

Minutes of the NBC-R meeting held on 2-1-2024

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on January 2nd, 2024. 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. Associate Prof. Dr. Amjad Mehboob	Member
6. Ms. Sualeha Shekhani	Member
7. Dr. Farkhanda Ghafoor	Member
8. Dr. Faiza Bashir	National Coordinator (NBC-R)
9. Mr. Waryal Ali Daheri	L.D.C (NBC-R-Secretariat)

The following projects reviewed / discussed:

Title: **FETAL AGE AND MACHINE LEARNING INITIATIVE (FAMLI): PROSPECTIVE OBSTETRIC ULTRASOUND STUDY PROTOCOL.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1033	Dr. Zahra Hoodbhoy, Dept of Pediatrics and Child Health, AKU, Karachi..	<ul style="list-style-type: none"> Why is Bhains Colony the only study site? Why can this study not also be implemented in Kharadar/Karimabad or main AKUH to ensure fair subject selection? The informed consent form may be simplified without mention of any US agencies/institutions. Will the data generated be handled in Pakistan? If so, by whom?

Title: **EFFECTIVENESS AND ACCEPTABILITY OF WEEKLY IRON FOLIC ACID SUPPLEMENTATION WITH CONDITIONAL CASH TRANSFER (WIFAS-CCT) AMONG ADOLESCENT GIRLS IN FOUR DISTRICTS OF PAKISTAN IN LOW-INCOME SETTING: A MIXED-METHOD STUDY IN FOUR DISTRICTS OF PAKISTAN.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1034	Dr. Sajid Bashir Soofi Aga Khan University National Stadium Road Karachi	<ul style="list-style-type: none"> We could not understand where is the conditional cash transfer as mentioned in the title? The informed consent form mentions that no financial incentive will be given, so where is the cash? The methodology was not clear to us. Please inform the PI to simplify it so that we can understand what is being done in these four districts.

Title: **QUALITY OF CARE AND CARDIOVASCULAR RISK ASSESSMENT IN PREGNANCY - A MIXED METHODS APPROACH TO DEVELOP EVIDENCE BASED CARE PATHWAY TO IMPROVE OUTCOMES IN WOMEN WITH PREGNANCY AND HEART DISEASE IN PAKISTAN - CAROBS INITIATIVE.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1035	Dr. Farhala Baloch Aga Khan University National Stadium Road Karachi	<ul style="list-style-type: none"> We would like to see the IRB approval of JPMC before giving our own approval.

Next meeting:

The next zoom meeting will be held at 02:30 pm on January 9th, 2024. The following projects will be reviewed:

Projects will be discussed.

1. NBC-1036
2. NBC-1037
3. NBC-1038



Focal person NBC-R



Chairperson NBC-R

Minutes of the NBC-R meeting held on 9-1-2024

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on January 9th, 2024. The following members of NBC-R attended the meeting:

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|----------------------------------|---------------------------|
| 1. Prof. Dr. Saima Pervaiz Iqbal | Chairperson |
| 2. Prof. Dr. Munir Saleemi | Member |
| 3. Prof. Dr. Jamshed Akhtar | Member |
| 4. Prof. Dr. Saqib Mehmood | Member |
| 5. Prof. Dr. Nazli Hossain | Member |
| 6. Prof. Dr. Marie Andrades | Member |
| 7. Mr. Waryal Ali Daheri | L.D.C (NBC-R-Secretariat) |

The following projects reviewed / discussed:

Title: **DISRUPTING HARM.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1036	Daniel Kardefelt Winther UNICEF Innocenti – Global Office of Research and Foresight Via degli Alfani 58 50122 Florence, Italy	<ul style="list-style-type: none">• Study Approved.

Title: **PREVALENCE OF NONALCOHOLIC FATTY LIVER DISEASE (NAFLD) AND ASSOCIATION WITH CARDIOMETABOLIC RISK FACTORS IN ADOLESCENTS AND YOUNG ADULTS IN A DEVELOPING COUNTRY CONTEXT; SINDH, PAKISTAN.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1037	Dr. Om Parkash Aga Khan University, Karachi, Pakistan	<ul style="list-style-type: none">• Study Approved.

Title: **INTEGRATED ANTENATAL CALCIUM, ASPIRIN, AND MULTIPLE MICRONUTRIENTS OR IRON-FOLIC ACID TO REDUCE PRETERM BIRTH: MIXED METHOD STUDY.**


Project #	PI Name & Address	Final NBC-R Comments
NBC-1038	Dr Sarah Saleem Aga Khan University Karachi	<ul style="list-style-type: none">• Study Approved.

Next meeting:

The next zoom meeting will be held at 02:30 pm on January 16th, 2024. The following projects will be reviewed:

Projects will be discussed.

1. NBC-1039
2. NBC-1041
3. NBC-1044



Focal person NBC-R



Chairperson NBC-R

Minutes of the NBC-R meeting held on 16-1-2024

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on January 16th, 2024. The following members of NBC-R attended the meeting:

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

The following projects reviewed / discussed:

Title: **BURDEN OF NON-COMMUNICABLE DISEASES AND ITS RISK FACTORS' ASSESSMENT THROUGH A MOBILE PHONE SURVEY IN REPRESENTATIVE POPULATION OF PAKISTAN.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1039	Dr. Zainab Samad Aga Khan University National Stadium Road Karachi	<ul style="list-style-type: none"> Study Approved.

Title: **A PILOT STUDY OF AN ADAPTIVE, DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED STUDY TO EVALUATE THE EFFECT OF METFORMIN IN REDUCING FATIGUE IN LONG-COVID ADOLESCENT SUBJECTS WITH PERSISTENT FEATURES.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1041	Dr. Zamir H. Suhag (Trust for Vaccines & Immunization), Karachi Prof. Farhat Bashir, Creek General Hospital, United Medical & Dental College, Karachi Prof. Junaid Rashid, Children Hospital, University of Child Health Sciences Lahore Prof. Dr Zia Ul Haq, Khyber Medical University, Peshawar	<ul style="list-style-type: none"> There is no assent form as this study is being done in adolescents. Urdu translation of assent/consent is missing. We would like to know if the PIs and co-PIs have any experience of dealing with patients especially adolescents with long COVID? Dr. Zia from KMU is the Co-PI, but how can he take on the responsibility of the research subjects? Questions regarding reproductive health, pregnancy, vasectomy etc may not be suitable for our local context. How will children be adjusted on a metformin dose? This needs clarification. Who is funding this project? This was not clear. Research subjects should be compensated for transport. What if a subject experiences any adverse events? What mechanism is in place for dealing with that?

Title: **COMPARE QUALITATIVE AND QUANTITATIVE HCVRNA RESULTS OF DIFFERENT VOLUMES OF VENOUS BLOOD SPOTTED DIRECTLY ONTO THREE SPOTS OF THE PLASMA SEPARATION CARD USING A SYRINGE AND COMPARE IT WITH THE SAMPLE COLLECTED IN PLASMA PREPARATION TUBE.**


Project #	PI Name & Address	Final NBC-R Comments
NBC-1044	Dr Huma Qureshi Clinic 553, Doctors Plaza, Clifton, Karachi	<ul style="list-style-type: none">• How is ROCHE involved in this study? This was not clear to us.• The consent form needs clarity? Why is this study being done and to what purpose?• How will study subjects be compensated?• What if someone is tested positive for HCV? How will he/she be managed further?

Next meeting:

The next zoom meeting will be held at 02:30 pm on January 23rd, 2024. The following projects will be reviewed:

Projects will be discussed.

1. NBC-1046
2. NBC-1047
3. NBC-1048



Focal person NBC-R



Chairperson NBC-R

Minutes of the NBC-R meeting held on 23-1-2024

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on January 23rd, 2024. The following members of NBC-R attended the meeting:

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

The following projects reviewed / discussed:

Title: **CARDIOVASCULAR DISEASE RISK REDUCTION: A COMPREHENSIVE PACKAGE FOR THE REDUCTION OF RISK IN SINDH, PAKISTAN.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1046	Prof. Zainab Samad, Chair, Dept of Medicine, Aga Khan University, Karachi.	<ul style="list-style-type: none">We can give approval for component 1.For component 2 we need more details about schools and their selection.

Title: **ACCEPTABILITY OF HYPERTENSIVE PATIENTS AND HEALTHCARE PROVIDERS ON ADOPTING AMBULATORY BLOOD PRESSURE MONITORING IN BANGLADESH, PAKISTAN, AND SRI LANKA.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1047	Dr. Almas Aysha Aga Khan University Karachi	<ul style="list-style-type: none">Study Approved.

Title: **RETHINKING HEALTH SYSTEMS RESPONSIVENESS IN LOW-AND MIDDLE-INCOME COUNTRIES.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1048	Dr Meesha Iqbal UTHealth School of Public Health Houston 1200 Pressler St, Houston, TX 77030 - USA	<ul style="list-style-type: none">Study Approved.

Next meeting:

The next zoom meeting will be held at 02:30 pm on January 30th, 2024. The following projects will be reviewed:

Projects will be discussed.

1. NBC-1049
2. NBC-1050
3. NBC-1051


Focal person NBC-R


Chairperson NBC-R

Minutes of the NBC-R meeting held on 30-1-2024

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on January 30, 2024. The following members of NBC-R attended the meeting:

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

The following projects reviewed / discussed:

Title: **ENHANCING HYPERTENSION DIAGNOSIS AND MANAGEMENT KNOWLEDGE AMONG GENERAL PRACTITIONERS IN PAKISTAN: EVALUATING THE IMPACT OF THE TRAIN THE TRAINER (TTT) INITIATIVE.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1049	Prof. Tariq Ashraf Karachi Institute of Heart Diseases (KIHD), Block 16 Gulberg Town, Karachi.	<ul style="list-style-type: none"> Sample size calculation mentions that the PI expects a 10% improvement in knowledge after the intervention. Is this a significant change especially with a condition like HTN which is so common in Pakistan? Please provide details as to the education activity. Where will it be held? Workshop content? Influence by the sponsor for the event? Does not Karachi Institute of Heart Diseases have its own IRB? If so, the project should be approved by the concerned IRB as well. Informed consent form needs to be looked at. It is asking for informed consent for surgery. How will the sample be collected from all 4 provinces to make it representative for Pakistan? How will this data reflect on the medical education institutions of the country if knowledge on HTN among GPs is determined to be poor? Which other countries are involved with this project?

Title: **ABILITY OF THE VE818 TO REDUCE ENTEROPATHOGEN COLONIZATION AND IMPROVE ENVIRONMENTAL ENTEROPATHY IN PREGNANT WOMEN: A PROOF OF CONCEPT AND PHASE II RANDOMIZED PLACEBO-CONTROLLED TRIAL IN BANGLADESH, PAKISTAN, ZAMBIA AND BURKINA FASO.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1050	Prof. Syed Asad Ali Dept of Pediatrics and Community Health Sciences The Aga Khan University, Stadium Road, Karachi	<ul style="list-style-type: none"> What are the results of the Phase 1 study which has prompted Phase 2? Please explain the need for giving vancomycin to a healthy pregnant woman before giving the probiotic. Why is vaginal sampling required when there is no indication for it as per protocol? What is the purpose of the Capscan in this project? Samples will be stored for 25 years? Why is this necessary?

		<ul style="list-style-type: none"> • The Sindhi consent form is not readable and needs to be in proper text. • Itemized budget needs to be provided. Travel expenses are totaling to 25 million. This needs justification.
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Title: **ASSESSING THE EFFECTIVENESS OF HEAT ADAPTATION & HEAT REDUCTION INTERVENTIONS FOR VULNERABLE POPULATION IN URBAN AND RURAL SETTINGS OF A LOW- AND MIDDLE- INCOME COUNTRY.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1051	Dr. Zulfiqar Bhutta Dept of Centre of Excellence in Women and Child Health Aga Khan University Karachi	<ul style="list-style-type: none"> • We were not clear as to the PIs experience on research related to this project? Is there an environmental researcher on this project as well? • How will the clusters be identified for the urban population? Why has Matiari been selected for rural setting? • Is there any collaboration with Govt. bodies and stakeholders? As LHWs are being involved, this will burden them further. Any incentives for them to take on this project?

Next meeting:

The next zoom meeting will be held at 02:30 pm on February 6th, 2024. The following projects will be reviewed:

Projects will be discussed.

1. NBC-1052
2. NBC-1053
3. NBC-1054



Focal person NBC-R



Chairperson NBC-R

Minutes of the NBC-R meeting held on 6-2-2024

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on February 6, 2024. The following members of NBC-R attended the meeting:

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

The following projects reviewed / discussed:

Title: **AN OUTCOME STUDY OF CONVENTIONAL STEROIDS VS. STEROIDS COMBINED WITH MYCOPHENOLATE FOR THE MANAGEMENT OF NEWLY DIAGNOSED IMMUNE THROMBOCYTOPENIA PURPURA: A COST EFFECTIVE MEASURE IN DEVELOPING NATIONS.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1052	<p>Rukh-e-Zainub NIBD and BMT hospital ST/2A Block 17 Gulshan-e-iqbal KDA scheme 24 Karachi</p>	<ul style="list-style-type: none"> The methodology for this project is mentioned as an RCT but this does not reflect in the proposal. How will cases be randomized? How many arms are there in this trial? Is there a control arm? What are the clinical end points that will be determined to see if one category is superior or not? Who will assess these clinical end points as the PI and her team are confined mostly within the laboratories? The informed consent form and assent form (for children) should reflect the purpose of the study and that this is an RCT and anyone can be assigned any arm. What harms or benefits are to be expected needs to be clearly mentioned in the form along with contact numbers of the PI and her team. Where will the drugs be administered? Will this require hospital stay? Is this covered for trial participants? What about tests? Will they be free of cost? We need to see the drug leaflet which gives information about the drug. Will a DSMB be established? Where is the funding for this project coming from?

Title: **GSED 2.0 - TESTING OF THE GSED TO IDENTIFY CHILDREN UP TO 36 MONTHS WITH OR AT RISK FOR NEURODEVELOPMENTAL IMPAIRMENT.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1053	<p>Dr. Imran Nisar Dept of Pediatrics and Child Health Aga Khan University and Hospital stadium road Karachi.</p>	<ul style="list-style-type: none"> We would like to know the benefit to the community being offered by this study? Study participants and families will be giving up at least 4 hours of their working day so they should be adequately compensated for their time. Is there any psychologist on board for this study? What if a child is in need of neurological/psychological services? How will that be facilitated?

Title: **GSED 2.0 - GLOBAL SCALES FOR EARLY DEVELOPMENT (GSED) 2.0 - DEVELOPMENT OF POPULATION NORMS FOR EARLY CHILDHOOD DEVELOPMENT UNDER 36 MONTHS.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1054	Dr. Imran Nisar Dept of Pediatrics and Child Health Aga Khan University and Hospital stadium road Karachi.	<ul style="list-style-type: none">Study Approved

Next meeting:

The next zoom meeting will be held at 02:30 pm on March 5th, 2024. The following projects will be reviewed:

Projects will be discussed.

1. NBC-1043
2. NBC-1064
3. NBC-1065



Focal person NBC-R



Chairperson NBC-R

Minutes of the NBC-R meeting held on 13-2-2024

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on February 13, 2024. The following members of NBC-R attended the meeting:

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| 1. Prof. Dr. Jamshed Akhtar | Chair the Meeting |
| 2. Prof. Dr. Munir Saleemi | Member |
| 3. Prof. Dr. Marie Andrades | Member |
| 4. Associate Prof. Dr. Amjad Mehboob | Member |
| 5. Ms. Sualeha Shekhani | Member |
| 6. Dr. Farkhanda Ghafoor | Member |
| 7. Ms. Ayesha Abid | Assistant (NBC-R-Secretariat) |

The following projects reviewed / discussed:

Title: **CHARACTERISTICS AND OUTCOMES OF PATIENTS WITH SEVERE DENGUE ADMITTED TO PAKISTAN REGISTRY OF INTENSIVE CARE (PRICE) COLLABORATING UNITS ACROSS PAKISTAN: A PROSPECTIVE SURVEILLANCE STUDY.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1055	Prof. Madiha Hashmi CEO SEARCH/Leading PRICE 199-E, Street 6 Cavalry Grounds Lahore Cantt	<ul style="list-style-type: none"> Dengue is already a condition that is mandatory to report to the governmental organization. All hospitals and laboratories are bound to upload on government portal / report. This is a more comprehensive method and applicable. How the study proposed by PI adds to the existing database. The case definition about dengue is not according to the standard practice of Pakistan, WHO and CDC. The operational definitions are required. Some of the main dengue management centers like Mayo Hospital Lahore is not part of data collecting site, while NICVD which has nothing to with dengue is included. How various study sites are chosen? What is the expertise of PI in context of dengue disease? Ethical approval from all study sites is warranted. Funding source and allocation and other details are not found. Laboratory tests results done in dengue patients are to be mentioned especially how it will be ensured that kits used were same as reports may vary. How data entry shall be done. Detail of the process is required as management of the patient's changes even over the hours based upon the condition of the patient. Redcap form is too extensive data entry may an issue. As this is not a pandemic and endemic condition, consent waiver is not applicable.

Title: **SEXUAL HARASSMENT: UNDERSTANDING THE PROBLEMS OF WOMEN ARCHITECTS AT THEIR WORKPLACE.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1057	<p>Humaira Nazir Assistant Professor- Dept of Architecture and Environmental Design Sir Syed University of Engineering and Technology Karachi,.</p>	<ul style="list-style-type: none"> • Subject is interesting. However, methodology and tool to be used are not clear. Many of the questions in the tool are not phrased properly, problematic and ambiguous. A validated tool is required in context of Pakistan. This study is of women thus gender related information is illogical. From which source subjects shall be identified? What shall be the sample size? The type of study design qualitative / quantitative is also confusing. • Consent form is required even if for an online survey. • Funding source and its allocation not found. What shall be done after data collection? • Some of questions may be emotionally stigmatizing. What shall be done in such a situation? • CV of both PI is required, especially in context of research question and previous experience.

Title: **PAKISTAN SOCIETY OF NEPHROLOGY (PSN) – RENAL REGISTRY.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1058	<p>Dr. Salman Imtiaz Indus Hospital and Health Network Main Shaharah-e-Faisal, Karachi, Pakistan.</p>	<ul style="list-style-type: none"> • ERC from institutions is required. Some of the institutes like PKLI Lahore is missing. How registry then may be considered as inclusive. • Many questions are incomplete or inadequate information is asked. This includes no mention of Single /divorced related information. • Psychiatric patient's exclusion is also not appropriate for a registry. • Study population ethnicity will be a good addition. CNIC is an important identifier so as to reduce redundant data (duplication). • How the inclusion of same patient from two different centers will be identified? • Consent waiver as mentioned in the form is not appropriate. • CV of the PI is also not in a proper format. • Society funds. • Why donors are expected to contribute towards data collection. Is there a clear policy in this context? • There is registry related to renal diseases is available of internet from Pakistan. This needs clarity. • Clarification is also needed as to the prospective versus retrospective data collection and quality control as mentioned.

Next meeting:

The next zoom meeting will be held at 02:30 pm on February 20th, 2024. The following projects will be reviewed:

Projects will be discussed.

1. NBC-1059
2. NBC-1060
3. NBC-1061



Focal person NBC-R



Chairperson NBC-R

Minutes of the NBC-R meeting held on 20-2-2024

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on February 20, 2024. The following members of NBC-R attended the meeting:

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|--------------------------------------|-------------------------------|
| 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. Associate Prof. Dr. Amjad Mehboob | Member |
| 6. Ms. Sualeha Shekhani | Member |
| 7. Dr. Farkhanda Ghafoor | Member |
| 8. Dr. Faiza Bashir | National Coordinator (NBC-R) |
| 9. Ms. Ayesha Abid | Assistant (NBC-R-Secretariat) |

The following projects reviewed / discussed:

Title: **BIOEQUIVALENCE STUDY OF FIXITIL-T D.S 400MG TABLET (CEFIXIME).**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1059	Prof. Dr Iftekhar Ahmed Institute of Biological, Biochemical and Pharmaceutical Sciences (IBBPS) Dow University of Health Sciences, (DUHS) Ojha Campus. Karachi, Pakistan	<ul style="list-style-type: none">• Study Approved

Title: **A SINGLE CENTER, OPEN LABEL, BALANCED, RANDOMIZED, SINGLE-DOSE, TWO-PERIOD, TWO-SEQUENCE, TWO-WAY, CROSS-OVER ORAL BIOEQUIVALENCE STUDY COMPARING RITBAN® 20MG (RIVAROXABAN) TABLET MANUFACTURED BY SAMI PHARMACEUTICALS (PVT) LIMITED WITH XARELTO® 20MG (RIVAROXABAN) TABLET MANUFACTURED BY BAYER HEALTHCARE AG IN HEALTHY, ADULT MALE SUBJECTS UNDER FED CONDITION.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1060	Prof. Dr. M. Raza Shah T.I. Center for Bioequivalence studies and Clinical Research (CBSCR), ICCBS, University of Karachi, 75270, Karachi.	<ul style="list-style-type: none">• Please submit advertisements and IRB approvals from the primary center.

Title: A single center, open label, balanced, randomized, single-dose, two-period, two-sequence, two-way, cross-over oral bioequivalence study comparing Ritban® 10mg (Rivaroxaban) Tablet manufactured by SAMI pharmaceuticals (Pvt) Limited with Xarelto® 10mg (Rivaroxaban) Tablet manufactured by Bayer HealthCare AG in healthy, adult male subjects under fasting condition..

Project #	PI Name & Address	Final NBC-R Comments
NBC-1061	Prof. Dr. M. Raza Shah T.I. Center for Bioequivalence studies and Clinical Research (CBSCR), ICCBS, University of Karachi, 75270, Karachi.	<ul style="list-style-type: none">Please submit advertisements and IRB approvals from the primary center.

Next meeting:

The next zoom meeting will be held at 02:30 pm on February 27th, 2024. The following projects will be reviewed:

Projects will be discussed.

1. NBC-1042
2. NBC-1062
3. NBC-1063



Focal person NBC-R



Chairperson NBC-R

Minutes of the NBC-R meeting held on 27-2-2024

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on February 27, 2024. The following members of NBC-R attended the meeting:

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| 1. Prof. Dr. Saima Pervaiz Iqbal | Chairperson |
| 2. Prof. Dr. Munir Saleemi | Member |
| 3. Prof. Dr. Jamshed Akhtar | Member |
| 4. Ms. Sualeha Shekhani | Member |
| 5. Dr. Farkhanda Ghafoor | Member |
| 6. Mr. Waryal Ali Daheri | L.D.C (NBC-R-Secretariat) |

The following projects reviewed / discussed:

Title: **LAY USER EVALUATION OF THE PANBIO™ HCV SELF TEST: A PROSPECTIVE, MULTI-CENTRE USABILITY STUDY TO EVALUATE LAY USER LABELLING COMPREHENSION AND TEST RESULT INTERPRETATION.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1042	Dr. SAEED HAMID Department of Medicine AKU, Karachi Dr Huma Qureshi Karachi	•

Title: **AN OPEN LABEL, BALANCED, RANDOMIZED, TWO TREATMENTS, TWO SEQUENCES, TWO PERIODS, SINGLE DOSE, CROSS OVER, BIOEQUIVALENCE STUDY OF VALSATRIL™ (SACUBITRIL/VALSARTAN) 24MG/26MG TABLET OF SAMI PHARMACEUTICALS (PVT) LTD VERSUS ENTRESTO® (SACUBITRIL/VALSARTAN) 24MG/26MG TABLET OF NOVARTIS PHARMACEUTICALS UK LTD., UNDER FASTING CONDITION IN ADULT MALE SUBJECTS.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1062	Prof. Dr. M. Raza Shah T.I. Center for Bioequivalence studies and Clinical Research (CBSCR), ICCBS, University of Karachi.	•

Title: **AN OPEN LABEL, BALANCED, RANDOMIZED, TWO TREATMENTS, TWO SEQUENCES, TWO PERIODS, SINGLE DOSE, CROSS OVER, BIOEQUIVALENCE STUDY OF VALSATRIL™ (SACUBITRIL/VALSARTAN) 97MG/103MG TABLET OF SAMI PHARMACEUTICALS (PVT) LTD VERSUS ENTRESTO® (SACUBITRIL/VALSARTAN) 97MG/103MG TABLET OF NOVARTIS PHARMACEUTICALS UK LTD., UNDER FASTING CONDITION IN ADULT MALE SUBJECTS.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1063	Prof. Dr. M. Raza Shah T.I. Center for Bioequivalence studies and Clinical Research (CBSCR), ICCBS, University of Karachi.	•

Next meeting:

The next zoom meeting will be held at 02:30 pm on March 5th, 2024. The following projects will be reviewed:

Projects will be discussed.

1. NBC-1043
2. NBC-1064
3. NBC-1065



Focal person NBC-R



Chairperson NBC-R

Minutes of the NBC-R meeting held on 12-03-2024

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on March 12, 2024. The following members of NBC-R attended the meeting:

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

The following projects reviewed / discussed:

Title: **FROM RELIGIOUS IDENTITY TO SOCIAL CLASS: THE COMPLEXITY OF DIFFERENTIAL TREATMENT OF HINDUS, CHRISTIANS AND SIKHS IN PAKISTAN.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1064	Dr. Javeria Shams Deakin University Melbourne Burwood campus, 221 Burwood Hwy, Burwood VICTORIA 3125, Australia.	<ul style="list-style-type: none"> Does the PI have a local collaborator in Pakistan? If so, please give details. The Urdu translation of the consent form needs to be simplified.

Title: **ASSESSMENT OF BIOLOGICAL VULNERABILITY AND EFFECTS OF EXTREME HEAT ON MATERNAL, FETAL AND NEWBORN HEALTH: IMPLICATIONS FOR POLICY AND ACTION.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1065	Dr. Jai Das Dept of Paediatrics and Child Health AKU, Karachi.	<ul style="list-style-type: none"> This proposal seems to be hastily written. Please give a clear methodology of how this study will be done. What wearable devices will the participants be given? Smart watches? What data will be collected from these devices? This was unclear to us. What devices will be set up in the houses? What kind of data will be accessed from this? Is there a risk of breach in privacy with these devices? Contact number of PI or his designee should be written on the informed consent form.

Title: **VIRAL DETECTION OF HBV, HCV AND HIV USING THE PLASMA SEPARATION CARD AND COMPARISON WITH GOLD STANDARD PLASMA PREPARATION TUBE METHOD.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1066	Dr. Huma Qureshi Ex. Executive Director PMRC Doctors Plaza, Clifton, Karachi.	<ul style="list-style-type: none"> Abbreviations need to be written in full especially when using it for the first time. We struggled with meaning and definitions. Please name the two community based organizations conducting the study. At one point it is stated that tests will be done in

		<p>public sector Hepatitis program sites in both cities, which are these and what is the link between the CBO and public sector Hepatitis program.</p> <ul style="list-style-type: none">• As stated, the study will be prospective and will be done in a high risk population, study proforma to record the study variables is missing.• The blood drawn will be 10 ml and divided into two 5 ml tubes, one tube for conventional PCR for the analytes under study, where will this be done? Will this be qualitative or quantitative?• Where will the HT LV serology be done? If in Pakistan who will certify the results as there is no laboratory person as a part of the team as far as we could determine.• The POC testing will also be done for the analytes using Alere, Unigold and SD Bioline devices and will be compared with gold standard PCR, where will these tests be done and who will verify the results?• Three spots 140 ul each, from the second 5 ml tube will be spotted on a plasma separation card, these three spots add to 0.42 ml of blood, for what will the extra blood be used for?• What is the specification of the Plasma separation card, who will verify the spotting, as the layering causes unreliable results? How will these be dried and packed as special envelopes are required for transportation? Who will verify the quality of blood spots for elution, how will these be eluted, where will these be tested for comparison with gold standard PCR.• Where will the samples be stored before shipping to Australia and who will be responsible for deidentifying the samples?• Who is the responsible person for data analysis?• English version of consent form is missing.• The Urdu version does not state that the blood samples will be sent to NRL-Australia.• Adverse events are very much detailed but the protocol does not state how these will be addressed and should be part of the consent form.• Material Transfer Agreement is missing.• How will the participants be benefited after HT LV DNA is done in NRL-Australia?• In this study, the technology is being tested. Why is there a need for collecting the samples from specified high risk groups when the leftover positive samples can be available for testing POC, Alere, Unigold and SD Bioline devices and also for the blood spots on Plasma separation card.• This study is purely lab related and we would like to know the responsible under whose supervision this will be carried out.• Please clearly state the methodology of this study.
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Next meeting:

The next zoom meeting will be held at 02:30 pm on 16th April, 2024. The following projects will be reviewed:

Projects will be discussed.

1. NBC-1067
2. NBC-1068
3. NBC-1069



Focal person NBC-R



Chairperson NBC-R

Minutes of the NBC-R meeting held on 16-04-2024

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on April 16, 2024. The following members of NBC-R attended the meeting:

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

The following projects reviewed / discussed:

Title: **PRIORITIES FOR GLOBAL RESEARCH IN MATERNAL SEPSIS (PROGRESS)**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1067	Dr. SHEIKH IRFAN AHMED Dept of Obs & Gyn AKU, Karachi	<ul style="list-style-type: none">The PROGRESS study, whose PI is affiliated with Aga Khan University has been initiated last year in 2023 according to their documentation. However, they have applied for NBC approval now, one year later. The issue was raised by our members whether we, the NBC-R should entertain such projects as they would require our approval in back dates.

Title: **CLINICAL VALIDATION OF BLOOD-BASED TUBERCULOSIS DIAGNOSIS TEST IN PAKISTAN**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1068	Maj Gen Prof Aamer Ikram Prof Microbiology NIH, Islamabad.	<ul style="list-style-type: none">The PI needs to re-look at this study for its methodology as there are several scientific flaws that need to be addressed. Please clearly document the procedures being followed from recruitment, informed consent process, to sampling of data, storage of specimens and so on. Please identify who is responsible at each step of the process.Please identify team members along with their CVs.We would also like to know the structure of the IRB at NIH which has reviewed and approved the study.

Title: **ASSESSING THE DMFT INDEX TO DETERMINE THE PREVALENCE OF CARIES IN MITHI, SINDH PROVINCE, PAKISTAN SUPPLEMENTED WITH ARTIFICIAL INTELLIGENCE.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1069	Dr. Fahad Umer Dental Clinics, First Floor, JHS Building AKU, Karachi.	<ul style="list-style-type: none">Please ask PI to let us know how will the development of the app benefit our population? What is the data sharing agreement with the app developers or sponsors.

Next meeting:

The next zoom meeting will be held at 02:30 pm on 7th May, 2024. The following projects will be reviewed:

Projects will be discussed.

1. NBC-1070
2. NBC-1071
3. NBC-1073



Focal person NBC-R



Chairperson NBC-R

Minutes of the NBC-R meeting held on 07-05-2024

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on May 7th, 2024. The following members of NBC-R attended the meeting:

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

The following projects reviewed / discussed:

Title: **ENGAGEMENT OF COMMUNITY THROUGH PARTICIPATORY LEARNING AND ACTION FOR CONTROL AND PREVENTION OF TYPE II DIABETES AND ITS RISK FACTORS [EMPOWER-D].**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1070	<p>Prof. Dr. Zia Ul Haq Phase-6 Rd, Phase 5 Hayatabad, Peshawar, KPK</p> <p>Prof. Dr. Abdul Basit Baqai Institute of Diabetology and Endocrinology (BIDE) Block 2 Nazimabad, Karachi</p>	<ul style="list-style-type: none"> The intervention is not completely described in the protocol as to what will be done in this arm. Please ask PI to explicitly explain the process in detail so that we are aware as to what is being done. Subsequently, please let us know what adverse events are to be expected. Please mention the Co-PIs from all collaborating institutions. This is to clarify as to who is taking responsibility of this project in their respective institutions. IRB approval letters from collaborating institutions is required. The PI in one IRB approval letter has approved the project himself. This raises serious concerns as to the transparency and bias of the institutional IRB. Please give details about the Independent Advisory Board and DSMB. The people who constitute these committees should be third parties not directly involved in the project. Where are the exact study sites and how much enrolment is expected from each site? A budget of 429, 628, 104 PKR could make this a non-sustainable venture in the long run considering the socioeconomic status of the country's population.

Title: **HEALTH SYSTEM RESILIENCE, ENHANCEMENT, AND REFUGEE RESPONSES – PAKISTAN**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1071	Dr. Zahid Ali Memon Director Projects, Centre of Excellence in Women and Child Health, AKU, Karachi, Pakistan	<ul style="list-style-type: none">• Please explain the rationale of this study in the simplest of language as it was quite confusing to the reviewers.• What is the operational definition adopted for a "refugee" in our context? Is it someone who has been residing in Pakistan for several years or recently migrated? Which clusters of refugees will be identified for this study?• Which stakeholders are on board for this project? How will they benefit from this study and how will it benefit the study population?• What is the experience that UNHCR will bring to this study? What is the expected impact of ownership by the international donor organization in this study where the hosting country in itself is facing challenges even to cater for its own native population?

Title: **PAKISTAN PRIMARY HEALTH CARE (PHC) LEARNING AGENDA.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1073	Dr. Sameen Siddiqui Dept of Community Health Sciences AKU, Karachi	<ul style="list-style-type: none">• Study Approved.

Next meeting:

The next zoom meeting will be held at 02:30 pm on 14th May, 2024. The following projects will be reviewed:

Projects will be discussed.

1. NBC-1043
2. NBC-1074
3. NBC-1075



Focal person NBC-R



Chairperson NBC-R

Minutes of the NBC-R meeting held on 14-05-2024

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on May 14th, 2024. The following members of NBC-R attended the meeting:

- | | |
|----------------------------------|-------------------------------|
| 1. Prof. Dr. Saima Pervaiz Iqbal | Chairperson |
| 2. Prof. Dr. Munir Saleemi | Member |
| 3. Prof. Dr. Jamshed Akhtar | Member |
| 4. Prof. Dr. Saqib Mehmood | Member |
| 5. Prof. Dr. Nazli Hossain | Member |
| 6. Prof. Dr. Marie Andrades | Member |
| 7. Prof. Dr. Amjad Mehboob | Member |
| 8. Dr. Farkhanda Ghafoor | Member |
| 9. Dr. Faiza Bashir | National Coordinator (NBC-R) |
| 10. Ms. Ayesha Abid | Assistant (NBC-R-Secretariat) |
| 11. Mr. Waryal Ali Daheri | L.D.C (NBC-R-Secretariat) |

The following projects reviewed / discussed:

Title: **LAY USER EVALUATION OF THE PANBIO™ HCV SELF TEST: A PROSPECTIVE, MULTI-CENTRE OBSERVED UNTRAINED USER STUDY.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1043		• Study Approved.

Title: **AN INTERNATIONAL COMPARATIVE STUDY OF NURSES' AND MIDWIVES' EXPERIENCES WITH PANDEMIC RESPONSE IMPLEMENTATION.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1074	Allison Patricia Squires Rory Meyers College of Nursing New York University 433 First Avenue, #656 New York, NY 10010	• We need more information about the local collaborator and how that collaborator will help in recruitment and data gathering. Urdu translation of information sheet and informed consent needs revision. Questionnaire needs to be looked at again.

Title: **CULTURAL VALUES AND INFORMED CONSENT PRACTICES: A QUALITATIVE EXPLORATION WITH VULNERABLE GROUPS IN PAKISTAN.**

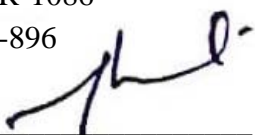
Project #	PI Name & Address	Final NBC-R Comments
NBC-1075	Muqaddas Asif Pakistan Institute of Living and Learning Suit no 301, 2 Talwar, Clifton, Karachi	• We need to know participants will be recruited and how will confidentiality be maintained in a focus group of vulnerable people?

Next meeting:

The next zoom meeting will be held at 02:30 pm on 21st May, 2024. The following projects will be reviewed:

Projects will be discussed.

1. NBCR-1076
2. NBCR-1077
3. NBCR-1086
4. NBC-896


Focal person NBC-R


Chairperson NBC-R

Minutes of the NBC-R meeting held on 21-05-2024

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on May 21st, 2024. The following members of NBC-R attended the meeting:

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

The following projects reviewed / discussed:

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

Project #	PI Name & Address	Final NBC-R Comments
NBC-896	Dr. Ume Sughra (Country PI) Al-Shifa Research Centre- Al-Shifa Trust Eye Hospital, Jhelum Road, Rawalpindi	<ul style="list-style-type: none"> • Discussion about the stoppage holds study. <i>The REC reviewed the reports submitted by sites and DRAP. Considering the number of deaths and adverse events, as well as protocol violations from various sites, the NBC-R decided not to give the go ahead for resumption of the trial at present until the safety profile of the Investigational Product is established.</i>

Title: **KARACHI MORTALITY ASSESSMENT STUDY (KARIMA).**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1076	Dr. Zainab Samad Department of Medicine, The Aga Khan University, Karachi, Pakistan.	As this study is representing Karachi why are other areas not included as study sites to give a more representative sample? We noticed that the same researched communities are being study sites which consist of mostly a vulnerable population. Are any government stakeholders also on board for this study? The information from this study would be most useful for them. The data from this research is likely to be used for development of an AI driven app. How would this app potentially help our population?

Title: **RANDOMISED EVALUATION OF A PREVENTIVE INTERVENTION FOR POSTNATAL DEPRESSION IN HIGH-RISK POPULATIONS IN PAKISTAN AND TURKEY: PREVENT-PND.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1077	Prof Atif Rahman University of Liverpool Institute of Population Health Department of Primary Care and Mental Health Waterhouse Building, Block B First Floor 1-5 Dover Street, Liverpool L69 3GL	<ul style="list-style-type: none">We would like to see the HSA IRB approval letter.

Title: **EXAMINING THE ROLE OF GENDER TRANSFORMATIVE COMMUNITY INTERVENTIONS TO STRENGTHEN GENDER EQUITY AND IMPROVE IMMUNIZATION OUTCOMES IN PAKISTAN**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1086	Elizabeth Arlotti Parish Jhpiego 1615 Thames Street, Baltimore, Maryland 2123 USA	<ul style="list-style-type: none">Study Approved.

Next meeting:

The next zoom meeting will be held at 02:30 pm on 28th May, 2024. The following projects will be reviewed:

Projects will be discussed.

1. NBCR-1078
2. NBCR-1079
3. NBCR-1080



Focal person NBC-R



Chairperson NBC-R

Minutes of the NBC-R meeting held on 28-05-2024

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on May 28th, 2024. The following members of NBC-R attended the meeting:

- | | |
|----------------------------------|---------------------------|
| 1. Prof. Dr. Saima Pervaiz Iqbal | Chairperson |
| 2. Prof. Dr. Munir Saleemi | Member |
| 3. Prof. Dr. Marie Andrades | Member |
| 4. Prof. Dr. Amjad Mehboob | Member |
| 5. Dr. Farkhanda Ghafoor | Member |
| 6. Mr. Waryal Ali Daheri | L.D.C (NBC-R-Secretariat) |

The following projects reviewed / discussed:

Title: **DELIVERY REDESIGN (SDR) FOR IMPROVED MATERNAL AND NEWBORN SURVIVAL IN THE PROVINCE OF SINDH, PAKISTAN.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1078	Mr. Zahid Ali Memon Dept of Community Health Sciences AKU, Karachi	<ul style="list-style-type: none">Study Approved.

Title: **DEVELOPING A COLLABORATIVE RESEARCH NETWORK TO IDENTIFY RESEARCH PRIORITIES IN MATERNAL AND INFANT NUTRITIONAL HEALTH RISKS LINKED TO CLIMATE CHANGE: A SCOPING EXERCISE IN PAKISTAN.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1079	Mr. Zahid Ali Memon Dept of Community Health Sciences AKU, Karachi	<ul style="list-style-type: none">Study Approved.


Title: **TWICE A DAY CLOPIDOGREL VS. TICAGRELOR IN REDUCING MAJOR CARDIAC EVENTS IN PATIENTS WITH ACUTE STEMI UNDERGOING PRIMARY PERCUTANEOUS INTERVENTION-TADCLOT-A DOUBLE-BLIND RANDOMIZED CONTROLLED TRIAL.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1080	Professor Abdul Hakeem National Institute of Cardiovascular Diseases (NICVD), Karachi.	<ul style="list-style-type: none">Why is there a need to give clopidogrel twice a day when it is given typically as a single dose per day?What is the composition of the DSMB and how frequently will it meet?How will patients be treated in case of adverse events?How will the randomization process occur?The informed consent form is too vague. It needs to mention that a patient will be randomized to one arm or the other, potential side effects, amount of blood drawn for labs, visits in follow up etc.Some compensation/remuneration for patients' time and follow-up visits may be allocated.


Next meeting:

The next zoom meeting will be held at 02:30 pm on 4th June, 2024. The following projects will be reviewed:

Projects will be discussed. NBCR-1081, NBCR-1082 and NBCR-1083



Focal person NBC-R



Chairperson NBC-R

Minutes of the NBC-R meeting held on 04-06-2024

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on June 4th, 2024. The following members of NBC-R attended the meeting:

- | | |
|-----------------------------|----------------------------------------|
| 1. Prof. Dr. Jamshed Akhtar | Co-Chairperson |
| 2. Prof. Dr. Munir Saleemi | Member |
| 3. Prof. Dr. Marie Andrades | Member |
| 4. Prof. Dr. Amjad Mehboob | Member |
| 5. Dr. Farkhanda Ghafoor | Member |
| 6. Dr. Faiza Bashir | Research Director/National Coordinator |
| 7. Mr. Waryal Ali Daheri | L.D.C (NBC-R-Secretariat) |

The following projects reviewed / discussed:

Title: **EVALUATION OF HEALTH SYSTEM'S STRENGTHENING INTERVENTIONS AND PROVISION OF OUTREACH AND REFERRAL SERVICES (HEALTH, NUTRITION AND IMMUNIZATION) TO IMPROVE MATERNAL AND CHILD HEALTH OUTCOMES.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1081	Mr. ZAHID MEMON Dept of Community Health Sciences AKU, Karachi.	<ul style="list-style-type: none"> The intervention "standardized primary health care (PHC) services" is not described in this proposal. Were previously done large number of services different from standardized primary health care (PHC) services that continued for decades? What were the shortcoming that may be considered as failure of those approaches and how this new model is expected to work for the communities? Kindly share the results. No support letter from Health Department of government of Sindh is found. Sixty of their participants are mentioned in this proposal who shall be involved. Based upon the intervention informed consent should be developed which at present is not clear. Questions like alcohol use (not known) is not clear. How dietary intake shall be "objectively" measured? It seems to be a mere recall as it asked in the survey.

Title: **FEASIBILITY AND BASELINE ANALYSIS OF CELL-FREE DNA IN PAKISTANI POPULATION: A PILOT STUDY.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1082	DR. KULSOOM GHIAS Dept of Biological and Biomedical Sciences AKU, Karachi	<ul style="list-style-type: none"> There will always be a small chance of having either a false-positive or false-negative results. How this issue shall be addressed? What if unwanted identification of genomic abnormalities is inadvertently done? Or sequence representative of tumor is found in controls? How will PI ensure that the so called cost effective investigation shall be available to Pakistani population? What are the provisions in this context? From which registry it is deduced that majority of the deaths from cancers occur in LMIC? In informed consent form why it is mentioned that it will not be possible to remove your already available samples and data from the study if you plan to withdraw. This may be described for the

		<p>participants.</p> <ul style="list-style-type: none"> • MTA is not found. • Genetic data being transferred abroad is a concern as well. Is there any agreement between the institutions?
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Title: **EFFECTIVENESS AND IMMUNOGENICITY OF ROTAVIRUS VACCINE BOOSTER AT 9 MONTHS OF AGE IN PAKISTAN: A TEST NEGATIVE CASE-CONTROL STUDY.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1083	<p>Dr. MOHAMMAD TAHIR YOUSAFZAI Dept of Community Health Sciences AKU, Karachi</p>	<ul style="list-style-type: none"> • IRB approval from many institutions is awaited and must be provided as soon as available as well as any observations from those IRBs in case they have observations. • Which vaccine is currently in use in EPI program? Is there any other vaccine available whose immunogenicity is not lost over the period of time? This information may help in selection of the appropriate vaccine and there may not be a need of a third dose. • 2.4: Provide clarity about the information in this section which is • “Remaining biological samples will be archived at the infectious disease research laboratory for any future studies/testing. If a need arises to transfer the specimen outside Pakistan for testing, material transfer agreement will be signed before shipment of the specimens” • Re visit informed consent form in Urdu. Number of mistakes are noted. • Draft agreement with other collaborating hospitals from Karachi is not found. What is the level of collaborations of these hospitals? What are their stakes? What measures are taken to facilitate their capacity building? • Is Health Department, Sindh Government involved in this venture? EPI authority’s willingness may be shared. Support letter may be shared. • Informed consent form does not mention about which tests can be performed in future. It is also not mentioned that samples shall be send abroad. Storage details are also not clear. • All informed consent forms in Urdu need correction. • MTA is not found. • The budget document has limited information. There is no mention of any monetary support for the hospitals from Karachi from where samples shall be collected and data obtained from their records.

Next meeting:

The next zoom meeting will be held at 02:30 pm on 11th June, 2024. The following projects will be reviewed:

Projects will be discussed. NBCR-1085, NBCR-1087 and NBCR-1089



Focal person NBC-R



Chairperson NBC-R

Minutes of the NBC-R meeting held on 11-06-2024

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on June 11th, 2024. 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. Ms. Sualeha Shekhani | Member |
| 5. Prof. Dr. Amjad Mehboob | Member |
| 6. Dr. Farkhanda Ghafoor | Member |
| 7. Mr. Waryal Ali Daheri | L.D.C (NBC-R-Secretariat) |

The following projects reviewed / discussed:

Title: **EFFECTIVENESS AND CHALLENGES OF AI-BASED DECISION SUPPORT SYSTEMS FOR BURNS TRIAGE IN EMERGENCY DEPARTMENTS IN PAKISTAN, OPTIMISED TO IMPROVE PATIENT OUTCOMES AND RESOURCE UTILISATION.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1085	Noor Us Saba University of Salford, 43 Crescent, Salford M5 4WT, England	<ul style="list-style-type: none"> Study Approved.

Title: **DEVELOPMENT, PRODUCTION AND COMMERCIALIZATION OF ALOESIN-BASED WOUND HEALING SCAFFOLD.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1087	Dr. Hussain Mustatab Wahedi Dept. of Biological Sciences National University of Medical Sciences C/O Military Hospital, The Mall Road, 46000 Rawalpindi	<ul style="list-style-type: none"> Please ask PI to simplify the methodology for our understanding. If this is Phase 1 then what do the animal studies show? Has this compound been tested and proven efficacious? What does the evidence from animal studies show? It is suggested to keep only adults aged 18 and above in this trial. Please tell us how randomization will be done as this is Phase 1 we just need to know that the product is as effective or more effective than the standard of care. What is the standard of care? Please clarify what is the criteria for subject selection? What is classified as a chronic wound as opposed to an acute wound?

Title: **SCHOOL-BASED EHEALTH NCD PREVENTION PROGRAM TO IMPROVE AWARENESS IN ADOLESCENTS FROM URBAN PAKISTAN.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1089	Dr. Tazeen Saeed Ali Dept of School of Nursing and Midwifery Aga Khan University Karachi	<ul style="list-style-type: none"> Study Approved.

Next meeting:

The next zoom meeting will be held at 02:30 pm on 25th June, 2024. The following projects will be reviewed:

Projects will be discussed. NBCR-1090, NBCR-1091 and NBCR-1092



Focal person NBC-R



Chairperson NBC-R

Minutes of the NBC-R meeting held on 25-06-2024

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on June 25th, 2024. The following members of NBC-R attended the meeting:

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

The following projects reviewed / discussed:

Title: **OPTIMAL PERSONALISED TREATMENT OF EARLY BREAST CANCER USING MULTI-PARAMETER ANALYSIS [OPTIMA].**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1090	Dr. Jamshed Ali Consultant Medical Oncologist SKMH Lahore.	<ul style="list-style-type: none"> The documents are scanned rather than filled. There must be a clear instruction for the PI in this regards. NBC R IRB form is incomplete. Many sections in the form are not found. Is the researcher based in Peshawar or Lahore? Where the study shall be conducted? Jamshed Ali the Co PI from Pakistan but his name is in budget document only. Is the study ongoing as approval date of IRB is of October 2023? What is the cost of the genomic test? Will it be available to Pakistani population in future? How many patients shall be enrolled from Pakistan? The test is usually recommended for women in postmenopausal group as mentioned in prostigna website. This may be clarified. Data transfer agreements and material transfer agreements are not found. Sample storage and any tests to be performed in future should be clearly mentioned. The informed consent must have a statement that NO Genetic testing shall be performed. There is no mention of how patients shall be followed in long run, as it is a longitudinal project? Who will pay for their transport. The treatment provided to two groups and genomic test to be performed, especially at what stage is not clear. The cut off level value of the test which is mentioned may be elaborated.

Title: **A COMMUNITY-BASED PARTICIPATORY STUDY TO IDENTIFY DRIVERS OF IMMUNIZATION DROPOUT AND DELAY AT THE 9-MONTH TOUCHPOINT AND CO-CREATE SOLUTIONS TO IMPROVE ON-TIME 9-MONTH VACCINATION COMPLETION.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1091	Emily Lawrence, 210 S Hudson St Suite 307, Seattle, WA 98134, United States of America	<ul style="list-style-type: none"> This proposal is well written. However, it is all theory. We as members of NBCR need an objective draft where each aspect is clearly defined. There is no mention of name of a person from Pakistan, geographical area where it shall be done, MOU with

		<p>the health department, informed consent to mention a few.</p> <ul style="list-style-type: none"> • There is no MOU / Co Pi / explicit program to be done like district, people and others. • What are the gaps in knowledge? Many studies are already conducted in Pakistan. Drop out reasons are well documented. • This project got funding from BGM, however, the PI in what capacity got this while it is not even described in context of Pakistan properly.
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Title: **CLINICAL AND COST-EFFECTIVENESS OF A CULTURALLY ADAPTED MULTICOMPONENT INTERVENTION FOR IMPROVING BURNS CARE AND REHABILITATION OF PATIENTS AND THEIR FAMILIES IN PAKISTAN.**

Project #	PI Name & Address	Final NBC-R Comments
NBC-1092	<p>Dr Maria Panagioti Suit 201, 2nd floor, Dr. Plaza, Do-Talwar, Clifton Karachi.</p>	<ul style="list-style-type: none"> • There are 12 hospitals mentioned in the protocol but IRB approval is from only three which is also quite vague. All study sites should send their IRB approval letters plus document showing that all are trial sites approve by DRAP. • Trial registration documentation is needed. • There is no mention of any co PI from different institutions. • Informed consent form is also not appropriate for a RCT. • It is also not clear what are the current practices of managing and rehabilitating burns patients in these centers. How an investigator from outside interfere into the existing protocols? Are there any studies from these institutions in which issues are identified? • The type of burns / extent is not mentioned. Rehabilitation is carried out based upon these factors. • How many patients shall be enrolled from each institution? • What are the benefits for the institution in providing study subjects to an outsider researcher working for other institution having external funding as well? • Informed consent form is to be made with appropriate details and in context of RCT. A long document as a standalone booklet for patients to read is not appropriate.

Next meeting:

The next zoom meeting will be held at 02:30 pm on 2nd July, 2024. The following projects will be reviewed:

Projects will be discussed. NBCR-1093, NBCR-1094 and NBCR-1119



Focal person NBC-R



Chairperson NBC-R