	Chairperson
2.	Dr. Farkhanda Ghafoor	Member
3.	Prof. Shahid Mehmood Baig	Member
4.	Prof. Akhtar Sherin	Member
5.	Dr. Sarosh Saleem	Member
6.	Mrs. Tayyab Rahat	National Coordinator
Regrets to join the meeting.		
7.	Prof. Nazli Hossain	Member
8.	Dr. Natasha Anwar	Member
9.	Prof. Saqib Mehmood (Sent Obsrevations)	Member
10.	Dr. Shaper Mirza (Sent Observations)	Member

The following projects reviewed / discussed:

Title: **Enterics for Global Health (EFGH) phase C.**

Project #	PI Name & Address
NBCR-1340	**Dr. FARAH QAMAR** Dept of Paediatrics and Child Health, Aga Khan University, Karachi

Final NBC-R Comments

1. PI must write complete title of the project which is not mentioned on the NBC form
2. Storing audio files and transcripts on "OneDrive" is a potential data security risks. How PI respond to that?
3. There is no mention of data transfer agreements (DTAs). A proper documentation is required.
4. Although no conflicts are declared, collaboration with the vaccine development sector (through funder) may present perceived bias.
5. Budget summary does not clarify whether the mentioned budget allocated to the Pakistan site or to the entire consortium.
6. Share itemized budget.
7. What is the actual involvement of the Funding agency (Gates Foundation) and the University of Washington?
8. The qualitative questionnaire is too long. The participants should know what they are getting into.
9. Some methodological inconsistencies are found. The KII plan combines *purposeful and snowball* sampling guided by data saturation yet sets *a fixed target of 10 participants per site*, which partially conflicts with the flexible nature of qualitative sampling and lacks clear justification for this number.
10. The DCE sample size is justified using the standard formula and underlying assumptions, but these parameters should be re-validated once the final attributes and levels are defined, and clarification is needed on whether DCE respondents will overlap with KII participants to avoid analytic bias and respondent fatigue.
11. *De-identified data will be stored at the University of Washington. Only de-identified data will be shared with the funder or other investigators, as specified under the section on data sharing.* The proposal does not specify how long the audio recordings and transcripts will be retained or the process for their secure deletion or destruction of all identifiable data after study completion, in compliance with institutional and national data protection policies.
12. Where and who will conduct the seminars, one-on-one meetings, webinars, and the provision of policy briefs and will provide the tailored study materials according to the audience, with the aim of informing policy.

13. Where the workshops will be conducted and who will be the facilitators
14. The support letter from Govt. authorities are required.
15. Consent form is missing.
16. Provide itemized budget.

Title: **Teachers' Social Competence and Its Impact on Students' Social-Emotional Learning and Academic Outcomes.**

Project #	PI Name & Address
NBCR-1341	**Dr. Seema Zainulabdin Lasi** Department of Human Development Program, Aga Khan University, Karachi

Final NBC-R Comments

1. How socioeconomic catchment areas shall be looked into? Why only public sector schools to be enrolled?
2. The study risks sampling bias. Socioeconomic status (SES) of schools and students strongly influences both teacher and student emotional development and academic outcomes.
3. In the objectives the terms such as "socioemotional competence" and "classroom climate" need operational definitions.
4. Do teacher and students understand these loaded terms? How PI has made such a conclusion?
5. The first three objectives are quantitative (assessment and correlation-based), while the fourth is qualitative (exploring challenges). There is no stated plan for integration of findings across these methods, leaving the mixed-methods approach disconnected.
6. The sample size and sampling frame are not specified
7. Teachers in schools may feel obliged to participate if research is endorsed by education authorities (school directorate). How this shall be addressed?
8. Do teachers are formally trained about socioeconomic competence delivery methods and know about classroom climate? Share the curriculum according to which teachers are trained.
9. The assent form does not contain Information on the duration of participation, the types of assessments (such as questionnaires, observations, or interviews), the individuals responsible for data collection, and whether data will be gathered once or repeatedly.
10. The terms like "social-emotional learning" and "classroom climate setting" may not be understandable for 7–12-year-olds.
11. In assent form it is labeled both "Assent" and "Consent" in some places — should consistently use Assent.
12. In parents' Consent form the terminologies like SEC and SLE are not defined.
13. The Teacher Self-Assessment SLE tool is based on a well-recognized source (Yoder, 2014), however the proposal does not state how it has been adapted for the Pakistani educational context, or whether cross-cultural validation has been performed.
14. The researchers must assure and demonstrate that participation is anonymous, voluntary, and strictly for research or professional development purposes. If teachers think their responses could affect employment, promotion, or appraisal, they are likely to give "safe" answers.
    a. (Section 1.2) states that a sample of students will be taken. More details are required. Also, what does "relevant stakeholders" refer to in the FGD section?
    b. (Section 1.2) Data Collection Mentions Classroom observations. How will the teachers and students be informed about that and how will that impact the results of observation?
    c. (Section 2.1) The researchers state that there are no foreseeable risks. There are risks of social stigmatization, emotional disturbance, and breach of privacy. These risks should be anticipated, and steps should be taken to mitigate them. The researchers can be told that there are some anticipated risks of harm. How do he researchers plan to mitigate these risks?
    d. (Section 2.10) The study may have an impact on the socio-cultural environment
    e. The consent forms do not mention anything about the observations and potential risks of this research.

15. Stated as “mixed methods” but lacks detail on integration strategy (how qualitative and quantitative findings will be merged).
16. The temporal sequence (concurrent vs. sequential) is unclear.
17. No sample size calculation or justification provided.
18. “**Cluster-based random sampling**” is mentioned but clusters are not defined (school, class, or teacher?).
19. Inclusion/exclusion criteria are not mentioned for either teachers or students.
20. Selection bias risk: public schools in Karachi may not represent other regions.
21. Standardized tool (CLASS); no citation of reliability/ validation in local context is mentioned.
22. Adaptation and language validation processes for Pakistan are missing.
23. Student academic outcomes are measured via grades/test scores, but these may vary by school and are not standardized.
24. Ethical concerns in classroom observation (children being observed) are not discussed.
25. FGDs and IDIs are described in excessive operational detail but *lacking justification for number of interviews* or participant selection (teachers only or administrators too?).
26. No mention of data saturation criteria.
27. Quantitative analysis plan is advanced [Mixed-effects regression models and Generalized Estimating Equations (GEE)], but the design does not mention hierarchical data structure clearly (teacher–student nested model).
28. For qualitative analysis, “**Data will be analyzed manually, following Creswell’s (2007) “data analysis spiral**.” may raise ERC concern regarding rigor and transparency, software (e.g., NVivo/ATLAS.ti) or inter-coder reliability could be added.
29. No clear sample size justification (e.g., based on expected effect size, confidence level, and intra-cluster correlation).
30. Clarify ethical handling of observer effect.
31. Generic statements; lacks specific detail on:
32. Consent from parents/guardians for student participation.
33. Anonymization during classroom observations.
34. Potential power dynamics (teachers being evaluated by researchers).
35. Data storage duration and responsible custodian?
36. Timeline is presented but activities overlap unrealistically, e.g., analysis and data collection run parallel.
37. No mention of pilot testing, training observers/interviewers, or data validation steps.
38. Dissemination plans are broad but lacks target audiences and formats (e.g., policy brief, teacher workshops).
39. What is the role of University of Oxford?
40. Approval of school directorate is missing.
41. Public schools from all nine districts of Karachi will be included in this research, selected through cluster-based random sampling to ensure representation across the towns to capture data from different socioeconomic contexts. Will the selection of schools be gender wise, co-education from different scio-economic groups, how the randomization will be done to minimize the bias?
42. Who will take the observational notes.
43. If short comings are seen, will teachers be guided?
44. What are the possible adverse events, what will insurance cover, this is detailed in study write up and not in consent form?
45. There should be some incentive for the schools included in the study, like books for library, toys for kindergarten etc
46. Provide itemized budget.

Title: **Embracing Ancestral Wisdom: Harnessing Indigenous Knowledge for Climate Adaptation and Resilience in Pakistan.**

Project #	PI Name & Address
NBCR-1343	**Dr. Jai Das** Department of Institute for Global Health and Development Aga Khan University, Karachi

Final NBC-R Comments

1. How will the participants be recruited? Can researchers share any recruitment materials, like flyers, etc?
2. Do researchers anticipate any risks related to stigma or bias regarding a certain community using certain ways that (may) negatively impact the climate?
3. **Phase 1.1- Rapid Systematic Review:**
4. The planned duration (June 2025–**May2026**…….??? **Phase 2 –**will take place from November 2025 to February 2026), the timeline seems generous for a "rapid" review, but realistic for a comprehensive mixed-method evidence synthesis. If truly a *rapid* review, the team must specify time-saving measures to justify the term.
5. The review mentions adherence to PRISMA guidelines, which is appropriate. However, there is no mention of prior registration (e.g., in PROSPERO or Open Science Framework).
6. The term *"rapid systematic review"* implies time constraints, but the proposal does not define what methodological shortcuts will be taken (e.g., single-reviewer screening, limited date range).
7. Inclusion/exclusion criteria are broadly stated but lack detail on:
    a. Handling of mixed-methods studies (how qualitative and quantitative data will be integrated).
    b. Assessment of study quality or bias (no mention of tools such as CASP for qualitative studies etc).
8. **Database search**
9. The search string construction is not specified (Boolean operators like *Parentheses* (), *Quotation*" "; *Truncation*(*), use of MeSH terms). Without this, reproducibility is limited.
10. No mention of ***language filters*** beyond English. This could bias findings, given that regional IK literature may exist in Urdu, Hindi, Nepali, or Chinese etc.
11. ***Embase***is a biomedical and pharmacological database focused on medicine, clinical research, drug trials, adverse events, epidemiology, and systematic reviews. It's relevant only when studying the health or biomedical impacts of climate change, not the social, environmental, or cultural aspects of Indigenous Knowledge.Better explored in environmental, social science, and interdisciplinary databases like Scopus, WoS, etc
12. **Screening and Data Extraction**
13. The screening process is mentioned but lacks procedural detail. There is no specification of number of reviewers, conflict resolution methods, or use of screening software (e.g., Covidence, Rayyan).
14. Data extraction variables are not listed, key data fields (study design, setting, participant type, IK category, outcome measures, contextual factors) should be predefined.
15. **Data Analysis and Synthesis**
    a. ***Quantitative Evidence***
16. Quantitative synthesis (e.g., impact of IK on agriculture, health, or water management) is mentioned as a "*proposed outcome*," but the analytical plan is vague.
    a. It is unclear whether *meta-analysis* or *descriptive summary statistics* will be used.
    b. Many studies in this domain are likely to be *heterogeneous*, making *formal meta-analysis* inappropriate; hence, a *narrative synthesis with quantitative tabulation* may be more realistic.
    Qualitative Evidence
    c. The proposal suggests thematic synthesis but does not describe a formal approach.
    d. Lack of reference to any established qualitative synthesis framework weakens methodological transparency.
    e. Quality appraisal of qualitative studies (e.g., CASP etc) is not mentioned.
17. **Review of Phase 1.2: Qualitative Component**
18. **Sampling Strategy**

19. The rationale for the sample size (32 IDIs + 40 FGDs) appears large for qualitative inquiry. This may risk superficial engagement and logistical strain. A more defensible approach would be to justify sample adequacy based on **data saturation per site or stakeholder group** rather than aggregate numbers.
20. There is no mention of **how sampling will ensure representation of marginalized voices** (e.g., low-income, minority ethnic or nomadic communities).
21. Purposive sampling should be complemented by **snowball or criterion-based sampling** to capture "knowledge keepers" recognized by their communities.
22. The **eligibility criteria** for community vs. stakeholder participants should be tabulated for clarity (education level, years of residence, occupation, etc.).
23. **PHASE 2 – CONSULTATIVE WORKSHOPS TO CO-DESIGN KNOWLEDGE-SHARING STRATEGIES:**
24. Duration (from November 2025 to February 2026) overlaps with **phase 1.1.**
25. Details of the experts from the community, government representatives, NGOs, civil society, and academia are not given.
26. **PHASE 3: CAPACITY BUILDING AND KNOWLEDGE-SHARING EVENTS:**
27. **Conceptual Clarity**: *Capacity-building* and *dissemination activities* are conflated; distinct learning objectives and measurable outcomes for each target group are not specified.
28. **Operational Planning**: Activity plan lacks operational details; no defined number, duration, or frequency of workshops/forums, nor identification of responsible facilitators or partners at each site.
29. **Monitoring & Evaluation**: Performance indicators are numerous but not SMART (Specific, Measurable, Achievable, Relevant, Time-bound); emphasis is on participation counts rather than knowledge or behavior change.
30. **Sustainability**: No clear plan for post-project continuation, follow-up mentorship, or integration of community networks into existing governmental or NGO structures.
31. **Gender & Cultural Sensitivity**: Although gender-specific sessions are proposed, facilitation safeguards (female moderators, culturally appropriate venues/timings) are not described.
32. **Risk Management**: Risk mitigation strategies are reactive; absence of proactive contingency mechanisms such as hybrid (in-person + virtual) event models or local co-facilitator training.
33. **Policy Translation**: Policy briefs and roundtables are planned, but no defined pathway for policy uptake, alignment with national/provincial frameworks, or engagement timeline with decision-makers.
34. **Resource Allocation**: No indication of budgetary distribution or logistical support required for multi-site implementation and production of knowledge products.
    a. What is the role of Alberta University is this project?
    b. The funding is coming from Global Affairs Canada. The budget sheet needs to be detailed and should also specify the currency.
    c. The PI and Co-PI are from AKU, whereas the Field activities will be conducted in Tharparkar and Badin (Sindh), Multan (Punjab), and Ghizer and Shigar (Gilgit-Baltistan). Who will be coordinating from these sites? There could be language barriers.
    d. The Interviews will be conducted with different stakeholders, who will be interviewing the females? There are many unrelated questions which females cannot answer, how that will be addressed.
        i. Who will conduct the FGDs of females?
        ii. The time line needs to be revised as the time frame of Phase -1 has already passed.
        iii. The time for interview, is not consistent, in consent form it is 45 -60 minutes and in study write up it is 60 – 90 minutes.
        iv. What will be the post research benefits for the community?
        v. Will there be any guidance in case if any short coming is seen?
        vi. CV of Co-PIs are missing.
        vii. Provide itemized budget.

Minutes of the NBC-R meeting held on 18-11-2025

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

Sr.#	Group-I	
1.	Prof. Saima Pervaiz Iqbal	Chairperson
2.	Prof. Munir Akhtar Saleemi	Member
3.	Prof. Marie Andradess	Member
4.	Prof. Amjad Mehboob	Member
5.	Prof. Ejaz Ahmed Khan	Member
6.	Prof. Rameeza Kaleem	Member
7.	Prof. Agha Riaz	Member
8.	Prof. Faheem Ashraf Khan	Member
9.	Mrs. Tayyab Rahat	National Coordinator
10.	Mr. Waryal Ali Daheri	LDC NBC
11.	Prof. Sualeha Siddique Shekhani (Regret to Join the Meeting)	Member

The following projects reviewed / discussed:

Title: **Co-Designing Culturally Responsive Engagement Strategies to Strengthen Polio Vaccine Uptake.**

Project #	PI Name & Address
NBCR-1344	**Dr. Jai Das** Department of Institute for Global Health and Development Aga Khan University, Karachi.
Final NBC-R Comments	
• **Study Approved.**	

Title: **Exploring prevalence, genomics, clinical outcome, psychosocial, financial and quality of life impact of antifungal resistant dermatophyte infections in Pakistan.**

Project #	PI Name & Address
NBCR-1345	**Dr. Kauser Jabeen** Department of Pathology and Laboratory Medicine Aga Khan University, Karachi.
Final NBC-R Comments	
1. Please add an assent form for children. 2. We would like to see the data collection form. 3. If an enrolled participant is found to have a fungal infection resistant to standard treatment what measures would be taken place to ensure that they get the required or second line treatment for it? The drugs may not be available in Pakistan, so would they be imported?	

Title: **Trial Regarding Eficacy and Safety of Synoflux Hollow Fiber Dialyzers and Comparison with other Popular Brands.**

Project #	PI Name & Address
NBCR-1346	**Dr. Faheem Usman Sulehri** Central Park Medical College and teaching Hospital, Lahore.

Final NBC-R Comments

1. We suggest that the PI resubmits the protocol after major revisions focusing on the following:
2. Please clarify the methodology of this trial. It was unclear to us if the intervention (new dialyzers) is being used for safety and efficacy purposes, acceptability and feasibility purposes or to see if it better than the standard of care?
3. What are the clinical end-points being measured to compare the standard dialyzers with the new ones? What is the expected effect size and is it significant enough to prove that one is better than the other?
4. How will randomization take place or how will one patient be randomly assigned to the standard dialyzer and the other to the new one?
5. There is a mention of taking photographs in the protocol. Please specify why they are necessary and is it a risk to patient confidentiality?
6. How will device-specific anticipated harms or injuries be managed? It is not enough to say that these devices have have no harmful effects in the consent form.
7. Please expand on the health insurance coverage provided to the participants in case of adverse events. This should be mentioned in consent form.
8. The consent form should also mention that patients will have a right to withdraw from the study without any affect on their care.
9. What is the benefit sharing plan with the Pakistani population if the devices are proven to be useful?
10. What is the role of Renacon in this study? How is this likely to affect the study results?
11. Are the PI and co-PIs trained and certified to conduct a trial? Please provide any evidence like CITI certifications.
12. After going through this project most reviewers detected a bias in favour of the new dialyzers. This bias would be unscientific on the part of the PI as it would skew the interpretation of results.

Minutes of the NBC-R meeting held on 25-11-2025

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

Sr.#	Group-II	
1.	Prof. Jamshed Akhtar	Chairperson
2.	Prof. Saqib Mehmood	Member
3.	Dr. Farkhanda Ghafoor	Member
4.	Prof. Akhtar Sherin	Member
5.	Dr. Sarosh Saleem	Member
6.	Dr. Natasha Anwar	Member
7.	Mrs. Tayyab Rahat	National Coordinator
8.	Mr. Waryal Ali Daheri	LDC NBC
Regrets to join the meeting.		
9.	Prof. Nazli Hossain (Sent Observations)	Member
10.	Prof. Shahid Mehmood Baig	Member
11.	Dr. Shaper Mirza (Sent Observations)	Member

The following projects reviewed / discussed:

Title: **Big steps for small babies - strengthening the cross-sectoral interventions in the flood affected areas for mother and child wellbeing in District Sujjawal, Tharparkar and Jaccobabad.**

Project #	PI Name & Address
NBCR-1347	**Dr. Zahid Memon** Department of Community Health Sciences Aga Khan University, Karachi

Final NBC-R Comments

1. Why context of flood affected districts of 2022 is used in this project. It is 2025. What are the current statistics and facilities rendered by the Sindh Health department? Why PI think that these districts are still affected by the aftermath of the floods on 2022?
2. There is a well-established system of BHU, RHC along with lady health visitors availability, all connected to tehsil and district level hospitals. Pediatricians of Sindh Health department are also posted at all levels including medical officers as well. Why existing resources are not used by Sindh Health department, in fact there is no presence in the project. UNICEF is expected to work with government but this is not found.
3. Researchers will go away. How it is expected that intervention will sustain?
4. Kangaroo is a well-establishedmethod; huge data exist on it from Pakistan. AKU has made videos available on the same subject on Youtube. What new is being explored?
5. The title is misleading because it implies a focus on both mothers and all newborns, whereas the proposal and sample population address only low-birth-weight and preterm infants.
6. Title is long, lacks clarity, and does not reflect the community-based KMC focus directly.
7. No meaningful maternal indicators are included.
8. Also the inclusion criteria contradict the title by limiting the sample to LBW/preterm babies rather than all newborns.
9. Although the objectives are relevant, the proposal lacks essential operational details: no timeline, no indicators, no role distribution, and no clear targets. This makes the feasibility of achieving the objectives unclear.
10. There is also a mismatch between the stated beneficiaries and the projected impact. Only about 1,200 LBW/preterm infants are eligible for KMC, yet the proposal claims benefits for around 10,000 newborns. It is unclear what interventions the larger group will actually receive. The proposal should clearly differentiate primary beneficiaries (LBW/preterm infants receiving KMC) from secondary beneficiaries (other newborns receiving general care improvements) and align outcome claims accordingly.

11. Research in disaster-hit areas requires ethical evaluation of a) justification of research in that area/situation, b) justification of the urgent need for knowledge for future use, c) protection of vulnerable populations, d) justification of risk of harms vs benefits (if any, in addition to new knowledge production)
12. What is the Standard of Care (SOC) for pre-term & low birth weight (LBW) babies in these areas (Jacobabad, Sujjawal, and Tharparkar)?
13. Section 2.1 says no harm. However, a potential risk of harm is present if KMC is initiated before stabilizing the baby. Is there any provision to train the staff to stabilize the baby first? What is the SOC?
14. Sections 2.1 and 2.5: If this strategy (KMC) has known/proven benefits, why is this a study and not just an intervention or regular training incorporated in neonatal care?
15. Are any local healthcare providers or community members engaged in the process of implementation? This might be useful in identifying local challenges in neonatal care, especially after floods. There is a chance that fathers may not be as available because of social responsibility of providing for a family, looking for/ doing work, and/or psychological distress due to the current socio-economic situation.
16. Where will the participants be recruited from (health facility/home or elsewhere)?
17. Can the researchers share the details of who and how the Community Health Workers will be recruited and what their training material will be used?
18. Can the researchers share what "culturally appropriate and gender-sensitive information and interventions" will be used to achieve Outcome 4, as mentioned in the proposal?
19. Lacks key elements of data confidentiality and security
20. Does not specify the data platform to be used, nor does it state the data retention period
21. There is no mention of compliance with relevant data protection regulations (GDPR, PECA, HIPAA), and no plan for data backup, encryption, password protection, or device security
22. Does not clarify data-sharing arrangements with UNICEF, Health department, or other partners
23. The Kangaroo Mother Care is proposed for interior Sindh, however, it is not clear if mothers will be trained in WASH and IPC techniques as well
24. WASH and IPC are proposed for the caregiving facility but not for mothers or fathers who will be handling the child.
25. Will the PI train LHVs in WASH and IPC so the service continues even after conclusion of the study?
26. Will they be delivering WASH service for the entire area, as floods are always accompanied by gut and respiratory tract infections. This will be one service that they can provide to all in the area and leave no one behind.
27. Itemized budget is required. The details are not found in the attached document. It is a six crores rupees' budget which is huge.
28. What is the role of PPHI Sindh?

Title: **Building Resilience to Climate Vulnerabilities through Education: Supporting Schools, Educators and Students in Pakistan.**

Project #	PI Name & Address
NBCR-1348	**Dr Shenila Rawal** ABMA UK Ltd 7 Queens Square Lyndhurst Road Ascot Berks UK SL5 9FE, United Kingdom **Co-(PI): Muhammad Uris Umrani** Indus Resource Centre (IRC) D-42/B, Block 1, KDA 5, Near Ziauddin Hospital, Clifton Karachi.

Final NBC-R Comments

1. Dr. Shenila is stationed in UK but the IRB is from SZABIST. What is the connection between two institutes? Is Dr. Shenila a part-time employee of SZABIST, because the CO-PI is from IRC.
2. What kind of institute is IRC?
3. Which language will be used to explain the study. The selected areas KhairpurMirs and Badin are purely Sindhi speaking and will need someone on the team who is proficient in Sindhi to speak to the students and their parents, or else the study will not make any sense to them.
4. The objectives are too broad and vague. They should be made clearer and more measurable with specific goals and indicators.
5. The proposal doesn't clearly explain the main ideas or theories that connect climate change, education, and teacher training. This makes it harder to understand the reasoning behind the study and how its parts fit together.
6. The PI should identify authorized individuals who will be handling data.
7. How long will they be storing this data for and are they informing participants that their data will be stored for an X amount of time and will be used (maybe) for other studies as well.
8. An approval or "No Objection" letter should also be requested from school leadership participating in the study.
9. The PI stated that staff will be trained to identify signs of distress, however, once again they don't have any Sindhi speaking person on the team. Listening to questions in another language, that participants are not very familiar with, might, in itself be stressful.
10. Why are research findings not being disseminated among school staff?They should be the first one to know so they can develop methods for disaster management including helping kids in school who had lost their families, belongings, houses etc. during floods, developing alternate study plans to bring student to speed once school start especially for students who could not attend school during times of disaster.
11. People who are facilitating the study are not getting ANY direct benefits??? Everything goes to FCDO ???
12. Clarify role of Oxford, JICA, OPM in context of funding.
13. The consent form does not clearly state the participants' rights, such as the right to ask questions at any time, the right to skip any questions they are uncomfortable with, and how their data will be stored or for how long.
14. The questioner for students has questions that might be beyond the comprehension at their age and level of understanding. They should be simplified
15. Assent form is too brief and without simplified details of what is expected from the child giving assent. Consent form from parents for children participation is missing.
16. Section 2.1: Raising awareness has been described as a study benefit, however, the study objectives do not mention anything about creating awareness. If so, researchers may also share what activities they plan in this regard and what awareness-creating material will be used (when and how).
17. There are no direct benefits for participating in this research
18. The section does not mention what risks of harm the study has. The study population is vulnerable, apart from risk of harm to privacy and confidentiality, there are risks of

stigmatization and also triggering psychological distress among populations that have suffered from climate related disasters

19. The questionnaire to be filled by pupil, particularly asks many questions that can trigger psychological distress. Is noting down the name necessary? (Can lead to breach in privacy).
20. The project includes extensive qualitative data collection including Key Informant Interviews (KIIs), In-Depth Interviews (IDIs), and Focus Group Discussions (FGDs) to explore climate impacts on education systems. While the approach is appropriate for the research aims, several methodological and ethical gaps require clarification.
21. Mixed-Methods Design is not explicitly defined. Without this, one cannot judge comment on the sequence of data collection, whether both strands have equal priority and how and when integration will occur?
22. The protocol only states: "findings will be compared and triangulated."However, mixed-methods standards require clarity on:***When*** *integration occurs****how*** *it will occur,* ***what*** *will be integrated?*
    The protocol provides large quantitative samples (324 students, etc.) but relies extensively on qualitative interviews. No explicit priority is stated.
23. Quantitative Sampling Issues; Sample appears predetermined, but no sampling frame or justification provided.
24. No explanation of representativeness, especially since sampling is purposive rather than probabilistic.
25. Qualitative sample sizes are fixed, not saturation driven.
26. There is no rationale for number of KIIs, FGDs, or interview depth.
27. Qualitative Research Designis not specified.
28. Fixed sample numbers listed (e.g., 324 students, 54 teachers), but no justification for these numbers in qualitative terms.
29. Potential ***selection bias*** via school leadership identifying participants.
30. Consent obtained "on the spot" immediately before interviews/FGDs, raising coercion concerns, especially for minors and teachers.
31. No detailed plan for parental consent workflow or timing.
32. There are no details on, Number and duration of FGDs, Interview Environment (privacy assurance), Handling of emotional distress in climate-affected populations
33. Audio recording implied but no detailed plan for the Encryption/secure storage/access control/retention period/destruction policy.
34. Use of cloud storage mentioned but no platform-specific compliance details.
35. No methodological description of **how qualitative findings will be merged** with quantitative survey results to produce integrated conclusions.
36. Funding information is scattered across two documents; total funds listed but no budget line justification is included in the protocol.
37. No explicit statement of conflict-of-interest for investigators.
38. Sponsor responsibilities not defined (OPM/IRC roles in safety, monitoring, compensation, data control).
39. Why females are a particular focus?
40. With whom data shall be shared? Data sharing document will be required.
41. There is nothing new in the tool that is used to collect data. This information is available.

Title: **Codesign of an implementation strategy for bubble continuous positive airway pressure (bCPAP) therapy for children with severe pneumonia in Pakistan.**

Project #	PI Name & Address
NBCR-1350	**Dr. Qalab Abbas** Department of Paediatrics and Child Health, Aga Khan University, Karachi.

Final NBC-R Comments

1. Abbasi Shaheed hospital: A hospital which is a tertiary care and attached with a university but has no IRB must not be included.
2. Exclusion criteria include caregivers who do not speak Urdu. Unfortunately, half of these individuals are from Hunza who barely speak Urdu they converse with nurses who are from the same region in their own language and often times it's the nurse who explain the problem to the attending physician.
3. The PI is enrolling a total of 20 participants including nurses, caregivers and physicians at each study site, however, no other site is mentioned.
4. What is the study question? Will this study provide evidence or training or develop a method that currently do not exist?
5. What is "codesign" which appears to be the focus? How it will develop, validated and then implemented. This is not explicitly addressed?
6. Implementation / intervention is the next step.
7. Is there a strategy to train caregivers in delivering bCPAP or just recommendation of use of bCPAP in NICU?
8. Since neonates are involved, the therapy should be administered by skilled staff not stressed out caregivers as kids are very sick and one little mistake can cause huge damage.
9. The protocol specifies that data will be de-identified in Pakistan and then transferred to Yale for analysis. This raises an important question: Why can't the analysis be conducted entirely at the local (Pakistan) level, especially when the data originates and is collected there?
10. Data transfer agreement is not attached.
11. Mixed-Methods Design is not clearly justified or described. It is mentioned that the study "exploratory sequential mixed methods" (page 14). However, thereisNo clear explanation of the sequence.
12. **Nominal group technique** (NGT) sessions produce qualitative discussions plus quantitative ranking scores, but the protocol does not explain how these datasets will be combined.
13. Lack of Clarity on Outcome Measures: The protocol (page 15).
14. Outcome variables are not listed, measurable, or described.
15. The protocol anticipates 12–18 participants (page 15) but gives No explanation of minimum number required for thematic saturation
16. There is no explanation of how power dynamics between physicians, nurses, and caregivers will be mitigated.
17. Mixed professional groups may silence caregivers, violating equal participation principles of NGT.
18. Caregiver participants may have low literacy. The protocol states: Consent will be "read aloud"
19. Child Data Access Requires Stronger Justification.
20. Data Transfer to Yale—Safeguards Incomplete. Protocol states that Identifiable data remain in Pakistan only de-identified data transferred to Yale. NBC-R Form (page 11) also outlines storage and transfer but does not include Data Transfer Agreement (DTA).
21. Retention period differs, protocol mentions 3 years. NBC form 7 years.

Chairperson NBC-R

Minutes of the NBC-R meeting held on 02-12-2025

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

Sr.#	Group-I	
1.	Prof. Saima Pervaiz Iqbal	Chairperson
2.	Prof. Amjad Mehboob	Member
3.	Prof. Sualeha Siddique Shekhani	Member
4.	Prof. Ejaz Ahmed Khan (Shifa)	Member
5.	Prof. Rameeza Kaleem	Member
6.	Prof. Agha Riaz	Member
7.	Prof. Faheem Ashraf Khan	Member
8.	Dr. Farah Asif	Member
9.	Mrs. Tayyab Rahat	National Coordinator
10.	Mr. Muhammad Usman	LDC NBC

The following projects reviewed / discussed:

Title: **Affordable Cardiac Rehabilitation: An Outreach Inter-disciplinary Strategic Study (ACROSS).**

Project #	PI Name & Address
NBCR-1351	**Prof. Imran Bashir Chaudhry** Pakistan Institute of Living and Learning Suit 201, 2nd floor, Dr. Plaza, do talwar, Clifton, Karachi. Pakistan.
Final NBC-R Comments	
1. Please give more details about participant recruitment? Where and when will they be recruited? Where will they be interviewed etc? 2. Has this study been approved by Univ of Glasgow and Univ of Manchester? Please provide a copy of IRB approval. 3. Please explain how this study will will translate into any benefit for the Pakistani population. 4. What are the "risk management costs" mentioned in the budget? This seems to be a low risk study otherwise.	

Title: **Strengthening the quality of midwifery education in the lower middle-income country of Pakistan.**

Project #	PI Name & Address
NBCR-1352	**Bakhtawar Khowaja** McMaster University 1280 Main St W. Hamilton, L8S 4K1 **Canada**
Final NBC-R Comments	
1. Study Approved.	

Title: **Cascade Genetic Screening Study of Family Members with Ectonucleotide Pyrophosphatase/Phosphodiesterase 1 (ENPP1) Deficiency.**

Project #	PI Name & Address
NBCR-1353	**Reda Elsahy** Al Jalila Children Hospital, Dubai Health UAE

Final NBC-R Comments

1. How much of a sample size (expected) will be required from Pakistan?
2. Is there a potential for stigma in the family members if they are positive for a certain gene? Can it cause disruption among the family members? If so, how will this be addressed on the ground.
3. Will any treatment be provided for this condition for someone who is suffering from this deficiency or from someone who tests positive on genetic testing?
4. Genetic counseling needs more information. Who will provide it? Are they trained for it? What would be the implications for the family?
5. Approval from Children Hospital IRB is required.
6. Informed consent needs to be more easy to understand (at level of an 8th grader)

Minutes of the NBC-R meeting held on 09-12-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on December 9th, 2025. The following members of NBC-R attended the meeting:

Sr.#	Group-II	
1.	Prof. Jamshed Akhtar	Chairperson
2.	Prof. Nazli Hossain	Member
3.	Dr. Farkhanda Ghafoor	Member
4.	Prof. Saqib Mehmood	Member
5.	Prof. Akhtar Sherin	Member
6.	Mrs. Tayyab Rahat	National Coordinator
7.	Mr. Waryal Ali Daheri	LDC NBC
Regrets to join the meeting.		
8.	Prof. Shahid Mehmood Baig	Member
9.	Dr. Sarosh Saleem	Member

The following projects reviewed / discussed:

Title: **A Multicenter, Open-label, Single-arm study to Evaluate the Efficacy of Hydroxyprogesterone caproate+Estradiol valerate (Gravibinan) ® for the Treatment of Threatened & habitual Abortions in the Pakistani Population.**

Project #	PI Name & Address
NBCR-1354	**Prof. Dr Haleema Yasmin** WARD-8, DEPTT. OF OBS. & GYNAE JINNAH POSTGRADUATE MEDICAL CENTRE, KARACHI.
Final NBC-R Comments	
Discussed in detail. The drug is suspended by DRAP and thus it is not ethical to discuss the proposal (though we did and noted huge number of deficiencies. We will not send those observations. Link is shared about DRAP notification. Ms. Tayyaba, National Coordinator (NBCR) was also informed to take up this case from secretariat and our observations shall be through chairperson. https://www.dra.gov.pk/wp-content/uploads/2025/07/58-Suspension-of-marketing-authorisations-of-17-OHPC-due-to-its-un-effectiveness.pdf	

Title: **Teachers' Social Competence and Its Impact on Students' Social-Emotional Learning and Academic Outcomes.**

Project #	PI Name & Address
NBCR-1355	**Dr. Bilal Qureshi** Department of Oncology Aga Khan University Karachi
Final NBC-R Comments	
1. The PI is already involved in 14 research projects. How this new project is justified as PI? 2. The mixed method is not described, mentioned in passing. Provide more details about the qualitative arm of the study. 3. The protocol provides no defined sample size or minimum expected numbers of cases, participants, workshops. Approximate estimates and justification that the data collected will be sufficient for meaningful conclusions is required. 4. The method of merit based selecting the physicians for the clinical attachment is not given. 5. Meetings and workshops add time pressure on already busy physicians, it is not explained how it will be make sure that representative number of physicians take part in all the activities. 6. The protocol identifies multiple potential endpoints but does not specify a primary outcome and clearly defined secondary outcomes.	

7. How impact / outcome of the educational activity will be assessed? Briefly.
8. Where the workshops / training shall be conducted? How long the sessions shall last?
9. Provide details of content and execution related protocols of the workshops and assessment of their outcome methods.
10. Will data be shared with US hospital? Provide data transfer agreement.
11. Consent form is still important be it a minimal risk or online participation activity.
12. Provide details of the study sites and teaching faculty.
13. Doctors or hospitals may feel embarrassed when mistakes are discussed and participants might guess the physician or the hospital involved
14. If the team finds a serious treatment error, it is not clear who must be told or how it will be handled safely.
15. Although the project affects children, parents are not included in planning or feedback.
16. Health facilities are not fully protected from identification even if names are removed, people in the field may still guess which hospital a case came from.
17. A detail of fund utilization is not given.
18. Provide itemized budget.

Title: **A Multicenter International Study of the Feasibility and Outcomes of Carboplatin Based and Methotrexate-Based Standard Treatment Regimens in Localized Osteosarcoma: A Two-Arm Pragmatic Study.**

Project #	PI Name & Address
NBCR-1356	**Dr. Sadaf Altaf** Department of Oncology Aga Khan University Karachi

Final NBC-R Comments

1. There is no funding for this project as mentioned in the ERC form. Kindly elaborate how it will be executed?
2. The proposal does not identify the Lead Investigator who will be responsible for receiving and overseeing all data transferred from the participating international institutions.
3. Study is a prospective two-arm interventional regimen-based clinical trial but is labeled as OBSERVATIONAL STUDY in the RISK DETREMINATION section … (with justification that no new treatment option is introduced).
4. How a trial can be a minimal risk study as mentioned in the ERC form?
5. Are both regiment to be used in this study are standard of care? If not, which arm is experimental? Same information related to experimental arm and issues must be present in ICF.
6. The proposal currently claims equal effectiveness but does not discuss toxicity differences between the MAP and OS99 regimen
7. From Pakistan is there any fixed number of patients with the tumor to be included?
8. Data sharing is with PIMS by researcher from Lebanon. This needs clarity. It is not on a legal form. It should be read again.
9. Though many sites from Pakistan are mentioned but in one place only three hospitals, AKU, NICH and ShaukatKhanum is mentioned?
10. There are multiple institutes across the country participating in this study. Is the submitted proposal intended to serve as a common ethical approval for all sites, or is each participating institute required to submit its own separate application to the NBC? IRB approval from NICH and many other participants' institutions are not found.
11. It appears that all the tests and treatment cost shall be borne out by the participating institutions / patients. This need clarity. This is a trial to find out the results of an intervention. Why patient may pay for the cost incurred?
12. There is no mention of the data storage duration
13. The protocol lacks reference to a Data and Safety Monitoring Board (DSMB), and no mechanism for independent monitoring of adverse events has been described.

14. Drugs information sheets are not provided
15. What will be the age ranges for Child assent and Adolescent assent?
16. The Child assent in Urdu is a bit difficult to understand by 6/7-10 years old.
17. What if the child dissents, but the parents agree to consent? (A child cannot be enrolled in a research if she dissents, AND the study offers no direct benefits to research participants…it's not the same if study offers some benefits unlike this study)
18. Who will sign the parental consent? (One parent or both?)What if both parents do not agree?
19. If the blood/tissue samples are being kept for future use, the risks of participating in research increase.
20. An overview of centers having treated the above case, in terms of numbers, survival with their existing regimen is required.

Minutes of the NBC-R meeting held on 16-12-2025

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

Sr.#	Group-I	
1.	Prof. Saima Pervaiz Iqbal	Chairperson
2.	Prof. Munir Akhtar Saleemi	Member
3.	Prof. Marie Andradess	Member
4.	Prof. Amjad Mehboob	Member
5.	Prof. Sualeha Siddique Shekhani	Member
6.	Prof. Rameeza Kaleem	Member
7.	Prof. Agha Riaz	Member
8.	Prof. Faheem Ashraf Khan	Member
9.	Mrs. Tayyab Rahat	National Coordinator
10.	Mr. Waryal Ali Daheri	LDC NBC

The following projects reviewed / discussed:

Title: **Effect of Workforce Shortage on Health System of Pakistan.**

Project #	PI Name & Address
NBCR-1357	**Zikra Rehman** University of Eastern Finland Yliopistonranta 8, 70210 Kuopio, Finland
Final NBC-R Comments	
1. Aims and Objectives not clearly defined. So better to provide 3-5 concise, specific objectives and align them with the proposed outcomes. 2. Frame one primary question and 2-3 secondary questions. 3. The application lists national-level healthcare workers, patients, and policymaker, but only one hospital (DHQ Narowal) appears as a collaborating site. For a national inference, sampling from only one geographic site is not ethically justifiable and will produce non-generalizable data. 4. Policymaker sample (10-20 experts) is stated, but recruitment mechanisms are unclear; obtaining access to national policymakers is typically low-feasibility. Would be good to provide a realistic sampling framework, recruitment strategy, and justification for representativeness. 5. Consent process not described adequately. The application states only that "consent forms will be shared"; but there is no explanation of 'How online consent will be obtained; How participants will confirm understanding; whether Urdu version exists? 6. Patients recruited from hospitals are potentially vulnerable population, and the application does not describe how coercion will be avoided; whether clinicians involved in their care will be excluded from recruitment; how privacy will be ensured during administration. 7. Institutional conflicts seem to be overlooked as the DHQ hospital management is a collaborator and also controls participant access. Therefore, better describe measures ensuring that employee respondents (HCWs) are protected from employer's influence. 8. Community engagement also needs to be elaborated.	

Title: **Trial: Clozapine For Treatment-Resistant Bipolar Disorder: A Pilot Randomized Clinical Trial.**

Project #	PI Name & Address
NBCR-1358	**Prof Imran Bashir Chaudhry** Pakistan Institute of Living and Learning Suite#201, 2nd Floor, The Doctors Plaza, Do-Talwar, Clifton, Karachi

Final NBC-R Comments

1. The trial involves a placebo in patients resistant to other medications. This does not appear to be safe. Will they continue their regular medications? Not clear.
2. Consent information sheet mentions: You may have been invited to participate in the study because you are between aged 18-65 years, had a diagnosis of Treatment-Resistant Bipolar Disorder (TRBD) and are currently receiving treatment and attending one of the hospitals or health care centres involved in the study. If he is receiving treatment then why should he be changed to another treatment?. Consnet does not mention that he will be withdrawn from other treatment
3. The proposal indicates "Assessments will occur at baseline, and weekly until week 12 and then at 6 months, either in person or via secure video conferencing". How will sampling be carried out if visit not done in person
4. MRI is mentioned under safety management plan BUT NOT MENTIONED IN THE TESTS THE PATIENT HAS TO UNDERTAKE. WHEN AND WHY WILL MRI BE DONE??
5. Consent does not mention any tests ONLY MENTIONS QUESTIONAIRRES. Also no mention of who will pay for their treatment if develops side effects
6. Rs 500 for each visit appears low for a person on whom multiple scales and tests are being used. There are 13 instruments along with tests
7. No mention of test costs in budget
8. Study sites not identified

- The document alternately refers to "clozapine vs placebo" and "clozapine vs treatment as usual (TAU)" (e.g., primary objectives mention placebo; sample description mentions TAU). This is a fundamental protocol inconsistency. Placebo-controlled antipsychotic trials raise higher ethical scrutiny (risk of withholding active treatment), especially in severe mood disorders with suicidality. Clarify which arm(s) and justify ethically.
- The inclusion criteria allow participants "can have active suicidal ideation." That is ethically sensitive for a drug trial with potential severe adverse effects. Patients with active suicidality are vulnerable; enrollment must ensure capacity, enhanced monitoring, and rapid access to emergency care. Risk-benefit must be explicitly assessed, and a clarification on the referral pathways and if there will be any budget for urgent care.
- The form states IP storage and authorized pharmacy staff, but lacks SOPs for dispensing, reconciliation, temperature monitoring, blinding maintenance, and drug accountability.
- There is a claim that the sponsor will bear costs of routine safety labs and management of adverse events, but does not provide clinical trial insurance / indemnity documentation or clear limits of liability.
- Since this is a clinical trial, there is no mention of its registration (in any foreign registry or even with DRAP).

Title: **Culturally Adapted Cognitive Behavior Therapy for Individuals At Risk of First Episode Psychosis: A mixed method study.**

Project #	PI Name & Address
NBCR-1359	**Dr. Ameer Bux Khoso** Pakistan Institute of Living and Learning Suite#201, 2nd Floor, The Doctors Plaza, Do-Talwar, Clifton, Karachi
Final NBC-R Comments	
1. Consent and Assent forms are missing. 2. Screening checklist mentions age 18 onwards whereas protocol mentions age 16 years onwards. 3. Participants will be recruited from Karwan-e-Hayat in Karachi as well as from community settings. WHICH COMMUNITIES AND HOW WILL THEY BE RECRUITED? 4. If found to have severe depression or anxiety what measures will be taken?? 5. CBT details missing	

Minutes of the NBC-R meeting held on 23-12-2025

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on December 23rd, 2025. The following members of NBC-R attended the meeting:

Sr.#	Group-II	
1.	Prof. Jamshed Akhtar	Chairperson
2.	Prof. Shahid Mehmood Baig	Member
3.	Dr. Farkhanda Ghafoor	Member
4.	Dr. Sarosh Saleem	Member
5.	Dr. Natasha Anwar	Member
6.	Dr. Shaper Mirza (Sent Observations)	Member
7.	Mrs. Tayyab Rahat	National Coordinator
8.	Mr. Waryal Ali Daheri	LDC NBC

Regrets to join the meeting.

9.	Prof. Nazli Hossain (Sent Observations)	Member
10.	Prof. Saqib Mehmood (Sent Observations)	Member

The following projects reviewed / discussed:

Title: **Trial: Drug coated balloon vs. Drug eluting stent in young patients with STEMI The DCB-STEMI Randomized trial.**

Project #	PI Name & Address
NBCR-1360	**Prof. Dr. Abdul Hakeem** Cardiology Department Natinoal Institute of Cardiovascular Disease (NICVD), Rafique HJ Shaheed Road, Karachi

Final NBC-R Comments

1. The PI is already recruiting the patients as per Clinicaltrial.gov website. This need clarity.
2. The date on screening form is that of February 2024. Needs clarity.
3. The PI is already involved in 29 ongoing trials. How this additional trial is justified?
4. For pilot study NICVD IRB gave approval in March 2025 and then for trial in September 2025. The study started without NBC R approval. Why approval is required now?
5. Itemized budget is not provided.
6. What is the competing interest of the company that has provided huge funding of 11 crores rupees?
7. The approval of DRAP requires GCP inspection before every trial. Provide the document of inspection and approval for this trial.
8. Though COI is attached but PI has not mentioned what financial gains will be for him while conducting this trial.
9. Provide an agreement with the funding company.
10. Benefit mentioned in the ICF is more of a coercion. Benefits such as fast-track OPD access, free tests, and specialist follow-up are listed without clear distinction from direct treatment benefit.
11. What is the cost of the interventional stent?
12. What is the cost of routinely placed (standard of care) stent at NICVD?
13. Who pays for these stents, patient himself or hospital free of cost at present?
14. How a patient in acute chest pain is expected to read a five page long consent form, understand and sign it?
15. The consent process does not adequately address the ethical challenges of obtaining consent during an acute, life-threatening emergency.
16. The consent form uses complex medical and research terminology inappropriate for a lay audience.
17. The study population is extremely vulnerable…how will the research team ensure that the patient is not under any influence to participate?
18. Will PI obtain consent from a surrogate?
19. In the informed consent, the details must be clear. Language is not comprehensible. It is not clear why the participants are being enrolled. No mention that this is a trial.
20. Details of routine (standard of care) vs trial must be informed.
21. Share the names of the members of DSMB. The role of **Steering committee, Data and safety**

monitoring board and Event Adjudication Committee is detailed. Who will be members of these committees?

22. Is there provision of insurance for the patients?
23. A pilot study on 50 patients is mentioned, but no outcomes, feasibility data, or results are given.
24. The role of SciLife Pharmaceutical role in the proposal is not given. Medtronic Pvt. Ltd. in providing devices or financial support is not clearly specified.
25. Randomization is not clear.
26. Which team shall take the consent and responsible for allocation? (Details required: Who is - Randomization & Allocation team, Screening & Recruitment Team, Event Adjudication Team)
27. How blinding shall be done?
28. Is there a chance of therapeutic misconception? How it shall be addressed?
29. How transparency shall be ensured?
30. How confidentiality shall be ensured as ID and date of birth related information is mentioned?How will the research team follow up on telephone – mention which identifier shall be used?
31. In section **"Data protection and confidentiality "**Patients will be identified by the patient ID, random number and date of birth. The patient's name will not be noted on the study documents to maintain patient's confidentiality" However in CRF forms the patient name is written at all three stages of the project.
32. How Paclitaxel associated complications shall be recorded and addressed?
33. Routine invasive follow-up is mandated for all participants irrespective of symptoms, without sufficient scientific justification.
34. Risks of repeat angiography and IVUS (bleeding, contrast nephropathy, radiation exposure) are not clearly explained in the patient information sheet.
35. Absence of financial compensation is stated without adequate contextual explanation.
36. Section 1.4. Justification for Study-Not satisfactory.
37. How NBCR will be informed about adverse events.
38. Section 2.7. Data retention for more than 10years. This needs clarity and purpose.
39. Since the patients consented for study will be study participants, who will bear the cost of each procedure, hospitalization, travel for follow up and treatment of adverse events. This all needs to be written in consent form.
40. In section **"Financing and Insurance**" it is detailed "This is an investigator initiated trial seeking funding from Medtronic. The sponsor will have no influence on study design, execution or outcomes of the study. The insurance is not explained, how the participant will be benefited.
41. It is mentioned that vessel dissection is a minor complication. It needs elaboration.

Title: **Trial: Optimal treatment duration for radiographically apparent, bacteriologically unconfirmed TB, identified through active case finding (Radio TB Trial).**

Project #	PI Name & Address
NBCR-1361	**Dr. Syed Mohammad Asad Zaidi** National University of Medical Sciences, Rawalpindi The Mall Road Rawalpindi

Final NBC-R Comments

1. The title of the study does not match with the content of the project.
2. While the stated primary aim of the study is to evaluate management strategies for individuals with radiographic evidence of TB identified through chest X-ray screening, the proposal also **includes multiple additional objectives**, including the evaluation of **novel molecular, immunological, and other diagnostic modalities, as well as the establishment of a passive follow-up cohort for screened individuals who do not enter the randomized trial**. The inclusion of these components expands the scope and complexity of the study, raising concerns about whether the project has become overly ambitious relative to its core objective.
3. Bacteriological identification is the gold standard. How can one start drugs, which do have hepatic toxicity be started without confirmation of diagnosis? What are the WHO protocols for such a cohort?
4. This expansion may increase participant burden, complicate the consent process, and divert focus from the primary research question.
5. It is mentioned that cohort will include in whom bacteriological culture is negative. This needs elaboration in context of intervention with risk / benefits based upon literature search.
6. Additional components involve collection, storage, and transfer of biological samples for future or off-site analyses; however, no Material Transfer Agreement has been provided and mentioned "is in process".
7. Storage of samples related details are needed/
8. 2.8 - Biological samples will be transported- what samples? why?shipped outside of Pakistan - Where? for what tests? "utilized for development of novel diagnostics for TB" What diagnostics? These are vague statements.
9. The proposal states that the study has strong support from key governmental bodies. However, no supporting documents are attached to substantiate these claims.
10. Itemized budget may be provided.
11. Section 1.2: What are the "novel tests'?
12. Potential Benefit-- Participating in study is not a benefit. This must be re checked.
13. Section2.6 - What are serious AEs that will be immediately reported?
14. Protocol = SAE NAE will be reported within 24 hours.The form says differently.
15. INFORMED CONSENT::What new tests will be done?
16. Following statement is not appropriate: Biased sentences= "laajkobehtarbananeymaimadaddenachehtayhain"
17. From where the participants be enrolled. It is mentioned within the area of 30 km. All sites must be mentioned with reasons?
18. Operational definitions like suspect and others are required.
19. Pakistan specific protocol is required.
20. The budget details for Pakistan are required.
21. Welcome trust IRB approval letter, Support letter of participating institute in Pakistan is missing.
22. The specific study protocol is missing; the investigators seem to have added their logo to the UCL protocol and submitted that.
23. The role of the NTP is not clearly reflected in the study proposal – study team ought to be identified with clear roles and responsibilities outlined for NTP especially if the active case finding is going to be done with NTP.
24. Is there current practice of ACF being done by NTP? Going into a TB high burden community comes with its own challenges. How these shall be addressed?
25. Need to also have details of the Xpert testing, will this be done at NUMS or the NTP site – it seems this study will be running in parallel to what NTP is doing on a routine basis so it will be critical to clarify who will be doing what and when.
26. Most of the Xpert testing now using the Xpert-Ultra assay which is more sensitive.
27. *"In an ongoing analysis of data from Pakistan, 1,214,289 individuals in 20 different districts were screened for TB with CAD-CXR followed by sputum Xpert. The average proportion of all TB cases*

treated that were bacteriologically unconfirmed was 41% but ranged from 0 to 78% across districts. Those with CXR changes who are not treated are at high risk of developing bacteriologically confirmed TB" no reference for this data, if ongoing which center is conducting this analysis, is it data from NTP?

28. At W0 the participants will be required to undergo induced sputum sample collection yet there is no mention of how the investigators will implement measures to ensure containment and exposure to others at the CTU at NUMS?
29. Broad consent is not sufficient for a genomics study and should be more specific in structure.
30. At present, host transcriptomic analyses performed in this study are for research purposes only and do not yield clinically actionable results. However, during the approved data-retention period, if future scientific evidence establishes validated clinical utility for specific transcriptomic signatures, the study governance committee may consider whether reanalysis and appropriate data sharing are ethically and practically feasible. Any such consideration would be subject to ethical approval, regulatory guidance, and feasibility of participant re-contact.
31. Participants will not receive individual results unless these conditions are met.
32. In DSMB there is only one person from Pakistan who appears to have a competing interest.

Title: **The Cross-Cultural Impact of the Baycrest Quick-Response Caregiver Tool TM: A Feasibility and Utility Study in Pakistan.**

Project #	PI Name & Address
NBCR-1362	**Prof. Mowadat Rana** Pakistan Institute of Living and Learning Suite#201, 2nd Floor, The Doctors Plaza, Do-Talwar, Clifton, Karachi

Final NBC-R Comments

1. The tool is already in use and also recommended by WHO. Is there a need of this study as no cross cultural related specific aspects are mentioned?
2. Recently PILL conducted an online session on this. Provide its details.
3. Are these educational videos, an instruction manual, and a pocket guide in Urdu language?
4. It also raises question what is the interest of funding agencies that provide support for such activities with huge sum of money?
5. Will data be transferred to outside Pakistan?
6. What is the actual sample size as conflicting numbers are mentioned?
7. The proposal claims a cross-cultural evaluation in the title, but it does not adequately explain how that cross-cultural evaluation will actually be conducted.
8. The proposal does not specify a single primary outcome or clear feasibility criteria, despite including multiple assessment tools.
9. Insufficient sample size justification
10. The study includes randomization to "BQRCT vs usual care," yet: "Usual care" is not operationally defined
11. The socioeconomic and the literacy status of the care givers is not given. These factors may influence the outcome of the study.
12. Pre and post questionnaires are not attached
13. Details regarding international data transfer, governance, secondary use, and commercial use of de-identified data require further clarification.
14. 1.2 – the study will improve the digital platform "for use in Ontario"…why is it being studied in Pakistan and not on Pakistani population in Ontario?
15. 1-3. Why exclude paid caregivers?
16. 2. 1. - Benefits: Biased (these are aims study not benefits)
    - Harms: - "mild" emotional discomfort? Who decides??
17. 2.2 Justify no consent of the patients themselves - as the discussion will be about them and may include personal /confidential information.
18. 2.4 Who will conduct these session, when? What? How?
19. Share how others team members shall be trained?
20. 2.5- "Digit platform"- what about those potential study participants who cannot read /write?
21. Study settings: PI has mentioned Karachi, Sukkur, Rawalpindi, and Peshawar in proposal, and recruitment will be done from Primary care settings. There should be clear mention of settings from where participants will be recruited.
22. Groups: mentioned in form and in proposal about 2 groups of 30 participants, but these groups have not been identified.
23. Stigma attached with caregivers of PLWD? Elaborate on this.

Chairperson NBC-R