Minutes of the NBC-R meeting held on 06-01-2026

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on January 6th, 2026. The following members of NBC-R attended the meeting:

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

The following projects reviewed / discussed:

Title: **The effects of tranexamic acid on anaemia, menstrual health and the wellbeing of women:an international randomised, placebo-controlled trial among menstruating womenwith anaemia (WOMAN-3 Trial)**

Project #	PI Name & Address
NBCR-1367	**Prof Rizwana Chaudhri** Head of Translational Research Department Shifa Tameer-e-Millat University Park Road Campus, P/O Tarlai Kalan, Islamabad.

Final NBC-R Comments

1. It is already established that tranexamic acid is effective in **preventing heavy periods**, then what is the rationale of this trial? It can be implicitly gathered that by decreasing blood loss anemia shall be prevented or minimized. However, other causes of anemia like those related to the nutrition and worm infestation shall remain.
2. The PI is also a CO PI. In NBC application form and in protocol the names of PI are different. This needs clarity and has affiliation with two of the study sites.
3. The short-term assessments need elaboration. In order to evaluate benefits, less bleeding doesn't automatically translate into rapid hemoglobin recovery without enough time and iron replacement.
4. Tranexamic acid has side effects, and these have not been provided in the study application form or in the ICF.
5. There is no clear explanation or reason in the study protocol or the ICF as to why stool and urine samples are required.
6. There are no details of long-term side effects of tranexamic acid are mentioned. This aspect needs clarification.
7. What is the cost of tranexamic acid and current standard of care treatment for reducing bleeding? What additional cost will it be if this treatment is eventually recommended for reducing anemia in young women?
8. What will be used in the Placebo arm?
9. How the drug shall be administered?
10. When the underlying cause of anemia in the 300-participant subgroup is identified will this be shared with the participant so that they can seek appropriate management?
11. The registration details of clinical sites are required.
12. IRB approval letters from different institutions are yet to be submitted.
13. Samples will be analyzed in accredited local laboratories in Pakistan and also in

Laboratory in France, During the study, blood, urine and stool samples will be collected, which tests will be done in Pakistan and for which tests samples will be transported to France.

14. In methodology the test details are different, and for urine and stool, it is not detailed which tests will be done. Will the participants receive the reports?
15. For tests to be done in France submit MTA on a legal page and clearly mention which test shall be done, not just that blood will be transported to the lab. In France.
16. In case of adverse events which can need hospitalization , persistent or significant disability/incapacity, congenital anomaly or birth defects, who will bear the charges for long and short term treatment. This needs to be added in consent form.
17. 2.1 The procedures are indeed low risk, as it only requires one blood draw but what about drug side-effects. The drug is known to reduce bleeding by increasing clotting. Will it increase the risk of clotting in women over 30 years of age? Will they do bleeding clotting time on all participants?

18. The Urdu version of the consent form is missing. In the English and Urdu version, the details of tests done in Pakistan need to be added.
19. Who are the members of DSMB?
20. Provide itemized budget.
21. Defined process for continued safety monitoring of IMP in study
    - Keep records of all adverse events/ adverse reactions
    - Report serious adverse events/ serious adverse reactions at least annually (or more frequently, asrequired), typically via a Developmental Safety Update Report (DSUR)
    - Ensure recording and prompt reporting of suspected unexpected serious adverse reactions (SUSARs)to all regulatory authorities, as required
    - Ensure all investigators on the trial are informed of SUSARs
22. Other than entering them in the form how will they be conveyed to local authorities?
23. In case of adverse events who will be responsible for the patient. Where will the patient be treated? Will patient be provided with compensation (like free treatment)?
24. Insurance related details are also required. Is Pakistan included in the insurance?
25. LSHTM accepts responsibility attached to its sponsorship of the trial and, as such, would be responsible for claims for any non-negligent harm suffered by anyone because of participation in this trial.
26. How will the team in LSHTM be notified and what actions will they take?
27. There is no clear plan for dealing with the adverse events
28. Not clear on how and where data will be stored. Looks like data will be transferred to LSHTM server in real time and samples will be stored in Pakistan.
29. To ensure consistency in laboratory results, nominating a single central laboratory may be more feasible than using multiple site-specific laboratories.
30. The transfer agreement is insufficient, lacking specifics on what data is shared, how, where, and with whom.
31. Patient Information Sheet is long and contains technical language.
32. Recruitment from "higher education institutions, vocational training centers, institutions with professional and apprenticeship training schemes and at healthcare facilities with community outreach" is not a fair subject selection. This can lead to stigmatization or inequitable subject selection. Is there a reference to show that women at these sites have a higher incidence of anemia as compared to other women?
33. Section 1.2: Hb<12 g/L will be included…will "severe anemia" not be excluded? What if the HB levels are <6 g/L ?
34. Section 2.1: Testing for anemia is listed as 'Benefit', shouldn't the research participants be the ones to decode whether a benefit is or harm (in participating in the study)?
35. Section 2.2: Details of community meetings, and "appropriate healthcare professionals" may be shared
36. Section 2.5: Even if TXA proves to improve anemia in addition to iron and folic acid, it cannot be regarded as a "treatment" for anemia as it does nothing to improve Hb levels

on its own (Copied from this section: "**After the trial**: If TXA in addition to standard iron and folic acid improves anaemia better, it may also provide a treatment route for anaemic women who cannot tolerate iron or folic acid supplementation due to their side effects."

37. What will happen if a participant has abnormal test results? (any incidental findings!?)

Title: **Pads, Power, and Participation: Local Navigation of Transnational Power Assemblages in Period Advocacy.**

Project #	PI Name & Address
NBCR-1368	**Dr. Priyanka (Priya) Ganguly** Texas Tech University, English Department 2500 Broadway MS3091, Lubbock, TX 79409, USA

Final NBC-R Comments

1. A U.S.-based researcher plans to collect sensitive data from Pakistan via Zoom without a local co-investigator. This is not allowed as per policy of NBC. Local partners are needed for accurate interpretation and community trust for sensitive cultural topics on menstrual health. Without a local co-investigator or institution, there is no local oversight or accountability if a participant is harmed or if data is misused.
2. The recruitment strategy is vague. Why Pakistan is chosen as a study site?
3. The interview will be on zoom, the participant will get the digital consent form, and in consent form signature/thumb impression is required how that will be possible. If the participant is putting the thumb impression, then the Urdu version is also required.
4. The structured questions those will be asked are missing.
5. The participant will get $35 dollars as reimbursement, how that will be paid, as it is an online interview?
6. There is no direct benefits to the research participants. What shall incline them to participate?
7. Does the researcher anticipate any language barriers? What if the research participants wish to give interviews in the local languages?
8. The attached IRB approval letter does not list Pakistan as one of the study sites
9. The protocol indicates that study materials may be in national or local languages; however, no clear description is provided regarding the translation process. Details on who will translate the materials, whether forward–back translation will be used, and how linguistic accuracy and cultural appropriateness will be ensured are not specified. This lack of clarity may affect the validity of informed consent and the reliability of data collected from participants.
10. The protocol states that written informed consent will be obtained through verbal consent recorded at the beginning of the Zoom interview, which reflects a conceptual and procedural inconsistency.
11. Verbal consent, even when audio-recorded, does not constitute written informed consent. If verbal consent is intended, it should be clearly justified, with reasons for not obtaining written (digital) consent explicitly stated.
12. Translation into Urdu is mentioned, no details are provided regarding the translation process, validation, or cultural appropriateness of the consent form. This ambiguity may compromise the robustness of the informed consent process and requires clarification to ensure compliance with ethical standards.

Title: **prophylaxis for prevention of left ventricular thrombus following anterior myocardial infarction: An open label, randomized clinical trial (POTAMI).**

Project #	PI Name & Address
NBCR-1369	**Prof. Abdul Hakeem** National Institute of Cardiovascular Diseases(NICVD) Rafiqui H.J. Shaheed Road, Karachi
Final NBC-R Comments	
1. T Study is already in progress. Why NBC R may review it. About 50% of the recruitment is already done. 2. The PI is involved in nearly 30 projects that are ongoing. PI is primarily US based and visits Pakistan for few months. How such arrangement justifies conducting research in Pakistan?	

Minutes of the NBC-R meeting held on 13-01-2026

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on January 13th, 2026. The following members of NBC-R attended the meeting:

Sr.#	Group-I	
1.	Prof. Saima Pervaiz Iqbal	Chairperson
2.	Prof. Marie Andradess	Member
3.	Prof. Amjad Mehboob	Member
4.	Prof. Sualeha Siddique Shekhani	Member
5.	Prof. Rameeza Kaleem	Member
6.	Prof. Faheem Ashraf Khan	Member
7.	Dr. Farah Asif	Member
8.	Mrs. Tayyab Rahat	National Coordinator
9.	Mrs. Ayesha Abid	Assistant

The following projects reviewed / discussed:

Title: **Trial: Randomized Control Trial on safety and efficacy of Mesenchymal Stem Cells in Grade 2-3 Knee Osteoarthritis.**

Project #	PI Name & Address
NBCR-1363	**Dr Raheel Iftikhar** Armed Forces Bone Marrow Transplant Centre (AFBMTC), AFBMTC Rd,CMH Rawalpindi

Final NBC-R Comments

1. There are several methodological and ethical flaws in this study which need to be addressed.
2. This proposal requires major clarifications and safeguards before approval as this study involves advanced therapy medicinal products (ATMPs), bone marrow aspiration, and placebo-controlled intra-articular injections; the ethical bar needs to be elevated.
3. Please provide evidence in the rationale that mesenchymal stem cells are likely to be of proven benefit for OA. What are the results from Phase 1 and Phase 2 studies? Where have they been conducted? Additional justification is needed to demonstrate that the use of placebo is ethically acceptable and consistent with patient welfare.
4. Harvesting of the MSCs will occur 2 to 4 weeks prior to the scheduled injection. There is no mention of the details of this in the consent. Informed consent form just gives one line that it will be taken from the experimental arm patient. This is a painful procedure and has risks attached to it. This needs to be mentioned in details.
5. Participants in the placebo arm undergo i) Bone marrow aspiration without receiving MSCs, or ii) Injection without expected therapeutic benefit. This exposes participants to risk without direct benefit. It must be explicitly stated that whether bone marrow aspiration occurs in placebo participants (this is critical), and whether rescue treatment is offered after study completion. Risks are understated, and not fully acknowledged. For instance, Infection, procedure-related pain, theoretical tumorigenicity, immune reactions, unknown long-term effects of MSCs
6. Study is double blind: Neither you nor your doctors will know which treatment you are receiving (study is double-blind). How can this be as since patient bone marrow /fat tissue will be harvested?
7. Informed consent process and language strongly emphasize benefit, which may lead participants to believe MSCs are proven therapy. The consent does not mention how adverse reaction will be managed. It just says “There will be no cost to you for participating in the study. You will not receive any payment for participation. In case of injury or adverse events related to the study, medical care will be provided as per institutional policy." Consent form mentions that Standard treatments for knee osteoarthritis include physical therapy, medications, lifestyle changes, or surgery. These

will remain available to you at all times. However, there is also mention that patients will only be given paracetamol for one year. This needs clarification.

8. The age group 30-60 includes economically active individuals who may feel pressured to participate due to perceived benefit. Participation is voluntary, that must be stated explicitly.
9. The application hints at future commercial development, but without a clear benefit-sharing framework. This matters because when commercial potential exists, participants must not be misled or exploited. Therefore, it must be explicitly mentioned that trial participation does not guarantee future access to MSC therapy, add a statement on post-trial access or justify why it cannot be guaranteed.
10. It is suggested that the parent institution of the PI also gets this study approved by its IRB once again.

Title: **ISARIC/WHO Clinical Characterization Protocol (CCP) for Severe Emerging Infections and Syndromes in Pakistan.**

Project #	PI Name & Address
NBCR-1365	**Prof. Dr Madiha Hashmi** Ziauddin University 4/B Shahrah-e-Ghalib Rd, Block 6 Clifton, Karachi,
Final NBC-R Comments	
• Study Approved.	

Title: **Biobank, an implementation science research pilot project.**

Project #	PI Name & Address
NBCR-1366	**Dr. Tahir Ahmad** ASAB, NUST NUST H/12, Islamabad.
Final NBC-R Comments	
The biobanking proposal raises substantial ethical, regulatory, and governance concerns and requires significant strengthening. The informed consent documents appear to have been picked up from somewhere without adequate contextualization or thoughtful integration into the proposed biobanking framework, suggesting limited consideration of biobanking-specific ethical requirements. This raises concerns regarding the study team's preparedness and understanding of the scope and responsibilities involved. The proposal lacks clarity on participating institutions, patient sources, study-level review and approval processes, and oversight mechanisms, giving the impression of a request for broad or blanket approval. Roles and authority related to sample access; use, sharing, and transfer are insufficiently defined, as are the responsibilities of the funder and collaborators. Given the sensitive and valuable nature of human biological samples, clearer articulation of participant rights, confidentiality safeguards, governance structures, and consent as an ongoing process is essential. A careful reconsideration and comprehensive ethical and scientific review are recommended prior to further consideration.	

Minutes of the NBC-R meeting held on 20-01-2026

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on January 20th, 2025. The following members of NBC-R attended the meeting:

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

The following projects reviewed / discussed:

Title: **Ability of the prebiotic KB195 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 and Burkina Faso.**

Project #	PI Name & Address
NBCR-1370	**Prof. Asad Ali** Department of Comunity Health Science The Aga Khan University **Karachi**
Final NBC-R Comments	
1. It appears that multiple objectives and studies are linked to this trial, providing additional detail on their scope and relationship to the primary study objectives will help in assessing if additional justification needs to be provided – right now it seems they want clearance for a multitude of studies under this one approval. 2. PI may provide details about studies conducted on same population about the gut pathogens conducted / ongoing. 3. While the *primary objective* (assessing the effect of KB195 on enteropathogen load) is appropriate and well aligned with a Phase II proof-of-concept design, and *secondary objectives* reasonably explore efficacy, *the overall objectives are excessively broad for a Phase II trial*. *Several tertiary objectives*, including gestational weight gain, fetal growth, placental function, perinatal and infant outcomes, and offspring microbiome analyses, extend into clinical and developmental domains that are typically underpowered and more *suitable for Phase III trials or dedicated follow-up studies*. The inclusion of complex intergenerational and sociodemographic interaction analyses further dilutes focus and may contribute to therapeutic misconception, particularly in a vulnerable pregnant population. 4. KB-195 originally developed to treat UCD. Vague claims that EED are source of low birth weight or prematurity. Has the compound been used in non-pregnant individuals? Or non-pregnant women? If the answer is NO, then it should be used first there.	

5. How can pregnant women receive this compound, starting from 18 weeks onwards? The recruitment begins at 13 weeks! The structural changes especially fetal heart formation is completed at 24 weeks, how we can subject women to receive it even after 24 weeks.

6. The basic idea of EED, leading to adverse outcome is presumptive. The gut microbiota of newborn is very important, as it is defining the future of newborn for rest of life. What changes will be made after its introduction will affect whole life of an individual.
7. The investigators need to run it on non-pregnant women first, as use during pregnancy is affecting two lives simultaneously.
8. The study targets *pregnant women with low BMI, poor WASH conditions, and rural residence*, constituting a *highly vulnerable population*. Despite this, the protocol includes Multiple blood draws, repeated stool and urine sampling, Lactulose/rhamnose permeability testing, CapScan capsule and *Eight* serial ultrasounds (screening, then 16th, 20th, 24th, 28th, 32nd, 34th, and 36th weeks of gestation (+1 week). The ethical justification for subjecting this population to such a substantial procedural burden, particularly when the primary endpoints are largely microbiological and exploratory in nature, has not been adequately addressed and requires clearer justification in terms of risk–benefit proportionality.
9. Women having a BMI < 21 will be included, as stated in inclusion criteria. The average BMI, as observed in many prospective studies by me, ranges btw 22-23. The target audience are then young individuals.
10. The information gathered from available sources indicate exclusion of gut diseases, which is not mentioned how they will be excluded from the study population.
11. The proposal does not adequately justify the direct relevance and downstream benefit for Pakistan, beyond contribution to global knowledge and future Phase III trials. There is no clear articulation of how findings will influence local maternal health policy, practice, or affordability in Pakistan.
12. The statistics of Matiari, shared by researchers, are not significantly different from those of the rest of Sindh and Pakistan, in general. (https://pakistan.unfpa.org/en/news/sindh-population-reach-957-million-2050-if-contraceptive-use-rises-1000-mothers-and-34000#:~:text=Karachi%2C%2025%20May%202023%20–%20With,to%20accommodate%20the%20growing%20population.) So, the justification of study site does not stand valid. In fact, this is a frequently selected research community.
13. Is there any justification for not using AKU Karachi campus and its satellite units in the city?
14. Further explanation of the rationale for selecting the Matiari site for a Phase II trial would be helpful, particularly with respect to safety monitoring, adverse event management, referral pathways, and follow-up capacity in a community-based setting, would an urban setting not be safer?
15. What is the Standard of Care (at all the collaborating institutions)?
16. Section 2.1: “Minor GI Side effects” - What is the evidence that these side effects are “minimal” and is this data for pregnant persons? What if the study participant does not perceive these side effects as “minimal”?
17. What steps are being taken by the researchers to reduce “time burden”?
18. What is the evidence that the KB 195 intervention is “potentially beneficial”?
19. The following “Anticipated Benefits to Communities” are mentioned…but have no direct link with the study objectives: (A justification is required). The same team from the university has been working there for a decade.
    a. Improved understanding of maternal gut health and its relationship to

pregnancy outcomes

b. Enhanced healthcare infrastructure and trained personnel in Matiari that may benefit
c. community beyond study
d. Strengthened referral systems and emergency transport capabilities
e. Increased health awareness about maternal nutrition, WASH practices, and antenatal care

20. Sections 2.2 and 2.3 contradict each other…the researchers claim that they will protect patient/research participants' privacy, yet they also claim that they will have other family member/s with them. How do the researchers ensure that this is supportive and not burdensome or coercive for the research participant?
21. Section 2.4: Pre-study community engagement: How come in the last 10 years the teams in Matiari have not already established a rapport with the local community and have not learned culturally sensitive and respectful practices?
22. During Study Engagement: How will "discreet" home visits be planned and executed?
23. Post-study engagement: Can the researchers share any evidence of such engagements from the past studies in that or other areas? Who will conduct these and what is the purpose?
24. Cultural Sensitivity: How will stigmatization be avoided as a very specific community is being engaged? There isn't any diversity in the study population (has not been since last 10 years)
25. Section 2.5: There is a claim that the research participants will have enhanced antenatal care…Question: Are these sites in Matiari free or paid for? If already free, then what is the additional benefit to the research participants?
26. Section 2.5: Comment-Society will benefit more if a diverse population from AKU Karachi site is studied
27. Will the community have access to these medications, if found effective and approved by DRAP, after the study is complete? At what cost?
28. Bio-banking Consent? Needs to be clearer in the consent form.
29. The Co-PIs of research team are from AKU Karachi, except Dr. Sana of Gynae/Obs from AKU center Hyderabad, Who will be responsible in Matiari?
30. Ultrasound scanning, anthropometry, and clinical assessment will be done at the AKU research office in Matiari, If any abnormality or anomaly in the ultrasound scan is detected, participants will be referred you to the nearest health care facility. Which is THQ hospital, when the whole team is from AKU, why the participants will be referred to Govt, facility, for screening as well as for adverse events?
31. Additional details on the management of incidental findings (e.g. from ultrasound or other assessments) would strengthen the protocol, including who will be responsible for disclosure, counselling, and onward care, and what support will be provided to participants.
32. It is stated in case participant experience psychological and emotional distress while undergoing an ultrasound while completing questionnaires, the study staff members will refer the participants and transport to a public healthcare facility, why not AKU?
33. Clear explanation of these processes may also help minimize the risk of therapeutic misconception, especially where research activities may overlap with routine clinical care in the community.
34. It is stated that samples may be shipped outside the country. Which country, which laboratory and for which of the tests?

35. The total reimbursement for participants may not exceed $10 (PKR 2700) in kind and cash, nothing is detailed about the payment of tests. Will the participants will get their

reports

36. It is also stated "your blood, urine, stool, and your newborn's stool sample may be shipped outside of the country for detailed analysis.' For which analysis and where?"

37. More transparency on which samples and analyses will be conducted locally versus sent abroad would strengthen the submission, including information on destination laboratories and governance arrangements.
38. MTA is also required.
39. Who will be the members of DSMB and how frequently they will monitor?
40. The details of Insurance policy: of AKU are required. "All adverse events will be managed in accordance with the sponsor organization's (AKU) insurance policy, and the associated costs will be covered accordingly." When the patients will be referred to Govt. facility, where the treatment is free, how this is justified?
41. Insurance coverage is stated but lacks details regarding coverage for maternal, fetal, and neonatal harm, critical in pregnancy trials.
42. Permission of Govt. is required as their facilities shall be used when referral shall be made.
43. The sample size is 134 (67 + 67) and not 143.
44. Periodic testing will be done, many adverse events are could come up during or even after the study as it is a new intervention, for how long the insurance will be covered?
45. In questionnaire, many questions are out of context.
46. Access to the full study protocol would be helpful to better understand the overall scope of planned analyses, particularly the laboratory and "omics" components.
47. Clarification would be useful on whether genomic analyses are limited to enteric pathogens or whether any host (maternal or fetal) DNA will be generated or analyzed, either intentionally or incidentally. This needs to be addressed adequately in the ICF document.
48. The informed consent document is lengthy and complex, particularly regarding long-term storage of samples and future research use.
49. Further clarification on how concepts such as biobanking will be explained and understood at the community level would be helpful.
50. The informed consent form, while comprehensive, is excessively lengthy, procedurally dense, and written in technical language that may limit comprehension among a socio-economically vulnerable pregnant population, thereby compromising the validity of truly informed consent. The cumulative procedural burden, including repeated biological sampling, prolonged urine collection, serial ultrasounds, optional CapScan capsules, and postpartum and newborn sample collection, is not clearly summarized in a manner that allows participants to readily appreciate the overall commitment and risks. Furthermore, the consent form does not clearly provide participants with the option to decline specific visits or individual procedures while continuing participation in other components of the study, thereby limiting informed choice and procedural autonomy.
51. In addition, provisions for long-term storage, future unspecified use, and international transfer of maternal and newborn biological samples are presented in a narrative format without clear, tiered consent options, increasing the risk of uninformed agreement. Importantly, although the study is claimed to be conducted in Pakistan (practically only in Matiari district of Sind), the consent form is available only in English and Sindhi; no Urdu version has been provided, despite Urdu being the national language and widely understood by the general population Sindh.

Title: **Disease Registry for Neovascular Age-Related Macular Degeneration (nAMD), Diabetic Macular Edema (DME), and Retinal Venous Occlusion (RVO) of Pakistan.**

Project #	PI Name & Address
NBCR-1372	**Dr. Rafeen Talpur** Sindh Institute of Ophthalmology and Visual sciences (SIOVS) Eye Hospital Journalist Society Hyderabad Sindh

Final NBC-R Comments

1. The English version of consent form plan is attached, which is for the researcher, whereas the Urdu version of consent attached is, when participant went under procedure. Proper consent is required to recruit the participant.
2. The license for data collection software is for two years, renewable (started on 15th NOV. 2025) supported by Roche company. How this registry will be sustainable, once the funding is stopped.
3. Who will be the custodian of data?
4. It is also stated, "Details of funding sources and any sponsors supporting the registry will be disclosed, and their roles will be documented transparently". What are the reasons for not disclosing now?
5. The statement *"no conflict of interest"* is overly simplistic given Roche's role in software provision and pharmacovigilance linkage. Potential perceived or indirect conflicts of interest are not critically analyzed.
6. If Roche provides the software and the funding, will they have access to the data, will it form part of their clinical data repository? The License Agreement Data Sharing section clearly states Roche will expect access to this data. This should be clear in the NBC from also.
7. Need to define who the data monitors are the project.
8. Roche has placed all the responsibility of data privacy and confidentiality on the user, does the institute have adequate IT resources and expertise to ensure data is protected and secure.
9. Follow-Up Duration is 5 years from the initial enrollment, with follow-up assessments every 3 to 6 month, the timeline of license is questionable
10. Approval from Institutional Review Boards (IRBs) at each participating center will be obtained, where as in NBC form only one institute is mentioned, however in study protocol there are two institute The Sindh Institute of Ophthalmology and Visual Sciences (SIOVS) and Shifa eye Trust Hospital Islamabad, to achieve the stated objectives. The IRB approval of Shifa Eye Trust Hospital is also required.
11. The Routine data quality audits and periodic monitoring by the registry team to maintain data integrity, will be done, who will the members of this team?
12. In NBC form Response to question (3.1) "How will the findings be disseminated and to whom?" is incomplete.
13. Response to question (3.3) "What will happen when the research is prematurely completed or discontinued before the proposed completion?" In NBC form the response "Since this is registry based study so there isn't any risk to patient if in case it is prematurely closed or discontinued." This shows the funders have interests and using patients as means to their ends.
14. The project budget details are missing.
15. The informed consent should clearly mention what the patients' data will be used for.
16. The consent form provides only a limited and technical explanation of the Anti-VEGF procedure, without clearly explaining its purpose, expected benefits, alternatives, or frequency of treatment.
17. The listed risks are incomplete and not explained in terms of severity, likelihood, or management.
18. There is no clear statement on voluntariness, the right to refuse or withdraw without

affecting care, or on confidentiality and data protection.

19. Information regarding costs, compensation, or management of procedure-related injury is missing.
20. Although the consent form is in Urdu, the language remains medical and may not be easily understood by individuals with low literacy.
21. Strong data security is required to ensure the protection of patients' data.
22. Data will be shared at the national level. What steps will be taken to ensure that the data remains anonymized and even when it is anonymized, there is a serious risk of re-identification of data with AI and machine learning? (the data security plan submitted by researchers is not enough)
23. What is the plan to respond to cyber-attacks or insider threats?
24. What is the role of the funding agency (the one providing the software)?
25. What is the plan of information sharing/disclosure if there is a security breach of data?
26. Passive AE reporting relies on **sponsor pharmacovigilance systems** is described. There is **no clear local reporting pathway**, timelines, or responsibility matrix for serious ocular or systemic adverse events related to standard-of-care treatments recorded in the registry.
27. No estimated sample size, enrollment targets, or strategy to ensure representativeness across regions or disease subtypes is provided.

Title: **DARSEM Trial: Diabetes and Ramadan Semaglutide Evaluation in Multicenters – A Real-World Study from Pakistan.**

Project #	PI Name & Address
NBCR-1373	**Dr Muhammad Daoud Butt** Umar Diabetes Foundation Umar diabetes Foundation, Malak shafait plaza, Mauza Mahal kot, Hathial, Main Murree Rd, Barakahu, Islamabad

Final NBC-R Comments

1. The investigators need to provide some helpline in event some help is required for fasting individuals.
2. The use of other drugs may precipitate hypoglycemic events.
3. Also there should be a proper dietary chart indicating amount of food which may be taken by the individuals.
4. The PI is not sure whether there will be transfer of biological material or not? Hence a blanket statement again.
5. The drug has been used in other countries, but the current trial is lacking clinical supervision, which is important, considering it is being done in Ramadan.
6. All sites must be DRAP approved for clinical trials.
7. The project is a collaborative project between Umar Foundation and Sains University Malaysia, funded by BF Biosciences. The PI Dr. - Daud Butt is PI of the project is based in Sains University Malaysia, he is also Board of Directors in Umar Diabetes Foundation, in Islamabad. The Co-PI is Dr Muhammad Umar Wahab of in Umar Diabetes Foundation, in Islamabad. The Ethical approval is from Health Alliance for Dr. Arshad of North West Hospital Peshawar. What is the link?
8. It is stated "The study will be conducted across multiple tertiary care hospitals in Pakistan, including urban and semi-urban centers. These sites provide access to a large and diverse diabetic population, "which tertiary care hospitals and semi-urban centers will be included, Support letters and IRB approval is required?"
9. The Co-Investigators includes endocrinologists, diabetologists, and clinical pharmacists from tertiary care hospitals in Pakistan. All investigators are experienced in managing

type 2 diabetes during Ramadan. Please provide the names, and their affiliation with tertiary care hospitals and semi urban centers.

10. The study is Multicenter observational study comparing the effects of biosynthetic semaglutide versus other anti-diabetic therapies during Ramadan. The total study duration will be 24 weeks, divided into three phases: the Pre-Ramadan Phase (4–12 weeks) at one place it is also written Baseline Visit 12 weeks before Ramadan. The timeline is already passed.
11. The participants will be randomized and grouped into two, based on physician judgment and patient preferences, this will cause the bias as it will not be true randomization.
12. The experimental group will include patients receiving biosynthetic semaglutide at a stable dose of ≥0.5 mg weekly for at least 3 months prior to Ramadan, along with other anti-diabetic agents The Ramadan is only four weeks away, how the true participation will be justified, to produce authentic results.
13. It is stated MOU/NOC from the KPK Health Department must be obtained and submitted. Since this study will be conducted across multiple tertiary care hospitals in Pakistan, including urban and semi-urban centers. Then why only from KPK the MOU/NOC will be obtained, what about other provinces?
14. Educational materials (Urdu and English) on diabetes management during Ramadan will be distributed to participants and shared with local diabetes clinics. Kindly provide the Urdu and English version of educational material.
15. How much blood will be drawn and where the tests will be done, also include in consent form, also will the participants will be getting the reports?
16. In case of adverse events where the participants be treated, and who will pay?
17. Who will be members of DSMB?
18. What will be the role of the funding agency? Will they have access to data?
19. Some scientific justification of what changes (routine, diet, blood glucose level, and response to Insulin/GLP1s, etc.,) must be provided to justify the research.
20. What is the standard of care? Is a decision is made (clinically) to keep the patient on either of the two regimens (anti-diabetics vs GLP 1)?
21. Section 1.2: "To determine the proportion of participants achieving an HbA1c target of <7%.".How can the researchers do that in just one month? (Ramadan is one month long, while the researchers wish to study the effects of GLP 1 during fasting…over three months)
22. How will the study address the outcomes associated with adjunct therapy to GLP 1?
23. The funding is from Malaysia, but Malaysia is not a study site. The justification is not satisfactory, as Malaysia has a significant (63%) population of Muslims who observe Ramadan.
24. Which mobile app will be used and how secure is that? Details are required. This is not found in the protocol. Is it in Urdu or English?
25. How will the researchers ensure that the research participants can use it effectively?
26. Generally diabetic patients do not check their blood glucose levels daily but they will be required to do so and save data in the app…who will pay for the glucometer and strips and how will the researchers ensure compliance?
27. The informed consent in Urdu (and questionnaires) are incomprehensible…must be revised in regular language spoken daily and must be understood by an average layperson (primary school education standard)
28. The risks of repeated blood sampling, data breach, hospital visits etc have not been mentioned in the informed consent.
29. What steps will be taken to respond to psychological risks associated with the study?
30. Who will pay for the tests?
31. Who will pay for any adverse events?
32. Details of educational interventions must be shared with the IRB to review…are the

educational materials improvised or it is what is regularly used? If it's the same as regularly used, how is this a benefit of the study?

33. Although the study is described as a prospective observational, real-world investigation, the current protocol language (e.g., use of terms like "*open-label*," "*two-arm parallel-group*," and statements implying continuation of semaglutide at a specified minimum dose) may inadvertently suggest *protocol-driven treatment allocation*. This creates ambiguity regarding whether the study is purely observational or interventional.
34. The protocol should explicitly clarify that all treatment decisions, including initiation, continuation, and dosing of biosynthetic semaglutide or other antidiabetic therapies, are made solely by the treating physician as part of routine clinical care and are not influenced by the study. Clear rephrasing is required to avoid regulatory misclassification and to confirm the non-interventional nature of the study.
35. This risk is generally for all diabetic patients, opting for keeping the fast, during Ramadan, and must be declared by treating physician to every patient. For an observational study, it is essential to clarify that such management decisions are made solely by the treating physician in accordance with standard clinical practice and are not dictated by the study protocol, with the study limited to observing and documenting outcomes.
36. Protocol should clarify what should be done for patients, who are advised to discontinue drugs due to repeated hypoglycemia.The approval letter is issued under the name of Alliance Healthcare, with Northwest General Hospital (NWGH), Peshawar mentioned; however, it is not clearly stated whether ethical approval has been formally granted by NWGH itself. Furthermore, while the study is explicitly described as multicenter (including collaboration between Pakistan and Malaysia) in the protocol and NBC-R application, ethical approval letters or site authorization documents from other participating centers have not been provided and should be submitted to ensure complete multicenter ethical oversight.
37. The attached adverse event (AE) reporting form is titled "Market Research / Patient Support Program" and appears to be a generic pharmacovigilance document of the sponsoring pharmaceutical company rather than a study-specific tool.
38. The AE/SAE reporting mechanism should be aligned with the current study, clearly reflecting the study title and objectives.
39. In addition, the protocol should explicitly define the reporting pathway, including identification of the recipient of the initial AE/SAE report (site Principal Investigator, sponsor, local IRB, and/or NBC-R), clarification of whether DRAP reporting requirements apply, and clear delineation of responsibility for causality assessment, follow-up, and management of adverse events.
40. The protocol allows inclusion of high-risk patients with physician approval and "additional counselling"; however, it does not clearly define what constitutes such counselling or whether it includes enhanced monitoring, specific break-fast criteria, or predefined emergency escalation and referral pathways. These elements should be explicitly described to ensure adequate risk mitigation and consistent management of high-risk participants during fasting.
41. In the ICF it would be a good idea to provide details of the sampling and testing that is planned.

Minutes of the NBC-R meeting held on 27-01-2026

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on January 27th, 2026. 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. Amjad Mehboob	Member
4.	Prof. Sualeha Siddique Shekhani	Member
5.	Prof. Babar Tasneem Shaikh	Member
6.	Prof. Rameeza Kaleem	Member
7.	Prof. Agha Riaz	Member
8.	Prof. Faheem Ashraf Khan	Member
9.	Dr. Farah Asif	Member
10.	Mrs. Tayyab Rahat	National Coordinator
11.	Mrs. Ayesha Abid	Assistant
12.	Mr. Waryal Ali Daheri	LDC

The following projects reviewed / discussed:

Title: **Community Health Needs and Assets Assessment (CHNAA) in District Charsadda, Pakistan.**

Project #	PI Name & Address
NBCR-1364	**Dr. Naveed Asghar** (WCO Pakistan) World Health Organization (WHO) WHO Country Office Chack Shahzad Park Road, Islamabad, Pakistan
Final NBC-R Comments	
1. What if during the survey, someone is suspected or diagnosed with having mental health illness. How will this be addressed in providing help to the involved participants? 2. Is there a local co-PI from Charsadda who will also be involved in this survey? Please identify. 3. Considering political tensions in the area is there any risk to the researchers?	

Title: **Evaluating the Efficacy of Low-Dose Tirzepatide in Reducing Liver Fibros is in Patients with MASLD.**

Project #	PI Name & Address
NBCR-1374	**Dr. Zaigham Abbas** Department of Hepatogastroentrology Ziauddin University, Karachi.
Final NBC-R Comments	
1. Declaration states "no conflicts of interest" yet the sponsor BF Biosciences Ltd is providing both drug and financial support. This creates an inherent potential for conflict especially if results can influence drug labelling or market expansion. 2. Plans for community engagement and benefit sharing are vague with no clear strategy for dissemination of results to participants or our local MASLD communities. 3. Open-label, single-arm design limits interpretability of results due to lack of control group. While this may be pragmatic it raises questions about "internal validity" and risk of bias. 4. The study excludes diabetic patients, yet Tirzepatide is a diabetes drug. This may limit generalizability and raises the question: Why not include diabetic MASLD patients who may benefit more? Justify the exclusion of diabetic MASLD on scientific grounds.	

Title: **Perceptions of Disability among Parents of Afghan Children with Pediatric Cancer.**

Project #	PI Name & Address
NBCR-1375	**Dr. Alina Sadaf** Department of Paediatric Oncology, Shaukat Khanum Memorial Cancer Hospital & Research Center, Lahore 7 A Block R-3, M.A. lohar Town, Lahore.
Final NBC-R Comments	
• Study Approved.	

Chairperson NBC-R

Minutes of the NBC-R meeting held on 03-02-2026

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on February 3rd, 2026. The following members of NBC-R attended the meeting:

Sr.#	Group-II	
1.	Dr. Nighat Murad	ED HRI, Member Secretary NBC
2.	Prof. Jamshed Akhtar	Member
3.	Prof. Saqib Mehmood	Member
4.	Dr. Farkhanda Ghafoor	Member
5.	Prof. Akhtar Sherin	Member
6.	Dr. Sarosh Saleem	Member
7.	Dr. Faiza Bashir	Focal Person NBC
8.	Mrs. Tayyab Rahat	National Coordinator
9.	Mr. Waryal Ali Daheri	LDC
Regrets to join the meeting.		
10.	Prof. Shahid Mehmood Baig	Member
11.	Prof. Nazli Hossain	Member

Discussed the digitalization online submission portal for NBC.

The following projects reviewed / discussed:

Title: **Impact of Meat Provision on Nutritional Status among Women of Reproductive Age and Children aged 6 to 10 in Rural Pakistan: An Analytical Cross-Sectional Study.**

Project #	PI Name & Address
NBCR-1376	**Dr. Syed Asad Ali** Chair, Department of Community Health Sciences, Aga Khan University Hospital Stadium Road, Karachi.
Final NBC-R Comments	
1. Following is the justification provided by the PI "Matiari District, Sindh, was selected due to its high burden of poverty, under nutrition, and anemia, particularly among women and children. The district is predominantly rural, with limited dietary diversity and low access to animal-source foods. Sindh accounts for a substantial proportion of chronic malnutrition cases in Pakistan, making it a relevant and high-priority setting for this research" 2. The above paragraph is almost always found in the studies from same university that has a presence in the name of research for decades in the same area. It is also mentioned that "During the study, participants identified with severe anemia or malnutrition will be referred to nearby health facilities". This is unethical to refer the patients out without even providing details and giving justification. 3. The project had no scientific background. We all know that animal meat raises hemoglobin levels, ferritin levels, improves maternal health. What new will be added by this research, in the absence of background information, stating poverty is rampant in Matiari is not enough! 4. The background household information about the population is not provided. It will be important to know, the number of people living in the household, their ages, the amount of meat they use, the amount of meat available for the individual as a routine. 5. The study does not include baseline measurements of hemoglobin, ferritin, or other nutritional indicators prior to exposure classification. Without pre-exposure or pre-treatment data, it is not possible to determine whether observed differences in end-	

point nutritional status are attributable to animal-source food provision or reflect pre-existing differences between groups. Consequently, causal attribution to ASF provision cannot be made, and findings should be interpreted strictly as cross-sectional associations subject to confounding and baseline imbalance.

6. Ideally there should be pre- and post-comparison for both groups
7. In the study there shall be a distribution of approximately 750 g of meat per household, six distributions per year. This is claimed a substantial addition of high-quality protein and bioavailability of iron. This is too presumptive and more of an exaggeration.
8. The study title should explicitly reflect that meat provision is charity-based, as the intervention is delivered through a charitable organization.
9. Since such provision is not accessible to all individuals, the findings may not be generalizable to the broader population.
10. The use of the term *"rural Pakistan"* constitutes an overgeneralization, as the study is to be conducted in a specific rural setting (Matiari, Sindh Province). The findings should therefore be contextualized to the study area.
11. If it is a research project, from institution like AKU, researchers should have applied for a proper research grant, rather than **sadqa funding**, which is primarily donated by someone for other purposes
12. Research questionnaire to collect demographic and food habits of the participants is not provided in the document. There is no CRF.
13. The letters of support from the relevant government department are not provided. The subjects shall be sent to the BHU, RHC.
14. In the Informed consent, the listed benefits are societal, not personal, benefit. Individual benefit of receiving health screening and nutritional status and the referral if needed should be provided and included in the informed consent.
15. Receiving "hemoglobin test results and referrals for care if severe anemia or malnutrition is detected" are not benefits "of" the research
16. Communities may benefit indirectly through improved understanding of nutrition and potential strengthening of charitable food programs." How? This is not addressed by the research objectives or methodology
17. AKU has a medical centre in Matiari, no one is engaged as Co-PI from there.
18. The Benefit to Participant is that they will receive hemoglobin test results and referrals for care if severe anemia or malnutrition is detected. Why they will get only the results of hemoglobin and why not of other tests when, ferritin, CRP, albumin, zinc, and vitamin B12 will be also done.
19. There is no reimbursement for the participants, it is stated "Additionally, the study materials/study supplies will be provided free of cost". Please provide the study material, how it will help the participant and study supplies are also need of researcher not of participant.
20. Support letter from Sadqa Pakistan Trust for access to program records required for classification of households based on frequency of Animal Source Food distribution is required.
21. Which governmental departments will be supporting the project and in what capacity, as detailed in NBC form?
22. It is a qualitative study, the outline of questionnaire is not provided.
23. For how long will the blood samples be stored?
24. What is the rationale for selecting children aged 6-10 years only?
25. The protocol does not clearly explain how this study will generate new or additional knowledge beyond what is already well-established regarding hemoglobin levels and anemia in socioeconomically disadvantaged populations. The scientific value and added contribution of the research question require further clarification, particularly in relation to whether the anticipated findings justify the use of time, financial resources, and biological samples from participants.
26. The study relies on sensitive household-level donation data provided by a charitable organization, but the protocol does not sufficiently describe data governance mechanisms or safeguards to prevent selection bias or undue influence on exposure classification and study conclusions.
27. The protocol does not adequately outline how scientific rigor, transparency, and

objectivity will be ensured, particularly given the relationship between the research team and the collaborating charity.

28. The rationale for defining exposure categories as ≥6 versus <2 ASF distributions over the past 12 months is not sufficiently justified. In addition, the protocol does not describe how the charity determines allocation frequency across households. Greater transparency is required to assess whether this allocation process could introduce systematic bias.
29. The protocol appears to assume ASF provision as the primary determinant of hemoglobin levels. Categorizing heterogeneous dietary patterns into two broad exposure groups risks oversimplification and does not account for type of ASF, portion size, bioavailability, overall dietary diversity, or frequency distribution, all of which may substantially influence nutritional outcomes.
30. The use of written assent for children aged 6–10 years is not developmentally appropriate, technical language and expectation that they will read and sign (thumb impression). A simple, age-appropriate verbal assent script, and verbal assent should be documented by study staff, it would be more suitable for this population.
31. The proposed collection of 6 ml of blood from young children requires further justification. Additionally, the protocol does not clearly specify the frequency of blood sampling, including whether hemoglobin and other biomarkers will be assessed at a single time point or at multiple time points. For participant safety and ethical clarity, this information should be explicitly stated in both the protocol and consent materials.
32. Given that the primary outcome is hemoglobin, the rationale for measuring additional biomarkers such as albumin, vitamin B12, zinc, and C-reactive protein requires clarification, particularly with respect to how these markers will be analyzed and whether they are central or exploratory outcomes.
33. Section 3.2 ("What will happen when the research is complete?") states that findings will be used to inform future nutrition programming. Given the long-standing involvement of the Aga Khan University Department of Community Health Sciences in nutrition research and programming, further clarification is needed on what specific gaps this study is intended to address and how it will meaningfully inform or improve existing programs.

Title: **Cultural Adaptation and Randomized Controlled Trial evaluation of an Online Parenting Intervention to Reduce the Risk of Depression and Anxiety in Adolescents.**

Project #	PI Name & Address
NBCR-1377	**Dr. Um I Lela** Pakistan Institute of Living and Learning (PILL) Karachi

Final NBC-R Comments

1. The total sample size is not distributed to specify the precise number of participants to be recruited in each of the eight cities.
2. The document lacks specific details on the exact method for allocating participants to the intervention and control arms.
3. The inclusion criteria specify "computer literate" participants, yet a consent form template for those "unable to read and write" is included, creating a logical inconsistency.
4. The stated exclusion criteria are phrased in a manner that is potentially incorrect or requires clarification to ensure accurate application.
5. Inadequate Safeguarding Pathways: Mental health referral pathways must be specified for each participating city, including protocols for emergency and after-hours situations.
6. Recruitment through schools and community health workers carries a significant risk of perceived coercion, undue influence, or compromised voluntariness of consent.
7. The protocol does not explain how participant confidentiality will be practically maintained during home-based or school-based assessments, where privacy cannot be guaranteed.

8. The role of Monash University beyond training and supervision is unclear. If data is to be shared internationally, a data transfer agreement is not provided.
9. The protocol states adherence to UK regulatory standards without justification for why local national ethical guidelines and regulations are not the primary framework.
10. 1.2 Although the study repeatedly uses the term "effectiveness", the design is a highly supported explanatory RCT, including weekly reminder phone calls, structured on-boarding, and intensive researcher involvement. This level of support is not reflective of routine care, thereby limiting true real-world applicability. The trial, as designed, is closer to efficacy testing, and the terminology should be corrected or justified explicitly.
11. 21 no anticipated harm", is ethically problematic for a mental health intervention involving adolescents and parents. Psychological distress, emotional discomfort, family conflict, and triggering of depressive or anxiety symptoms are foreseeable risks and should be acknowledged with a graded risk description rather than being dismissed
12. Is there any adverse event reporting form?
13. 2.2 Limited detail on adolescent assent, particularly: Age-appropriate assent procedures
14. Capacity assessment for adolescents, Handling disagreement between parent and adolescent
15. 2.3 Data are stated to be stored for 10 years, but justification, access governance after study completion, and cross-border data sharing (with Monash University) are not clearly outlined
16. The study participants will be approached in schools, colleges and community settings in 8 cities i.e. Karachi, Hyderabad, Lahore, Rawalpindi, Multan, Qamabar Shahdad Kot, Larkana, and Sukkar. Will the schools/ colleges be Government or Private, urban / rural what will be gender?
17. How many participants from each site shall be included?
18. Approval from all the sites is required.
19. What does community settings in this case mean?
20. Clearance from Secretary Education and support letters from head of institution is also required.
21. What will be qualification and experience of Lived experienced expert, will the same team will move in 8 cities of Pakistan, or will there be regional teams?
22. For what age group SMFG score of 8 will be considered significant for child version, as participants will be in age group of 6 – 19 years.
23. The project will be in collaboration with Monash University, Manchester UK and Australia, please specify the institutes, Co-PIs and their role.
24. Who will be the bilingual experts as the project will be done in different areas of Pakistan where there is huge difference in local language?
25. To train the CHWs script is designed who will be the role models?
26. Assessment will be done by trained researcher after 3 months, what will be their expertise and experience?
27. How the gaps will be filled if the score is low, especially of control group.
28. Exclusion criteria 1: "Absence of any physical or severe psychiatric illness". Do the researchers mean "presence of"?
29. Approaching adolescents via schools/educational institutions may lead to stigmatization. What will the researchers do to minimize this risk?
30. The protocol says that the recruitment will be through CHWs?
31. The students/parents participating may feel labeled, judged or questioned about anxiety disorders and/or parenting styles. What will researchers do about this?
32. Are the 6 study tools validated for use in Urdu?
33. How do these tools help the researchers "assess the effectiveness of PiP"?
34. Since PiP is an intervention in this study, it needs elaboration. It seems to be highly technical/analytical…is it in Urdu or any of the regional languages?
35. How there can be no anticipated harm of the study as mentioned in the protocol.

36. The Patient Information Sheet and Consent forms should be in simple Urdu language that is comprehensible.
37. Consent form for research team are required and 'who' in the research team is eligible is not mentioned anywhere.
38. The document lacks specific details on the exact method for allocating participants to the intervention and control arms.
39. The stated exclusion criteria are phrased in a manner that is potentially incorrect or requires clarification to ensure accurate application.

Title: **Evaluation and Validation of Screening Tools for Tuberculosis in Active Case Finding (Acf) Settings in Pakistan.**

Project #	PI Name & Address
NBCR-1379	**Dr. Abdullah Latif** MERCY CORPS (MC) PAKISTAN MERCY CORPS, 189/190, STREET 6, I-9/2 ISLAMABAD.

Final NBC-R Comments

1. The protocol assumes digital auscultation can detect TB-specific acoustic patterns, but biological rationale is not sufficiently discussed
2. Only presumptive cases and a small fraction of screen-negative participants undergo GeneXpert testing, which may result in undiagnosed TB among some participants and raises concerns about missed diagnoses and delayed treatment.
3. Data ownership and control are not clearly defined, particularly regarding whether device manufacturers or technology partners will have access to raw audio data or derived datasets.
4. The protocol does not include a conflict-of-interest statement regarding financial or in-kind support from device manufacturers or relationships between investigators and technology developers.
5. Although gender-sensitive practices are mentioned, there is no detailed description of how privacy will be ensured during chest auscultation or whether same-gender staff will be available upon request.
6. No clear plan is described for managing incidental findings detected on chest X-ray or digital auscultation, including disclosure, counseling, and referral.
7. Funding sources is not disclosed
8. The statement in the data management section; "Mercy Corps will make available the data... to its partners for research and evaluation purposes, this excludes personally identifiable information... unless specifically stated by the data recipient as necessary." It creates a loophole that could allow partners to request identifiable data. This clause must be removed and should be assured that all data sharing will be governed by a formal data transfer agreement.
9. The list of 14 districts is detailed, which is the huge area, what will be the catchment area.
10. Approval of DHQ is also required.
11. Who will be the Co-PIs in 14 districts?
12. All electronic records will be securely stored on Mercy Corps' encrypted servers with restricted access, where it will be in Pakistan or outside Pakistan, if it is outside, then data transfer permission is required.
13. In technical group, which Academic institutions and research institutions will be included, only name of AKU is given.
14. Algorithm development details are required. How validity of it will be done? Who are the experts? How hallucination might be tackled?
15. Which of the diseases may be considered in differential diagnosis?
16. Is the device approved to be used in Pakistan?
17. Any conflict of interest between device developers and research team?

Minutes of the NBC-R meeting held on 17-02-2026

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on February 17th, 2026. The following members of NBC-R attended the meeting:

Sr.#	Group-II	
1.	Prof. Jamshed Akhtar	Chair the Meeting
2.	Prof. Saqib Mehmood	Member
3.	Dr. Farkhanda Ghafoor	Member
4.	Prof. Akhtar Sherin	Member
5.	Mrs. Tayyab Rahat	
6.	Mr. Waryal Ali Daheri	

The following projects reviewed / discussed:

Title: **Effectiveness of Small-Quantity vs Medium-Quantity Lipid-Based Nutrient Supplements for Prevention of Undernutrition in Children Aged 6-12 Months: An Individually Randomized, Parallel-Group Non-Inferiority Trial.**

Project #	PI Name & Address
NBCR-1380	**Dr. SHABINA ARIFF** Department of Paediatrics and Child Health Aga Khan University, Karachi

Final NBC-R Comments

1. The data related to stunting from KPK is not shared so as to identify need of conducting the research in that geographical location and selection of Peshawar as a site.
2. Why specifically Dadu is identified as a site must be based upon some convincing reason rather than ease of conducting a research.
3. Who are the Co-PIs from Dadu and Peshawar?
4. Which area will be selected in Dadu and Peshawar, and on what basis these will be selected and who will be conducting the study in these areas?
5. Breast feeding needs to be practiced till 2 years, though the project states that it will continue along with the alternatives food, how the efficacy will be assessed
6. The stability of supplement, for how long it can be kept at room temp, considering the weather will be warm in coming days, the taste and acceptability related data may be provided specially of the intervention product.
7. By excluding moderately malnourished children, the trial tests prevention on a healthier subset, potentially denying a beneficial intervention to those who need it most and limiting generalizability.
8. It is not mentioned how the severely malnourished children found during the screening process will be given treatment and support.
9. Participants have the right to know what ingredients are being given to their child, yet the composition of the intervention is missing from the documentation. There is missing information on supplement administration and potential for child refusal. These practical details are necessary for parents to make an informed decision about their child's participation.
10. False claim of 'no side effects' for LNS in the consent form. There is possibility of allergic reaction or other potential gastrointestinal issues which should be mentioned.
11. There is a lack of a plan for post-trial care (e.g., anemia management) after study completion.
12. There is also ambiguity over who bears the cost of treatment for research-related medical conditions.
13. SQ is known/recommended for treatment of malnutrition while MQ for prevention. What is the justification for study objectives? (i.e., to evaluate of effectiveness of SQ vs MQ in

'reducing' malnutrition and anemia)

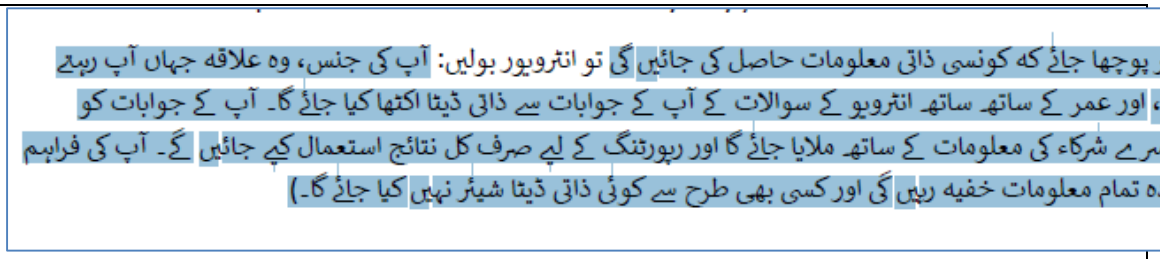
14. Section 2.1: Since the children will be receiving supplements through BISP nutrition program, receiving (or an effect thereof) either LQ or MQ cannot be stated as a "benefit" of the study
15. Section 2.2: Kindly specify what will be done to ensure that the caregivers (already on BISP) do not assume that the provision of food supplements is subject to consent to participate in the study. This is being asked based on the historical proof of therapeutic misconception and exploitation of the vulnerability of research participants.
16. Section 2.5: Here, "benefits" include not only the sharing of information but also the provision of supplements among communities. (The researchers may appreciate the difference)
17. What is the justification of all the questions in "02. SQ-LNS_RCT_Child Recruitment-Household Information Form_v3_Urdu"? (Since most of these questions are not justified based on the research objectives)
18. The consent forms must be translated to local languages both for the ease of participants and data collectors.
19. The consent forms must contain information about: a) Purpose of study, that the two types of sachets are being tested to see which ones are better at 'treating' malnutrition and anemia (writing the following statement is not justified:آپ سے ایک تحقیقی مطالعہ میں حصہ لینے کے لیے کہا جا رہا ہے جس کا مقصدآپ کے بچے کی صحت کو بہتر بنانے کے لیے غذائیت کےسپلیمنٹس کا استعمال کرناہے۔ ان سپلیمنٹس کی وجہ سے بچوں میں وزن اور قد میں اضافہ دیکھا گیا ہے)
20. The consent forms must contain all anticipated adverse events of the supplements (GI effects and allergies, etc.). It is not justified to write that there are no side effects.
21. Heel prick for a blood drop to test anemia will also cause mild, temporary discomfort to the baby and must be mentioned in the consent form
22. At one point it is written *"Potential risks to participants may include minor pain or discomfort during finger-prick hemoglobin testing*" whereas at other "*Participants experiencing any morbidity which includes diarrhea (liquid stools defined as ≥3 loose or watery stools within 24 hour), respiratory infection (cough plus rapid, difficult breathing), vomiting, fever, rash/sores, coughing, wheezing and pneumonia, will be referred immediately to the nearest health facility for appropriate management*." The study investigators will be notified within 24 hours, and follow-up will be conducted until the participant's condition has resolved." When the whole study team is from AKU, why this study cannot be conducted in AKU where the morbidities could be addressed and followed.
23. The study participants will be infants how they can give consent, it is detailed "*Written consent will be taken from the study participants before enrolment in the study, and their participation will be voluntary"* This is mentioned in the document.
24. Detailed itemized budget for each site may be submitted.
25. DSMB related details are required.
26. Adverse events related form is required.

Title: **People's Voice Survey: A Cross-Sectional Assessment of Population Perspectives on Health Systems in Pakistan.**

Project #	PI Name & Address
NBCR-1381	**Margaret Kruk, MD** Washington University in St. Louis 660 S. Euclid Ave, St. Louis, MO 63110, United States **Mr. Naveed Akhtar** Senior Manager Operation IPsos Pakistan, D-21, 2nd Floor, Talha Heights, D-Block, 6th Road, Rawalpindi
Final NBC-R Comments	
1. The IRB approval is of IPSOS is dated January 26, 2026, whereas the time frame for fieldwork given November 2025 through February 2026.	

2. All members are of IPSOS which is a bias. The PI and one Co-PI is from USA and Naveed Akthar from IPSOS. All members of the IRB committee are from IPSOS, which is a bias (The permission letter from Ipsos's internal review board was signed by the same individual listed as the local Co-PI. Furthermore, the composition of this internal board includes only the members of the institute with no mention of external, independent members).
3. The local Co-PI is listed as an "Assistant Manager Operations" from Ipsos, and no curriculum vitae or evidence of their research credentials is provided nor Ipsos's registration as a recognized research entity in Pakistan is not documented.
4. Furthermore, the specific role of the collaborating Aga Khan University is not outlined.
5. The CV of Co-PI from IPSOS Pakistan is missing, along with the name and CV of Co-PI from AKU.
6. The submission date of the NBC application is 18.1.2026, in the application it is detailed Washington University is under review, whereas the approval letter attached is dated 9.1.2026 and is not signed.
7. The survey is all over Punjab for recruiting the participants the cell phone numbers will be taken from a database including telephone numbers from the country's four main service providers (Jazz, Telenor, Zong & Ufone). Can these providers share the numbers without their consent?
8. Who will be in the Co-PI team to conduct the interview, telephonically as well as face to face?
9. While institutional IRB approval is mentioned, there is no evidence of mandatory approvals from national authorities such as National & Provincial Health Departments. Given the survey's breadth—including questions on trust in government and health system performance—clearance from the Ministry of Interior may also be legally required to permit the collection and international transfer of citizen data.
10. While data collection is detailed, the protocol lacks a correspondingly detailed plan for data analysis. It mentions weighting but does not describe the specific statistical methods that will be used to answer the primary research objectives.
11. The proposal creates a significant privacy risk by stating that "a selection of audio recordings" will be made for quality control. These recordings capture identifiable voices and potentially sensitive health information. There is no mention of a storage, access, or deletion protocol for these files, nor is there a plan for their secure transfer to international collaborators. Saving phone numbers is again a significant privacy risk.
12. The proposal states that de-identified data will be shared with Washington University in the US. Data Transfer Agreement (DTA) provided must ensure the data is handled according to both US and Pakistani laws, preventing unauthorized use or re-identification.
13. The survey includes questions on voting behavior (Q52) and sexual orientation/gender identity (Q53). These are highly sensitive topics in the Pakistani cultural and legal context. The protocol does not justify how these questions directly contribute to the study's stated objectives of assessing health system quality and utilization.
14. The budget lists "incentives" for participants, but the nature and value of these incentives are not described. This lack of transparency makes it impossible to assess whether the incentives are ethically appropriate.
15. The sampling strategy relies on a pre-existing (known list) phone database while claiming cross-national representativeness, which may introduce coverage bias and should be statistically justified.
16. Sample is collected only from Punjab province and may be generalized to whole Pakistan.
17. Personal data is collected, lacking details of storage of call recordings, data retention period, cross-border transfer to international collaborators, & applicable data protection safeguards.

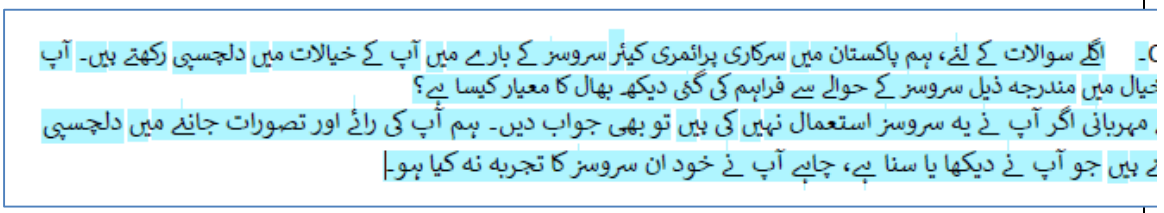
a.



پوچھا جائے کہ کونسی ذاتی معلومات حاصل کی جائیں گی تو انٹرویور بولیں: آپ کی جنس، وہ علاقہ جہاں آپ رہتے
، اور عمر کے ساتھ ساتھ انٹرویو کے سوالات کے آپ کے جوابات سے ذاتی ڈیٹا اکٹھا کیا جائے گا۔ آپ کے جوابات کو
ے شرکاء کی معلومات کے ساتھ ملایا جائے گا اور رپورٹنگ کے لیے صرف کل نتائج استعمال کیے جائیں گے۔ آپ کی فراہم
ہ تمام معلومات خفیہ رہیں گی اور کسی بھی طرح سے کوئی ذاتی ڈیٹا شیئر نہیں کیا جائے گا۔)

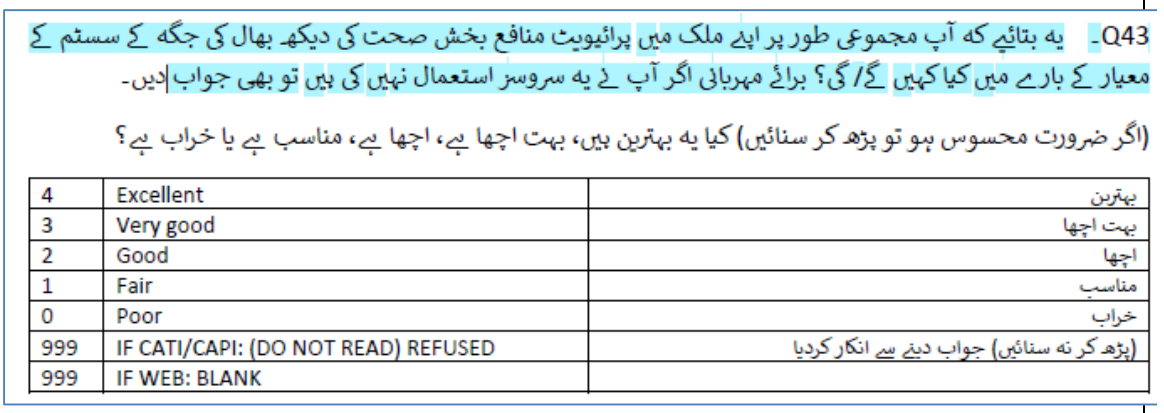
18. The questionnaire includes politically sensitive items, such as voting preference. .
19. Several items request perception-based ratings even when services have not been used, which may affect validity.

a.



۔Q اگلے سوالات کے لئے، ہم پاکستان میں سرکاری پرائمری کیئر سروسز کے بارے میں آپ کے خیالات میں دلچسپی رکھتے ہیں۔ آپ
خیال میں مندرجہ ذیل سروسز کے حوالے سے فراہم کی گئی دیکھ بھال کا معیار کیسا ہے؟
، مہربانی اگر آپ نے یہ سروسز استعمال نہیں کی ہیں تو بھی جواب دیں۔ ہم آپ کی رائے اور تصورات جاننے میں دلچسپی
ے ہیں جو آپ نے دیکھا یا سنا ہے، چاہے آپ نے خود ان سروسز کا تجربہ نہ کیا ہو۔

b.

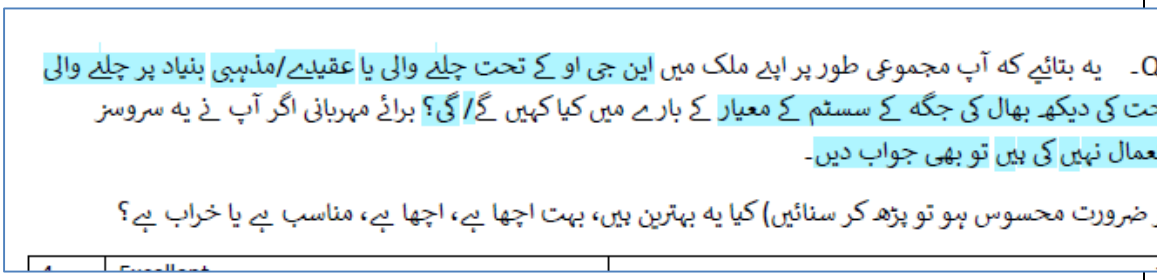


Q43۔ یہ بتائیے کہ آپ مجموعی طور پر اپنے ملک میں پرائیویٹ منافع بخش صحت کی دیکھ بھال کی جگہ کے سسٹم کے
معیار کے بارے میں کیا کہیں گے/ گی؟ برائے مہربانی اگر آپ نے یہ سروسز استعمال نہیں کی ہیں تو بھی جواب دیں۔

(اگر ضرورت محسوس ہو تو پڑھ کر سنائیں) کیا یہ بہترین ہیں، بہت اچھا ہے، اچھا ہے، مناسب ہے یا خراب ہے؟

4	Excellent	بہترین
3	Very good	بہت اچھا
2	Good	اچھا
1	Fair	مناسب
0	Poor	خراب
999	IF CATI/CAPI: (DO NOT READ) REFUSED	(پڑھ کر نہ سنائیں) جواب دینے سے انکار کردیا
999	IF WEB: BLANK	

c.



Q۔ یہ بتائیے کہ آپ مجموعی طور پر اپنے ملک میں این جی او کے تحت چلنے والی یا عقیدے/مذہبی بنیاد پر چلنے والی
حت کی دیکھ بھال کی جگہ کے سسٹم کے معیار کے بارے میں کیا کہیں گے/ گی؟ برائے مہربانی اگر آپ نے یہ سروسز
عمال نہیں کی ہیں تو بھی جواب دیں۔

ضرورت محسوس ہو تو پڑھ کر سنائیں) کیا یہ بہترین ہیں، بہت اچھا ہے، اچھا ہے، مناسب ہے یا خراب ہے؟

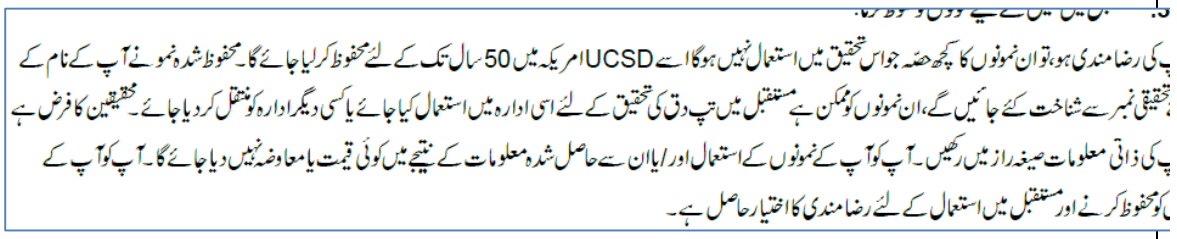
20. In study write up it is detailed “(INTERVIEWER IF ASKED ABOUT WHO IS OUR CLIENT: Our clients are Aga Khan University and Washington University, based in the United States of America.)” This needs clarification on what IPSOS is collaborating with AKU.
21. It is also detailed “Collaborators from Aga Khan University and leadership within the Punjab Ministry of Health are expected to play an active role in supporting uptake and dissemination of insights from the data, ensuring that results inform both provincial and national health system discussions” what about the other provinces.
22. The questionnaire is quite lengthy and needs more time than 30 minutes, will the participants get any compensation for telephonic as well as face to face interview.
23. In consent form it is written “This study is being conducted by Professor Margaret Kruk and the Quality Evidence for Health System Transformation (QuEST) Network at Washington University in St. Louis, USA, in collaboration with Ipsos Pakistan and Aga Khan University” who is Co-PI from AKU.
24. In consent for the question “Does the study involve any EXPERIMENTAL drug or procedure?” The response to this is “An experimental drug/procedure is the one which is still under testing and is yet not approved by relevant authorities for routine use due to inadequate scientific knowledge regarding safety and efficacy of the drug/procedure. This study does not involve any experimental drug or procedure.” This seems interesting.
25. In consent for the question “Whom should I contact for any query regarding the study?” The name of PI Professor Margaret Kruk, at Washington University in St. Louis.
26. Contact information for Ipsos Pakistan can be provided must be made available.

27. What is the advantage to Washington University after carrying out this research?
28. How will the research participants be recruited?
29. What is the role of Ipsos in Pakistan if all the data will be transferred to and analyzed at Wash U?
30. Why in the Informed consent, research participants are being told that the project is run by AKU (and Wash U)? While according to the application, this is a collaboration between Ipsos and WashU?!
31. Describe the inclusion and exclusion criteria
32. The informed consent needs revisions, must explain the purpose of the study, and what is required of the research participants.

Title: **Rapid Antigen Detection for TB Diagnosis from a Single Drop of Blood.**

Project #	PI Name & Address
NBCR-1382	**Antonino Catanzaro, MD** Professor Emeritus Department of Medicine, Division of Pulmonary, Critical Care, Sleep Medicine, and Physiology, University of California San Diego (UCSD)-USA **Dr Sabira Tahseen,** Dopasi foundation 61-62 Tipu Boulevard, Sector D DHA Phase II, Islamabad.

Final NBC-R Comments

1. The protocol involves international transfer of identifiable biospecimens (blood, saliva, urine) to UCSD with storage for up to 50 years; however, it does not clearly articulate compliance with applicable Pakistani regulatory requirements, defined timelines for sample destruction, safeguards against re-identification, governance mechanisms for secondary sharing, or procedures allowing participants to withdraw their stored samples in ***the future***.
2. Although the consent forms state that participation is voluntary, they provide limited explanation regarding the implications of long-term biobanking, the *justification* for extended storage duration, the scope of future *unspecified research*, the blanket provision for sharing with *other (unspecified) organizations*, potential commercial use disclaimers, and the practical limits of confidentiality in the context of cross-border data and specimen transfer.
   a. 
   پ کی رضامندی ہو،تو ان نمونوں کا کچھ حصہ جو اس تحقیق میں استعمال نہیں ہوگا اسے UCSD امریکہ میں 50 سال تک کے لئے محفوظ کرلیا جائے گا۔محفوظ شدہ نمونے آپ کے نام کے
   تحقیقی نمبر سے شناخت کئے جائیں گے،ان نمونوں کو ممکن ہے مستقبل میں تپ دق کی تحقیق کے لئے اسی ادارہ میں استعمال کیا جائے یا کسی دیگر ادارہ کو منتقل کر دیا جائے۔محققین کا فرض ہے
   پ کی ذاتی معلومات صیغہ راز میں رکھیں۔آپ کو آپ کے نمونوں کے استعمال اور/یا ان سے حاصل شدہ معلومات کے نتیجے میں کوئی قیمت یا معاوضہ نہیں دیا جائے گا۔آپ کو آپ کے
   ں کو محفوظ کرنے اور مستقبل میں استعمال کے لئے رضامندی کا اختیار حاصل ہے۔
3. The experimental test results performed in the USA will not be shared with participants, raising ethical considerations regarding clinically actionable incidental findings.
4. There is a commercial aspect of this study. When samples are being sent abroad then there must be some kind of negotiations between the researchers from US and Pakistani authorities.
5. As national TB reference lab is also involved then it is obligatory for CO PI from Pakistan to involve authorities from National TB control program.
6. What shall be amount paid to the study participants for travel?
7. The role of DOPASI foundation is more of biological material transfer. How this may be considered justified while regulatory authorities are not involved?
8. Ethics approval letter from Leprosy center is required.
9. What are the conflict of interest of Dr. Sabira Tahseen? To which organization she is currently working for?
10. What is the role of Dr. Sabira Tahseen in this research?
11. Who is the Co PI from the leprosy center?
12. What are the roles of healthcare providers from leprosy center?

Minutes of the NBC-R meeting held on 24-03-2026

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on March 24th, 2026. 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. Amjad Mehboob	Member
4.	Prof. Saira Afzal	Member
5.	Dr. Sualeha Siddique Shekhani	Member
6.	Prof. Ejaz Ahmad Khan (HSA)	Member
7.	Prof. Rameeza Kaleem	Member
8.	Prof. Ejaz Ahmad Khan	Member
9.	Prof. Faheem Ashraf Khan	Member
10.	Prof. Abubakar Ali Saad	Member
11.	Mrs. Tayyab Rahat	National Coordinator
12.	Mrs. Ayesha Abid	Assistant

The following projects reviewed / discussed:

Title: **Defining Antibiotic Levels in Intensive care patients (DALI-2).**

Project #	PI Name & Address
NBCR-1384	**Dr. Syed Faisal Mahmood** Department of Medicine Aga Khan University Karachi
Final NBC-R Comments	
1. Please clarify the need to ship the samples to University of Queensland? Can the testing not be done within the country? If need for transfer then an MTA is required. 2. Which other countries are involved in this project? 3. If it is detected that a patient received sub therapeutic levels of a drug, how would that eventuality be dealt with? Would it be communicated to the patient's family? Is there a mechanism to identify how such an event would be handled transparently?	

Title: **Estimation and Monitoring of Mortality from Cirrhosis and Hepatocellular Carcinoma Attributable to Viral Hepatitis B and C at a National Level.**

Project #	PI Name & Address
NBCR-1385	**Dr. Huma Qureshi** GI Clinic, Doctor's Plaza, Clifton Karachi
Final NBC-R Comments	
1. IRB approval from all collaborating sites is required. 2. There is a high risk of attrition bias and selection bias in this study. How will this be accounted for? 3. We could not find the data collection tool. 4. If this is an observational study then why are SAEs mentioned in the protocol? What events does the PI envisage? 5. Patients will be followed up for at least 5 years. Is there a budget approved for this study? We could not see it. 6. Are there any plans to export any material abroad? If so, please give details. 7. Does Doctor's Plaza have the necessary infrastructure to be labelled as a research site?	

Title: **DARSEM Trial: Diabetes and Ramadan Semaglutide Evaluation in Multicenters – A Real-World Study from Pakistan.**

Project #	PI Name & Address
NBCR-1386	**Dr Muhammad Daoud Butt** Umar Diabetes Foundation Umar diabetes Foundation, Malak shafait plaza, Mauza Mahal kot, Hathial, Main Murree Rd, Barakahu, Islamabad
Final NBC-R Comments	
1. The Informed consent form needs to be in a more simplified language. It would be difficult for participants to understand the term thromboembolic disorders. 2. How will this trial be advertised? Please provide details. 3. How will participants be compensated for their time involved in the trial? Is there any indemnity insurance provided in case of adverse events? Please provide details in the budget document. 4. Is there a trial oversight committee or DSMB? Who are the people involved in it? 5. DUHS IRB letter is missing.	

Minutes of the NBC-R meeting held on 31-03-2026

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on March 31st, 2026. The following members of NBC-R attended the meeting:

Sr.#	Group-II	
1.	Prof. Jamshed Akhtar	Chair the Meeting
2.	Prof. Nazli Hossain	Member
3.	Prof. Saqib Mehmood	Member
4.	Dr. Farkhanda Ghafoor	Member
5.	Dr. Natasha Anwar	Member
6.	Mrs. Tayyab Rahat	National Coordinator
7.	Ms. Ayesha Abid	Assistant

The following projects reviewed / discussed:

Title: **Perceptions and Preferences for Cardiovascular Disease Prevention: A Study on the Development of an mHealth Application for High-Risk Urban Sedentary Workers in Pakistan.**

Project #	PI Name & Address
NBCR-1387	**Dr. Samina Akhtar** Aga Khan University, Stadium Road, Karachi

Final NBC-R Comments

1. Title is deceptive as Pakistan is mentioned. It may be removed. The study shall be done at three selected sites in Karachi only.
2. The study employs a combination of qualitative (interviews), quantitative (KAP questionnaire), and usability (SUS) assessments. However, the study design is not explicitly stated.
3. There is no description of how different data components will be integrated. Clearly define the study design (e.g., **convergent mixed-methods**: simultaneously collecting and analyzing separate quantitative and qualitative data during a single study phase) and describe the integration strategy.
4. Any reference of AKU policy on code of good research?
5. The study will be conducted at the Aga Khan University, Institute of Business Administration, and branches of United Bank Limited in Karachi, Pakistan. From how many branches the participants will be enrolled.
6. The signature of the PI is missing from the NBC form
7. Recruitment within institutional workplaces (AKU, IBA, UBL) raises concerns of possible pressure or obligation to participate. There are no details in the proposal or NBC submission outlining how voluntariness will be ensured or how undue influence will be mitigated. The investigators should clearly describe how recruitment will be conducted independently of supervisors or line managers, and what measures will be in place to ensure that employees do not feel pressured to participate and explicitly communicate in the form of an interview script that participation or refusal will have no impact on employment, performance evaluation, or workplace relationships
8. Collection of sensitive health data in workplace settings may present risks of perceived or actual breaches of confidentiality and re-identification within subgroups. The PI must ensure no individual-level data sharing with institutions and limit reporting to aggregated, de-identified data, this should be mentioned in the proposal.
9. While the proposal states that a multidisciplinary team (including clinicians, mHealth experts, developers, and others) will be consulted during the brainstorming and design phases, there is insufficient clarity regarding the composition of this team, their formal involvement, and defined roles and responsibilities. It remains unclear who will lead key components such as app development, selection and implementation of behavior change strategies, and interpretation of KAP findings within a socio-cultural and

behavioral framework. The described process appears consultative rather than structurally integrated, raising concerns about whether appropriate expertise will meaningfully inform decision-making. The investigators should clearly specify team composition, expertise, and accountability across stages of design, analysis, and interpretation to ensure both scientific validity and ethical robustness of the intervention.

10. The PI has not addressed issues related to Digital Data Governance (mHealth App), the proposal lacks detail on data ownership, storage, access, and future use of app-generated data. The PI should include a clear data governance framework, including ownership, storage location, access control, retention, and prohibition of unauthorized secondary use.
11. The study may inadvertently reflect existing workplace wellness policies or employee adherence. The investigators should recognize this and clearly state that the study does not evaluate institutional performance; ensure aggregated reporting only, no inter-institutional comparisons, and define a data use and dissemination plan.
12. There should be a statement within the informed consent and proposal that data will not be used for employee monitoring.
13. Restricting participation to smartphone users introduces digital inequity. The investigators should acknowledge this as a limitation and discuss implications for generalizability.
14. Excluding individuals with prior CVD is scientifically valid but raises equity considerations. The PI should provide ethical justification and indicate potential inclusion in future work.
15. Voice recordings and consent for Voice recordings. It is hoped they are letting them know that they will be storing these voice recordings for a while.
16. PI must add a line or two on how long the voice recordings will be saved after being transcribed how they will be destroyed.
17. Consent should be both in English in Urdu
18. Why are they only engaging with staff sitting behind computer? What about the guard or the lower staff who sits in the office all day and have many more risk factors for a heart disease than those who are sitting behind computer and have some knowledge of the disease also.
19. The use of reminders and behavior change techniques within the app needs to be approached carefully and with transparency. Participants should be clearly aware that these features are designed to influence behaviour and should have the ability to customize or disable prompts. At present, there is no reference to established behaviour change frameworks or guidelines, despite these being well developed and widely available. This also links back to the need for appropriate expertise within the team, having individuals experienced in behavioural and mHealth interventions would strengthen both the design and ethical robustness of the proposed app.
20. Audio recording in workplace settings may compromise privacy, many organizations have strict policies about this but there is a lack of awareness and planning related to this aspect in the proposal. The investigators must outline how they will ensure strictly private settings and secure handling and deletion of recordings.
21. Given the mHealth element, additional oversight is advised such as a data and ethics oversight mechanism for monitoring compliance and data security.
22. Will there be a gender wise distribution?
23. The support letters from Institute of Business Administration, and branches of United Bank Limited in Karachi, may be shared.
24. In total 242 participants will be enrolled, how many from each institute and of which gender?
25. The questionnaire to be used will take more 30 minutes to complete.
26. There are irrelevant questions, especially on alcohol use, and also in WHO step questionnaire, which are not study related.
27. The alcohol section, drawn from the WHO STEPS instrument, is overly detailed. This level of detail may increase non-response or social desirability bias, as well as participant discomfort or suspicion.
28. The IPAQ-derived physical activity section is lengthy, and many questions on vigorous

work activity are likely irrelevant for sedentary office workers as in inclusion criteria f the study.
29. How validation of the study instrument done?
30. The study and informed consent forms describe participation as having "no foreseeable risk," which underestimates potential harms. The investigators should acknowledge possible psychological, privacy, and workplace-related risks and outline mitigation strategies.
31. The app involves ongoing data collection and behavioral prompts but this is not clear in the informed consent document and if there are options to opt out of certain features.
32. Clarity of study phases and consent process is needed, there are two separate informed consent forms, one for Phase 1 (KAP survey and risk factor assessment) and another for Phase 2 (mHealth app usability testing). However, the relationship between these two phases and the participant flow is not clearly described. Will all Phase 1 participants will be invited to Phase 2, or a subset will be selected, and if so, based on what criteria?
33. What will be the process for re-contacting participants from Phase 1? It seems as if Phase 2 is more of a sub-study. The participant pathway across phases (e.g., who progresses from Phase 1 to Phase 2) needs to be provided including the selection criteria for Phase 2 participants. The process for re-contacting and inviting participants for Phase 2 needs to be in the NBC form.
34. The consent form for assessing knowledge, attitude, practice, and CVD risk factors does not mention that body measurements (height, weight, waist circumference) will be taken, despite this being specified in the research proposal.
35. The protocol does not address how abnormal findings, such as severely elevated blood pressure, will be managed and referred for medical care.
36. Who will develop App? Professional?
37. Why multidisciplinary meetings shall cost a huge amount?
38. AKU IRB approval is of October 2025.
39. The budget include subscription of Nvivo. This huge subscription is required for analysis of 15 interviews that shall be conducted as a part of study. It needs justification as PI and CO PI belong to a university that can provide access to its faculty and students.
40. Travel cost appears too much. Justification is required as it will be used to visit IBA which is about six Km from AKU and probably the same distance for UBL.

Title: **Predictors of rate of weight gain in a CMAM program with a novel approach to moderate acute malnutrition in Sindh, Pakistan.**

Project #	PI Name & Address
NBCR-1388	**Dr. Alexandra Coria** Mount Sinai Hospita 1468 Madison Avenue, New York City, NY United States of America.
Final NBC-R Comments	
This project raises number of issues. This is supposed to be a secondary data analysis. NBC R Group 2 members would like to know of NBC has approved the primary data collection? The observations shall be shared once the clarity is made.	

Title: **The Health Sector Response to Gender-Based Violence and Sexual and Reproductive Health Programmes in Pakistan.**

Project #	PI Name & Address
NBCR-1390	**Dr Olive Shisana,** Honorary Professor EB Consulting (PTY) Ltd, aka Evidence Based Solutions 50 Long Street, Cape Town, South Africa.
Final NBC-R Comments	

1. Donor XX is mentioned in the form. It may be clarified.
2. The study involves a highly vulnerable population (GBV survivors), which elevates ethical risk. Potential psychological distress, re-traumatization, and social harm are not adequately addressed. No clear mitigation strategies are described for managing distress during or after interviews (Clear referral pathways like psychological, medical, legal, shelter services etc).
3. What is the interest of donors and researchers from outside Pakistan to collect the data on a very sensitive issue? How can this arrangement is justified?
4. The subject is very much known and being addressed in local context through governmental policies and legal framework. It is an internal matter of the country and data can be used for exploitation Pakistan in international arena.
5. This proposal it is not clear whether this is research, program evaluation, or quality improvement. It should be stated how this is research and not just quality improvement project.
6. There is limited evidence of understanding of operational realities in Pakistan. There is no clear description of how facilities will practically support this level of data collection, the feasibility of accessing survivors and sensitive populations.
7. The project is dependent on structured tools without reflection of contextual constraints (cultural, institutional, and logistical).
8. There appears to be very little stakeholder engagement and local ownership, with no clearly defined local institutional partner in Pakistan.
9. Why data is collected from ICT, Punjab & KPK only? Exclusion of provinces such as Sindh and Balochistan raises concerns about national representative.
10. Provide letter of support by the government health department (KPK, ICT, and PUNJAB) as well approval from all the facilities / centers from where data shall be accessed.
11. Selection of facilities appears partly purposive and partly random, which undermines generalizability.
12. Provide details of all the facilities from where data shall be collected.
13. There is no provincial health department involvement, program implementers or service delivery partners. Engagement with Ministry of Health appears limited to facility identification, not study design or implementation. As a result, it is not obvious how outputs (toolkits, scorecards, and roadmap) will be adopted, implemented, or sustained.
14. Study involves highly vulnerable population (GBV survivors) and yet there is limited discussion of context-specific risks in Pakistan, cultural sensitivities and stigma. The safeguards described are largely generic and not context-adapted.
15. Written consent process is described but how feasible it will be in sensitive GBV settings is not fully considered. Potential risks of participation (privacy, coercion, safety) require stronger contextualization, and the role of gatekeepers is mentioned but not clearly defined.
16. The plan is to include 10 facilities across Pakistan, 200 GBV survivors and multiple stakeholder interviews, without a clear feasibility and implementation plan there is a risk of superficial data collection, inconsistent data quality across sites.
17. Multidisciplinary approach stated but not clearly operationalized. There is limited clarity on involvement of local social scientists, gender/GBV experts within Pakistan which risks misinterpretation of context-specific findings.
18. Outputs include roadmap, toolkit, and scorecards but there is no clear pathway for policy uptake, no implementing body involved or referenced. Without stakeholder integration, outputs risk remaining theoretical rather than actionable.
19. Who owns the data generated in Pakistan?
20. The sampling approach lacks internal consistency and does not justify claims of representativeness.
21. The number of 10 facilities is justified mainly on logistical considerations, not on a defensible analytic framework
22. Provide itemized budget allocated for Pakistan. 15,000 dollars are for PI for a project that shall end in October 2026.
23. In consent form there is no mention of the contact person from Pakistan.
24. Where counseling services shall be provided for the victims in case psychological

distress occur?

25. Provide approval of collaboration with government of Pakistan for conducting this study.
26. Solutions are already available in literature and legislation in context of Pakistan, too. What additional information from desk reviews shall be gained?
27. The important data from Pakistan shall be shared to PI from other country and organization. How this arrangement can be justified?
28. Specific data transfer agreement is required.
29. Why high income countries in Commonwealth are excluded in this study. Huge literature is available that points towards gender based violence from those countries. By ignoring this aspect, it appears that LMIC are stigmatized.
30. The statement on confidentiality is vague and does not clearly specify the circumstances under which confidentiality may be breached or the measures in place to manage such breaches.
31. Your consent, bearing your name, will be gathered with your study responses is mentioned. This is how PI will ensure responses are anonymous?
32. Although every effort will be made to keep participant information confidential, complete confidentiality cannot be guaranteed. This is mentioned in Informed consent, page 3, under section, Risk and discomfort. This needs clarity.
33. The use of AI-assisted translation for questionnaires is inappropriate for sensitive research. Using artificial intelligence to translate questionnaires for local languages—followed by back-translation and correction by a local person—is risky. AI may mistranslate culturally sensitive terms and create confidentiality concerns depending on the platform.
34. No evidence of validated tools in local languages is found.
35. The sample is limited to Islamabad Capital Territory, Punjab, and Khyber Pakhtunkhwa, entirely excluding other provinces, including Karachi—the country's largest city and financial hub. This geographic exclusion introduces significant selection bias, limiting the generalizability of findings. The two facilities in Islamabad were selected purposively based on accessibility and location in the capital. This convenience sampling introduces selection bias and fails to represent typical facilities elsewhere.
36. In Punjab, facilities were selected using probability proportional to size (PPS) based on the highest number of victims, whereas in Khyber Pakhtunkhwa, simple random sampling was used due to unavailable victim data. Mixing sampling methods across provinces introduces inconsistency and undermines cross-provincial comparability.
37. The study does not clearly differentiate between facilities offering primarily sexual and reproductive health (SRH) services and those serving as dedicated gender-based violence (GBV) centers. Without this stratification, it is unclear whether service delivery gaps stem from a facility's core mandate, staffing, infrastructure, or broader systemic issues.
38. The statement that risks are "not more than those encountered in everyday life" is problematic and may indicate inadequate understanding of trauma-informed research.
39. Referral to "professional counsellors in a public facility" is insufficient, as public facilities may lack GBV-trained counselors and no on-site or immediate counseling is provided during data collection.
40. The numbering of data collection tools is inconsistent (e.g., after Tool 4, "Routine Evaluation Data Extraction Tool," the next listed is Tool 8, "Stakeholder Interview Guide").
41. Recruiting GBV survivors using an attendance register while they are receiving services at facilities raises coercion concerns, as participants may feel obligated to take part.
42. The confidentiality clause (Tool 2, p. 31) for GBV survivors states that confidentiality "may be broken … when you describe committed crime which requires to be reported" but does not specify which crimes, to whom, or under what legal obligation.
43. The proposal fails to account for Pakistan's specific cultural, religious, and legal context. For example, it asks about "forced to abort a baby" and "abortion services" without acknowledging Pakistan's restrictive abortion laws, potentially exposing survivors to fear of legal repercussions.
44. The study design does not adequately address the availability and quality of forensic

medical services for GBV survivors. Although tools include items on forensic equipment and staff training, the sampling strategy does not ensure inclusion of facilities with established forensic or medico legal services.

45. The protocol and tools lack clear, consistent definitions for "key stakeholders" versus "key informants." The terms are used interchangeably, and respondent groups overlap without clear distinction, creating confusion about interview purposes, respondent selection, and data analysis.
46. The data collection tools are lengthy, with repeated questions both across and within tools, increasing the risk of interview fatigue.
47. The major concern is population from three Dar-ul-Amans. Why are they including these institutions and the very vulnerable population? How will they protect the rights of these women any note on data safety measures.
48. These women will be forced to talk, consent is just a formality. There has to be a study neutral individual who will observe and report of the procedure. Also, we need clarity on how the responses are recorded, stored and presented.
49. There will be significant amount of data on STI in women how will it be protected.
50. There are "Notes" to the data collector to probe for "more or less" that needs to be explained.
51. In Dar ul Aman women are relatively free to speak, how will they ensure participants safety if they still live in the same household.
52. As far as the individual interviews are concerned very personal information is asked. How it shall be ensured that appropriate measures are taken to safeguard the data and the participants.

Chairperson NBC-R

Minutes of the NBC-R meeting held on 05-05-2026

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on May 5th, 2026. The following members of NBC-R attended the meeting:

Sr.#	Group-I	
1.	Dr. Faiza Bashir	Chair the Meeting
2.	Prof. Ejaz Ahmed Khan (HSA)	Member
3.	Prof. Amjad Mehboob	Member
4.	Assistant Prof. Sualeha Siddique Shekhani	Member
5.	Dr. Farah Asif	Member
6.	Dr. Faheem Ashraf Khan	Member
7.	Assistant Prof. Agha Riaz	Member
8.	Prof. Ejaz Ahmed Khan (Shifa)	Member
9.	Mr. Mazhar Iqbal	National Coordinator
10.	Mr. Waryal Ali Daheri	LDC

The following projects reviewed / discussed:

Title: **Diagnosis of postpartum haemorrhage at caesarean section: a multi-country diagnostic and prognostic accuracy study.**

Project #	PI Name & Address
NBCR-1391	**Dr. Sidrah Nausheen** Department of Obstetrics and Gynecology The Aga Khan University Karachi.
Final NBC-R Comments	
1. The reviewer appreciated the scientific merit and methodological rigor of the proposed study; however, several ethical and operational concerns were identified. Major observations included incorrect use of the term 'verbal assent' for competent adult participants, absence of clarity regarding relevant Pakistani regulatory authorities, lack of participant reimbursement details, and inadequate provisions concerning post-trial access to the investigational technology within Pakistan. Concerns were also raised regarding data retention policy, dissemination of study findings to participants and communities, and equitable access to the technology if validated.	
2. The reviewer questioned the rationale for not conducting the study at the main Aga Khan University Hospital and sought clarification regarding Pakistani investigators' access to pooled international data. Additional concerns included absence of local insurance coverage, ownership of intellectual property rights by the sponsor, affordability and accessibility of the technology for Pakistan after study completion, and lack of an itemized budget. The informed consent documents were also considered insufficiently developed.	
3. Clarification regarding details of the verbal consent process was recommended.	
4. The committee provided a comprehensive methodological and ethical appraisal of the protocol. While acknowledging the protocol as scientifically robust and aligned with internationally recognized methodological standards, including STARD-compliant diagnostic evaluation, Bland–Altman agreement analysis, and implementation science frameworks, the reviewer highlighted several substantive concerns requiring revision prior to approval. The reviewer observed that the study's sample size assumptions relied heavily upon optimistic estimates derived from limited prior evidence and recommended introduction of an internal pilot phase for empirical reassessment of variance and event rates. Concerns were also raised regarding the validity of the haemoglobin mass dilution method as the sole reference standard, with recommendations for sensitivity analyses and additional safeguards to account for systematic bias. From an ethical governance perspective, the reviewer emphasized the absence of a clearly articulated post-trial access	

strategy for participating low- and middle-income countries, particularly in relation to affordability and sustainability of the investigational technology following study completion. The existing data ownership framework was considered disproportionately centralized in the sponsoring institution, potentially limiting equitable scientific participation of LMIC investigators. The reviewer further noted that participant compensation and reimbursement mechanisms had not been adequately addressed despite the additional procedural burden imposed upon participants. Particular concern was expressed regarding the validity of postoperative consent in women recovering from emergency caesarean section, with recommendations for defined recovery intervals and formal assessment of decisional capacity prior to obtaining written consent. Additional recommendations included establishment of community advisory mechanisms, strengthening confidentiality safeguards for photographic data collection, implementation of comprehensive missing-data management strategies, and development of explicit participant dissemination plans utilizing culturally and linguistically appropriate formats.
5. The Committee acknowledged the national importance of improving TB diagnostics at primary healthcare level. However, the protocol requires significant ethical and methodological revisions, particularly concerning informed consent standards, adolescent participation safeguards, ethics oversight, participant reimbursement, and conflict-of-interest disclosure.
6. The reviewer questioned, how was this approved by FDA and in use in USA? If all the formalities are met, why is Oxford interested in its validation in LMICs?
7. The reviewer questioned, what is the long-term goal? Will these patients who are enrolled for this study get the treatment FREE or they will be charged in routine and is this the case with all the participating countries?
8. The reviewer questioned, can we afford the hardware and software required for this in LMIC or will this be provided by Gates foundation in future?
9. The reviewer asked, what is future risk of Tied AID?

Title: Capturing Women's Experience of Maternal Care in Sindh.

Project #	PI Name & Address
NBCR-1392	**Dr. Zahid Ali Memon** Department of Community Health Sciences Aga Khan University Karachi
Final NBC-R Comments	
1. The committee identified multiple ethical and procedural deficiencies requiring substantial revision. Concerns included potential coercion associated with consent procedures conducted by Lady Health Supervisors, lack of safeguards for postpartum women, absence of consent documentation in local languages, and inadequate mechanisms for illiterate participants. Additional concerns related to management of emotional distress, confidentiality obligations of government personnel, lack of data-sharing agreements, missing approvals from Sindh Health Department, and inconsistencies in study timelines.	
2. The committee expressed concern regarding additional workload being imposed upon Lady Health Workers and questioned the justification and novelty of the proposed study. Clarification was requested regarding consultant involvement, compensation for Lady Health Workers, and detailed budgetary allocation.	

3. The committee observed that the participant questionnaire appeared lengthy and raised concerns regarding administration in crowded or non-private settings. Clarification was also requested regarding language translation and local linguistic appropriateness of study instruments.
    - The committee noted that the protocol addressed an important public health gap relating to maternal healthcare experiences in Sindh and appreciated the collaborative engagement with government stakeholders. However, the reviewer identified major deficiencies in ethical governance and operational planning. The reviewer observed that:
    - The protocol lacked a dedicated and adequately developed ethics section despite involving postpartum women from socially and economically vulnerable communities.
    - Significant concern was raised regarding the use of Lady Health Supervisors as consent administrators due to the inherent power imbalance and potential for perceived coercion.
    - The reviewer further highlighted absence of structured safeguards for postpartum participants, inadequate confidentiality protections, and lack of procedures for handling sensitive disclosures such as obstetric violence or abuse, and absence of clearly defined participant withdrawal mechanisms.
    - Methodological concerns included an overly ambitious implementation timeline, insufficiently detailed quantitative analysis plan, limited operationalization of the TELOS framework, and absence of robust data quality assurance procedures. Recommendations were made for development of an independent consent process, establishment of trauma-informed interviewing protocols, implementation of formal data governance mechanisms, introduction of participant compensation procedures, and strengthening of statistical and operational planning.

Title: **Optimizing Tuberculosis Diagnosis at Primary Health Care Facilities in Pakistan through Integration of Near Point-of-Care NAAT.**

Project #	PI Name & Address
NBCR-1393	**Ms Kinz ul Eman** Dopasi Foundation Plaza 61 and 62, Tipu Blvd, Sector D, DHA phase 2, Islamabad.
Final NBC-R Comments	
1. The committee appreciated the relevance of the research in addressing tuberculosis diagnostic gaps at primary healthcare level. However, concerns were raised regarding absence of formal sample size justification, inadequate informed consent procedures, lack of participant reimbursement provisions, absence of community engagement strategies, unclear psychosocial support pathways for TB-positive participants, missing data-sharing agreements, and insufficient institutional ethics oversight documentation.	
2. The committee requested submission of a detailed itemized budget.	
3. The committee advised revision of the informed consent process in accordance with NBC standards and requested submission of revised consent documentation.	
4. The committee considered the scientific rationale acceptable in view of collaboration with national and provincial TB control programs and WHO evaluation of the proposed diagnostic approach	
5. Clarification was sought regarding district selection criteria, rationale for selecting the proposed point-of-care diagnostic technology, identification of personnel responsible for obtaining informed consent, and engagement of district health authorities.	
6. The committee acknowledged the protocol's relevance in addressing a major operational gap in Pakistan's tuberculosis control efforts and appreciated the pragmatic diagnostic framework. However, the reviewer identified several critical ethical and methodological shortcomings requiring substantial revision prior to implementation. The reviewer strongly objected to reliance upon verbal consent alone for a diagnostic	

research study involving clinical implications and recommended transition to documented written consent procedures with provisions for low-literacy participants. Serious concern was also expressed regarding inclusion of adolescents without appropriate parental consent and assent mechanisms. Additional concerns included absence of clearly identified ethics review bodies, inadequate de-identification procedures for participant data, unclear management protocols for tongue-swab-positive participants unable to produce sputum, and lack of adverse event reporting pathways. Methodologically, the reviewer considered the proposed enrolment target excessively large relative to calculated statistical requirements and recommended reduction of sample size with reallocation of resources toward implementation fidelity and qualitative strengthening. Recommendations were also made for propensity-adjusted site selection methods, formal conflict-of-interest disclosures, and explicit consent for international data sharing, and adoption of difference-in-differences analytical approaches to reduce temporal confounding.
7. The Committee observed that all three protocols addressed significant public health priorities relevant to Pakistan and other low- and middle-income country settings. Common strengths included operational relevance, policy-oriented objectives, and implementation-focused research methodologies. However, recurring deficiencies were identified across protocols, particularly with respect to informed consent standards, participant compensation mechanisms, data governance frameworks, community engagement, and protection of vulnerable populations. The Committee emphasized the need for stronger adherence to NBC-R ethical standards and recommended comprehensive revision of all protocols prior to reconsideration.

Minutes of the NBC-R meeting held on 05-05-2026

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on May 5th, 2026. The following members of NBC-R attended the meeting:

Sr.#	Group-II	
1.	Dr. Faiza Bashir	Chair the Meeting
2.	Prof. Shahid Mehmood Baig	Member
3.	Assistant Prof. Sarosh Saleem	Member
4.	Prof. Akhtar Sherin	Member
5.	Dr. Natasha Anwar	Member
6.	Prof. Shapper Mirza	Member
7.	Mr. Mazhar Iqbal	National Coordinator
8.	Mr. Waryal Ali Daheri	LDC

The following projects reviewed / discussed:

Title: **Preventing Mother-to-Child Transmission of Hepatitis B in Urban Slums of Islamabad: Community-Based Screening, Antiviral (Tenofovir) Intervention and Birth Dose Administration.**

Project #	PI Name & Address
NBCR-1394	**Dr Hassan Mahmood** Integral Global Consulting (IGC) office no.211B, Second Floor , Evacuee Trust Complex F-5 Islamabad
Final NBC-R Comments	
1. This proposal lacks clarity.	
2. Study settings are not defined, though CHW will be carrying out investigations, where will delivery take place, the procurement of vaccine and antiviral for mother and child. From where the meds will be provided. Quality and quantity of the medicines.	
3. The investigators should clarify why a community-based screening model in urban slums	

	is ethically preferable to strengthening antenatal clinic-based HBV screening and birth-dose vaccination. If poor access to antenatal care is the justification for the study, then the intervention should include a clear plan to link women to comprehensive antenatal and delivery care, rather than focusing only on HBV testing, Tenofovir referral, and vaccination follow-up.
4.	At what gestational age, mothers will be investigated, the diagnostic services which will be carried out, and later the antiviral.
5.	The proposal identifies the target population as women of reproductive age, 15–49 years. This means that girls aged 15–17 years may be recruited, including potentially pregnant adolescents. However, there is no specific framework for minors, assent, parental or guardian permission, married minors, unmarried pregnant adolescents, safeguarding, confidential counselling, domestic violence risk, or legal and social vulnerability. A 15-year-old pregnant girl in this context may raise concerns about child marriage, sexual exploitation, coercion, family violence, stigma, or lack of autonomy. Even if she is married, this does not remove the need for an adolescent-specific ethical and safeguarding plan.
6.	The investigators should describe how privacy will be maintained during door-to-door recruitment, consent, testing, counselling, and result disclosure. The protocol should explain where testing will occur, who may be present, how women can decline privately, and how positive results will be communicated without exposing women to household or community stigma.
7.	Community engagement should be clearly separated from individual informed consent. The protocol should state that engagement with community leaders, elders, LHWs, TBAs, and facility staff will not substitute for individual voluntary consent. It should also clearly state that refusal to participate will not affect access to healthcare, vaccination, referral, or other services.
8.	The study should include a baseline co-infection assessment for all HBsAg-positive pregnant women, including HIV and HCV testing, or provide a clear justification if these are not included. This is clinically important because co-infections may alter maternal risk, counselling, referral, treatment decisions, and long-term follow-up. HIV testing is particularly important before initiating Tenofovir, as undiagnosed HIV infection should not be inadvertently exposed to functionally incomplete antiretroviral therapy. The protocol should also describe referral pathways for women found to have HCV, HIV, advanced liver disease, renal impairment, or other clinically significant abnormalities.
9.	The proposal suggests that LHWs and TBAs may be trained to administer HBV birth-dose vaccine at home for home-based deliveries. This may be programmatically useful, but it requires more detail. The protocol should clarify who is legally authorized to administer vaccines, how cold chain will be maintained, how adverse events following immunization will be reported, how documentation will be linked to the EPI card, what will happen at night or during unplanned deliveries, and how missed birth-dose cases will be handled.
10.	The proposal plans to screen 7,500 women and vaccinate 7,312 HBsAg-negative mothers with three HBV vaccine doses. However, the budget lists only 1,000 rapid diagnostic kits and 3,000 Hepatitis B vaccine doses. The KPI table also states that 7,312 HBsAg-negative mothers will receive three doses, which would require far more than 3,000 doses if fully implemented. The investigators should reconcile the budget with the proposed targets and clarify which supplies will be project-funded and which will be provided through government or other sources.
11.	The budget allocates substantial funds to radio messages, print media, and cellphone awareness messages. The proposal also describes awareness campaigns using SMS, radio, pamphlets, and posters. While this may be appropriate for public health messaging, in a slum-based HBV study, communication must be carefully designed to avoid stigma. HBV can be associated with sexuality, drug use, infection risk, or "contamination." Public messaging that identifies slum communities as HBV targets may unintentionally reinforce discrimination. Messaging should avoid stigmatizing slum communities, pregnant women, HBV-positive mothers, or families. The protocol should also clarify whether the messages are general public health messages or targeted recruitment messages.
12.	The protocol should be revised to clarify whether this is research, service delivery, or implementation science. This distinction is important because the ethical obligations differ. The revised protocol should ensure that participant protection, adolescent

safeguarding, clinical monitoring, and antenatal care linkage are adequately addressed.
13. The English consent form is too generic for a slum-based PMTCT study. It does not adequately address adolescent participants, privacy during door-to-door screening, stigma, household disclosure, Tenofovir monitoring, co-infection testing, withdrawal from research versus continuation of care, or independent complaint mechanisms. These issues should be corrected before approval.
14. In the English consent form, it is stated: "If your test is negative: You may receive Hepatitis B vaccination (if needed)." This requires clarification. What does "if needed" mean in this context? If HBsAg-negative women are eligible for vaccination under the project, the criteria for vaccination should be clearly explained

Title: **Nursing Teleconsultation to Optimize Heart Failure Care and Reduce Emergency Visits in Low-Resource Settings of Pakistan: A Mixed Method Feasibility Study.**

Project #	PI Name & Address
NBCR-1395	**Dr. Rubina Barolia** Department of School of Nursing and Midwifery Aga Khan University Karachi
Final NBC-R Comments	
1. Pl identify the contribution of 2 other institutes, apart from Multan Institute of Cardiology.	
2. Why this study cannot be conducted at AKUH, since they also receive large number of patients from peripheral hospitals. Even Karachi, itself is so spread out that reaching the hospital itself requires a lot of efforts.	
3. The proposal should define what is meant by "low-resource settings." Where will the study be conducted? Does low resource refer to rural residence, low income, poor access to specialist care, lack of transport, limited digital access, or a combination of these? This is important because the intervention requires smartphone and WhatsApp access, which may exclude some of the very patients the study aims to support.	
4. Most of the PI's and the student are from AKU, why hasn't this study been done in Karachi?	
5. There is inconsistency in the study design.	
6. The synopsis describes Phase III as a single-arm pre-post feasibility study, but the consent form refers to randomization, intervention and control groups. This must be corrected. The title, objectives, methods, sample size, analysis plan, and consent form should all reflect the same study design.	
7. If this is a feasibility study, the primary focus should be feasibility, acceptability, safety, recruitment, retention, adherence to teleconsultation, and whether emergency referral pathways are practical. Reduction in emergency visits may be explored but should not be presented as a definitive effectiveness outcome.	
8. The clinical safety framework requires strengthening. Heart failure patients are clinically vulnerable, and teleconsultation should not create a false sense of safety or delay emergency care. The protocol should include symptoms to look out for, response times, cardiologist availability, documentation requirements, escalation pathways, and what happens if the nurse or cardiologist cannot be reached.	
9. The scope of the nurse-led intervention should be clearly defined. The protocol should clarify what advice nurses can provide independently, what requires cardiologist approval, how medication-related advice will be documented, and who carries clinical responsibility if a patient deteriorates after teleconsultation.	
10. The emergency referral pathway needs more detail. The protocol should clarify who will arrange transport, whether transport or emergency care costs are covered, which facility will receive the patient, how referral notes will be shared securely, and whom the patient or family should contact in an emergency.	
11. A stronger digital privacy and data protection plan is needed. The study involves phone calls, WhatsApp communication, and possible sharing of lab reports or referral notes.	

The protocol should explain whether personal or institutional phones will be used, who will access messages and call logs, whether messages will be deleted or archived, and how confidentiality will be maintained if family members answer the phone.
12. The role of caregivers requires clarification. If caregivers are involved in calls or care support, the protocol should explain whether they are research participants, whether consent will be taken from them, what information will be shared, and how patient confidentiality will be protected.
13. The study tools and interviews should be reviewed for sensitivity and privacy. Some questions may be personal, including income, marital status, employment, sexual activity, illness experience, and financial burden. Participants should be told they may skip any question, and interviews should be conducted in a private setting.
14. Data sharing and international collaboration require clearer explanation; there are clearly several international Co-PIs. The protocol should specify what identifiable and de-identified data will be collected, who will access it, whether any transcripts, recordings, analysis files, or de-identified data will be shared with international collaborators or sponsors, and whether data-sharing agreements are in place.
15. The study claims to address community-based heart failure care in low-resource settings, but recruitment appears to be from a tertiary cardiac clinic. The investigators should explain how "community-based" is being defined in this context.
16. The protocol should provide more detail on tele-nurse training, competency assessment, supervision, call audits, documentation standards, refresher training, and management of protocol deviations.
17. The study should include a clear adverse event and serious adverse event reporting plan, including clinical deterioration, emergency admission, death, medication-related errors, delayed referral, breach of confidentiality, and distress during interviews or calls.
18. Nurse-led teleconsultation may not have been formally evaluated for heart failure in Pakistan, but telemedicine and nurse-led chronic disease support are not new concepts. The novelty should be framed more modestly as a feasibility study of a context-adapted nurse-led teleconsultation model for heart failure care in this setting.
19. The Urdu consent form requires substantial revision before approval. The translation is not participant-friendly and contains several awkward or confusing phrases, formatting errors, incomplete contact information, and problematic consent language. The form does not adequately explain the clinical safety limits of teleconsultation for heart failure patients. Participants must be clearly told that teleconsultation is not a substitute for emergency care and that they should seek urgent medical attention for symptoms such as severe breathlessness, chest pain, fainting, worsening swelling, or sudden deterioration. The form should also explain the number and duration of calls/visits, digital privacy protections for phone or WhatsApp communication, whether calls will be recorded, what happens in an emergency, whether transport or emergency care costs are covered, and whether compensation is retained if the participant withdraws. Overall, the form should be rewritten in simple Urdu and reviewed for comprehension before use.
20. The English consent form also requires revision to include complete contact details, clearer adverse event support, independent complaint mechanisms, and a clearer distinction between research and routine care. 21. The consent form should not state that treatment for adverse experiences is "not applicable." Participants may clinically deteriorate, require emergency referral, experience distress, or face study-related communication issues. The consent form should explain what support will be provided, what costs are covered, and how adverse events will be managed.
22. The investigators should also explain how requiring smartphone/WhatsApp access aligns with the stated focus on low-resource settings

Title: **Social Determinants of Health and Surgical Outcomes in Children Undergoing Pediatric Surgery: A Multicenter, Longitudinal, Prospective Cohort Study in Pakistan.**

Project #	PI Name & Address
NBCR-1396	**Dr. Saleem Islam** Department of Surgery Aga Khan University Karachi.
Final NBC-R Comments	
1. The investigator is trying to compare apple with oranges.	
2. It is not clear who the participant is in this study. The child is the surgical patient, but most data appear to be collected from the parents and/or caregivers. The consent form should clearly state whether the participant is the parent/caregiver, the child, or both.	
3. Parental/guardian consent is needed, but age-appropriate assent should also be considered for older children and adolescents where appropriate. The current consent documents do not adequately address child assent.	
4. The timing of recruitment needs careful consideration. Families may be approached during surgical evaluation, admission, or before surgery, when they may be anxious or under pressure. The protocol should clarify how consent will be obtained at an appropriate time and how families will be reassured that refusal will not affect surgical care.	
5. The study asks sensitive questions about food insecurity, housing instability, transport problems, borrowing money, selling assets, and children leaving school, job loss, and household violence. These questions may cause distress, shame, or fear of disclosure. Participants should be clearly told they may skip any question without affecting care or participation.	
6. Domestic violence/safety questions require a specific response plan. If a caregiver discloses being physically hurt, threatened, insulted, or screamed at by family members, the study team should have a referral and safety pathway. It is not enough to collect this information without explaining how distress or risk will be managed.	
7. The protocol should explain what happens if serious social needs are identified, such as food insecurity, homelessness, inability to afford transport, or lack of follow-up care. If the study is identifying unmet needs, there should be at least a basic referral/resource pathway, even if the study is observational.	
8. The protocol should include a plan for managing emotional distress during interviews, including pausing/stopping interviews and offering referral if needed.	
9. The data protection plan should clearly explain how identifiers will be separated, who will access the linkage file, how long data will be retained, and how confidentiality will be protected.	
10. The protocol states that data will be stored on encrypted Stanford servers and available to researchers across participating institutions, while the NBC application suggests data sharing with the funding institution will be limited/de-identified. This needs to be clarified and consistent. The consent form should clearly state whether data, recordings, transcripts, or de-identified datasets will be shared with Stanford or any other international collaborator.	
11. The protocol should clarify whether the survey tools have been validated or adapted for the Pakistani context. Some terms and categories, such as “racial minorities,” housing examples, and social need categories, may not translate well into the local context and should be culturally adapted.	
12. The protocol mentions enrolling approximately 300–400 patients, but the qualitative aim states at least 10 participants from each hospital with a total of 40, which does not align if there are only two Pakistani hospital sites.	
13. The hypothesis should be revised for local relevance. The term “racial minorities” may not be appropriate in the Pakistani context unless the investigators define exactly what	

they mean and justify its use. More relevant categories may include ethnicity, language, province/region, migrant status, religious minority status, caste/community background, or other locally meaningful markers of structural disadvantage. These are sensitive categories and should only be collected if clearly justified, respectfully worded, and linked to a clear analysis plan.
14. "*This study will benefit society through an increased understanding of prevalent SDOH in pediatric surgery populations and how they impact surgical outcomes, allowing better, informed and directed interventions to prevent and limit their negative effects".* 15. This study may benefit society by generating Pakistan-specific evidence on social determinants of health among families of pediatric surgery patients and how these factors are associated with access to care, follow-up, and recovery. The findings may help inform future support systems, referral pathways, and policy-level interventions for vulnerable families. However, the study itself is not designed to prevent or resolve structural social determinants of health.
16. Semi-structured interviews with families experiencing food insecurity, housing instability, or transport barriers are appropriate, but this should be framed as understanding local mechanisms and lived experience rather than establishing that SDOH affect surgical care.
17. The children coming to AKUH, and Stanford, and then at Lahore Children Hospital, all belong to different sets of populations, how can the social determinants be identified.

Minutes of the NBC-R meeting held on 12-05-2026

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on May 12th, 2026. The following members of NBC-R attended the meeting:

Sr.#	Group-I	
1.	Prof. Nazli Hossain	Chairperson
2.	Dr. Faiza Bashir	Focal Person NBC
3.	Prof. Marie Andrades	Member
4.	Prof. Ejaz Ahmed Khan (HSA)	Member
5.	Prof. Amjad Mehboob	Member
6.	Assistant Prof. Sualeha Siddique Shekhani	Member
7.	Prof. Rameeza Kaleem	Member
8.	Dr. Farah Asif	Member
9.	Dr. Faheem Ashraf Khan	Member
10.	Assistant Prof. Agha Riaz	Member
11.	Prof. Ejaz Ahmed Khan (Shifa)	Member
12.	Mr. Mazhar Iqbal	National Coordinator
13.	Mr. Waryal Ali Daheri	LDC

The following projects reviewed / discussed:

Title: **RENEW: Recovery and Climate Resilience in Flood-Affected Areas of Sindh, Pakistan.**

Project #	PI Name & Address
NBCR-1397	**Mr. Yaqub Wasan** Department of Centre of Excellence in Women and Child Health Aga Khan University Karachi
Final NBC-R Comments	
1. The informed consent process is not described in sufficient detail. The justification for obtaining verbal consent instead of written consent is insufficiently explained. Adolescents are included in the study; however, assent procedures are only briefly mentioned.	
2. The process for documenting verbal consent is vague. There is no explanation regarding assessment of participant comprehension among low-literacy populations. Verbal consent has been proposed for brief procedures; however, written consent should also be considered, particularly where other procedures require written consent. English consent forms are missing from the submission.	
3. Mental health screening using PHQ-9 is not a trivial procedure and may uncover severe depression or suicidality. *If identified, the next steps should be clearly identified.*	
4. The proposal involves highly vulnerable populations including pregnant women, adolescent girls, malnourished children, disaster-affected communities, and economically disadvantaged populations. Although vulnerability is acknowledged, the proposal does not adequately operationalize participant protections.	
5. There is concern that participants may perceive participation as mandatory in order to receive services. *Since these are emergency situations, participants may feel that they are being coerced to participate.*	
6. Clarification is required regarding minimization of coercion or undue influence; whether refusal to participate will affect access to services; management of power dynamics involving LHWs and community mobilizers; protection mechanisms for adolescents discussing mental health issues.	

7. Guardian consent provisions for pregnant minors under 18 years referencing “husbands or household heads” are inconsistent with child protection standards and require revision.
8. Mental health ethics and referral capacity are insufficiently detailed.
9. The proposal includes large-scale PHQ-9 screening among women and adolescents, but downstream management of identified cases is inadequately described.
10. Clarification is required regarding emergency referral pathways, availability of trained counselors; crisis management procedures; psychiatric referral capacity in rural districts; management of suicidal ideation; emergency escalation procedures, qualifications of mental health personnel.
11. There is ethical concern regarding screening for mental illness without reliable treatment access.
12. Clarification is required regarding referral pathways for women scoring PHQ 15–27 and whether a psychiatrist is available within the study structure.
13. The application does not adequately specify: sampling methods, Statistical assumptions, sample size calculations, primary outcomes, implementation evaluation framework, and criteria for selecting facilities.
14. A discrepancy exists regarding study duration activities are proposed from October 2025 to September 2027, clarification is required regarding whether activities have already commenced.
15. Climate resilience outcomes are repeatedly referenced but not clearly operationalized with measurable indicators.
16. The proposal does not clearly specify participant compensation, travel reimbursement, management of referral costs, and financial support for severe cases.
17. High-risk pregnancies are proposed to be referred to public health facilities; however, many public health facilities lack adequate quality services.
18. Clarification is required regarding how best possible care for women will be ensured.
19. Children screened for Severe Acute Malnutrition (SAM) or Moderate Acute Malnutrition (MAM) without complications will receive supplementation; however, no management plan has been described for children with complications.
20. Clarification is required regarding whether verbal autopsies will be conducted for children who die during the study
21. Mandatory documentation gaps include local language informed consent forms; validated questionnaires; principal Investigator CVs, MOUs from all sites, CITI certifications; crisis protocols, conflict of interest declarations.

Title: **Impact of Postnatal Multiple Micronutrient Supplements on Rotavirus Vaccine Immunogenicity in Infants.**

Project #	PI Name & Address
NBCR-1399	**Dr. Fyezah Jehan** Department of Paediatrics and Child Health Aga Khan University, Karachi

Final NBC-R Comments
1. No explicit plan has been provided for post-trial access to an effective intervention.
2. If MMS Plus proves beneficial, clarification is required regarding continued access for participating communities after study completion.
3. The application states that consent will be signed; however, many participants may be illiterate. No mention is made of thumbprint procedures or independent witnesses for non-reading participants. No assent process has been described for minors.
4. Community leader engagement and permission processes should be documented where applicable.
5. Urdu-only consent documentation is inadequate for a multi-ethnic population including Sindhi, Pashtun, Punjabi and Urdu speakers. Consent materials should be provided in Sindhi and Urdu, with bilingual staff available for Pashtun and Bengali speakers. Biological Samples and International Transfer
6. Consent forms do not mention the amount of blood to be taken from mothers and infants.
7. Samples will be transferred to Cincinnati Children's Hospital Medical Center (CCHMC).Clarification is required regarding why sample testing cannot be conducted within Pakistan.
8. Clarification is required regarding Material Transfer Agreement (MTA), DRAP export authorization, CCHMC IRB approval, Chain-of-custody documentation.
9. Applicant should provide copies of data access agreements with the Gates Foundation and agreements governing sample transfer to CCHMC.
10. Confirmation is required that the funder cannot veto publication or alter primary findings.
11. A contradiction exists regarding participant compensation, one section states PKR 1,000 per visit (total PKR 4,000), another section states there will be no direct personal benefit or monetary compensation. These inconsistencies must be reconciled.
12. No independent Data Safety Monitoring Board (DSMB) or external safety monitor has been proposed.
13. Repeated infant venous blood collection requires independent oversight and clearly defined safety review mechanisms. *Most of the infants born are low weight infants, premature, how much blood and how many times it will be taken?*
14. As the study relates directly to the national immunization program, relevant governmental departments should be involved.
15. Clarification is required regarding selection of the three study areas.
16. Concern was raised regarding potentially over-researched communities and cumulative research burden.
17. Embedded study designs may create ambiguity regarding informed consent when new components are added.
18. Concern was raised regarding PI workload and concurrent management of multiple funded projects.
19. Clarification is required regarding dedicated FTE allocation and appointment of a deputy with day-to-day oversight authority.

Title: **Piloting a Standardized Breast Cancer Registry in Sindh Province, Pakistan: Replicating the WHO Global Cancer Registry Model.**

Project #	PI Name & Address
NBCR-1400	**Prof Nasim Chaudhry** Pakistan Institute of Living & Learning (PILL) Suite No. 201, 2nd Floor, The Plaza, Karachi.

Final NBC-R Comments
1. Clarification is required regarding ownership and long-term management of the cancer registry.
2. Clarification is required regarding whether the registry will transition to government ownership after completion of pilot funding.
3. Concern was raised regarding legal authority for non-governmental organizations to maintain disease registries.
4. Clarification is required regarding alignment with Pakistan's National Cancer Registry framework.
5. Registry data collection involves patient information despite the statement that there will be no direct patient contact except interviews.
6. Clarification is required regarding legal basis for data collection and storage under Pakistani law.
7. The proposal references UK GDPR-style data protection law without adequately explaining applicability within Pakistan.
8. Relevant Pakistani legal frameworks should be incorporated, including: article 14 of the Constitution of Pakistan, Prevention of Electronic Crimes Act (PECA) 2016, and Proposed Personal Data Protection Bill 2023.
9. Clarification is required regarding statements on confidentiality breaches related to misconduct or illegal activity disclosures.
10. Informed Consent and Participant Communication. Patient Information Sheets are available only in English. Urdu and local language versions are required. No mention has been made regarding thumbprint procedures or independent witnesses for illiterate participants.
11. Concern was raised regarding whether online privacy notices are sufficient for populations with varying literacy levels.
12. Consent procedures for cancer patients are inadequately described. No consent forms, interview guides, or participant information materials were submitted.
13. No evidence has been provided regarding engagement with community leaders; patient advocacy groups, religious or cultural representatives.
14. Clarification is required regarding official communication with relevant government departments.
15. The qualitative interview tool is missing.
16. Clarification is required regarding the role of the critical care doctor and joint PI.
17. Statistical objectives such as survival analysis and incidence trend analysis appear unrealistic for a six-month pilot.
18. Data storage location and possible international data transfer are unspecified. No data retention or destruction schedule has been provided.
19. No independent adverse event monitoring mechanism has been described. Risk management and community engagement budgets appear inadequate.
20. No Principal Investigator has been named. No co-investigators or accountable researchers are identified.
21. Funding body details are absent.
22. Institutional ethics approval is absent.
23. The "Moving on After Breast Cancer Programme" is mentioned but not defined.
24. Mandatory NBC-R documentation is largely missing.
25. *In presence of National Registry, participation in which is mandatory as per law, the need for this WHO led registry needs to be clarified.*

Minutes of the NBC-R meeting held on 12-05-2026

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on May 12th, 2026. The following members of NBC-R attended the meeting:

Sr.#	Group-II	
1.	Prof. Nazli Hossain	Chairperson
2.	Dr. Faiza Bashir	Focal Person NBC
3.	Prof. Saqib Mehmood	Member
4.	Assistant Prof. Sarosh Saleem	Member
5.	Prof. Akhtar Sherin	Member
6.	Mr. Mazhar Iqbal	National Coordinator
7.	Mr. Waryal Ali Daheri	LDC

The following projects reviewed / discussed:

Title: **Impact of Biosynthetic Semaglutide on Glycemic Control (HbA1c) in Patients with Type 2 Diabetes Mellitus: A Cohort Study from a Tertiary Care Hospital in Karachi, Pakistan.**

Project #	PI Name & Address
NBCR-1401	**Dr. Najmul Islam** Professor, Department of Medicine Aga Khan University, Stadium Road, Karachi

Final NBC-R Comments

1. The Committee asked investigators to clearly explain what participant data will be shared with the sponsor and whether any identifiable information will be accessible to the sponsor.
2. It was suggested to add a clear statement regarding data confidentiality, data storage, and protection of participant privacy.
3. The Committee requested clarification regarding who will bear the cost of treatment and medical care in case of study-related adverse events or complications.
4. Members asked whether participants will receive any reimbursement or compensation for travel, investigations, or research-related injury.
5. Clarification was requested regarding whether the study medication (Sematide) will be provided free of cost or purchased by participants as part of routine care.
6. The informed consent form should clearly mention that participation is voluntary and refusal will not affect routine treatment.
7. The Committee advised simplifying participant information and consent language for better participant understanding.
8. Further clarification was requested regarding safety monitoring, reporting of serious adverse events, and emergency management procedures.
9. The Committee noted that the study primarily evaluates change in HbA1c as the main outcome measure. Members suggested that the investigators clearly justify the selection of HbA1c as the primary endpoint and explain whether additional clinically relevant effectiveness and safety outcomes will also be adequately assessed during follow-up.
10. The Committee asked investigators to clarify post-study access to medication for participants who benefit from treatment.
11. Members recommended adding more details regarding sponsor role in data analysis, publication, and access to study data.
12. The investigators were advised to address possible selection bias due to recruitment from a single tertiary care hospital.

Title: **An open-label, randomized, single-dose, two-treatment, two-period, 2 x 2 crossover bioequivalence study ofTAGIPMET XR (Sitagliptin-Metformin Extended-Release) 100/1000 mg tablet in healthy volunteers under both fasted and fed condition..**

Project #	PI Name & Address
NBCR-1402	**Dr. Sadia Asim** Institute of Biological, Biochemical & Pharmaceutical Sciences (IBBPS) Dow University of Health Sciences, (DUHS) Ojha Campus, Karachi, Pakistan

Final NBC-R Comments

1. Sponsor involvement should be clearly defined and limited. Sponsor should have no influence on data analysis, interpretation, or publication.
2. The study flyers have emotional language; it should be informative not emotional.
3. Consent is not informative. Participant information should clearly explain risks, duration, and compensation in more details and information regarding multiple visits must be given in consent. Further, timing of consent should be clearly stated, it will be taken before screening or after.
4. Although insurance coverage is mentioned, the protocol should include copy or confirmation of insurance certificate, clear statement that insurance covers all study-related injury, including hospitalization and delayed adverse events
5. Total number of visits should be clearly stated in participant documents. All phases (screening, Period I, washout, Period II, follow-up) should be clearly outlined. Time commitment, fasting requirements, and overnight stays should be clearly mentioned.
6. Screening cost is high. All screening investigations should be free of cost for participants.
7. Clear glucose thresholds for intervention should be defined. Stopping and withdrawal criteria must be operationally specified. Safety monitoring procedures should be simple and actionable.
8. Total number of blood samples and total blood volume should be clearly stated. Participants should be reassured about safety limits and procedural burden.

Title: **An open-label, randomized, single-dose, two-treatment, two-period, 2 x 2 crossover bioequivalence study of Nuberol Forte (Paracetamol 650mg + Orphenadrine 50mg) tablets in healthy volunteers under fasting conditions.**

Project #	PI Name & Address
NBCR-1403	**Dr. Sadia Asim** Institute of Biological, Biochemical & Pharmaceutical Sciences (IBBPS) Dow University of Health Sciences, (DUHS) Ojha Campus, Karachi, Pakistan.

Final NBC-R Comments

1. The comparator/reference product name should be clearly mentioned in the title along with Nuberol Forte. This ensures clarity in regulatory and ethical review.
2. Sponsor involvement should be clearly defined and limited. It should be stated that the sponsor will not influence data analysis, interpretation, or publication. Investigators must retain full independent access to study data and publication rights.
3. Consent is not informative. Participant information should clearly explain risks, duration, and compensation in more details and information regarding multiple visits must be given in consent. Further, timing of consent should be clearly stated, it will be taken before screening or after.
4. Total number of visits should be clearly stated in participant-facing documents. Study periods (Period I and Period II), washout phase, and follow-up should be clearly explained. Time commitment, fasting duration, and any overnight stay requirements should be explicitly mentioned.
5. All screening investigations should be free of cost for participants. Participants should not bear any financial burden even if screen-failed. Reimbursement policy for time and inconvenience should be clearly defined, if applicable.
6. Specific safety monitoring parameters should be defined for anticholinergic and analgesic-related adverse effects (e.g., dizziness, sedation, dry mouth). Clear stopping rules and withdrawal criteria should be included. Emergency management plan should be simple, operational, and readily implementable.
7. Total number of blood samples and total blood volume should be clearly stated in participant documents. Participant information should reassure that sampling remains within safe clinical limits for healthy volunteers.

Minutes of the NBC-R meeting held on 19-05-2026

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on May 19th, 2026. The following members of NBC-R attended the meeting:

Sr.#	Group-I	
1.	Prof. Ejaz Ahmed Khan (HSA)	Chair the Meeting
2.	Dr. Faiza Bashir	Focal Person NBC
3.	Prof. Marie Andrades	Member
4.	Prof. Amjad Mehboob	Member
5.	Prof. Rameeza Kaleem	Member
6.	Dr. Faheem Ashraf Khan	Member
7.	Assistant Prof. Agha Riaz	Member
8.	Mr. Mazhar Iqbal	National Coordinator
9.	Mr. Waryal Ali Daheri	LDC

The following projects reviewed / discussed:

Title: **Multiple sclerosis Registry via clarum software/tool.**

Project #	PI Name & Address
NBCR-1389	**Dr. Naila Shahbaz** Neurology Department, Dr. Ruth K.M. Pfau Civil Hospital Karachi, Dow University of Health Sciences, Baba - e - Urdu Road, Karachi
Final NBC-R Comments	
1. The application does not specify the number of participating centers or the estimated total patient enrollment. This information is fundamental for assessing the feasibility and scope of a national registry and must be provided.	
2. Data quality assurance mechanisms are entirely absent, particularly for a multi-site setting where standardized data collection and monitoring are critical to registry integrity.	
3. The consent form is missing critical details. Use of local languages is mandatory when the registry extends to provincial centers. Mechanisms to ensure comprehension among low-literate populations — such as verbal explanation and back-translation — must be described.	
4. IRB contact information and researcher contact numbers are absent from the consent form and must be added.	
5. Data ownership is not specified. It is unclear whether Roche Pakistan has access to identifiable or anonymized participant data, and whether Roche may use registry data for commercial purposes such as market analysis or treatment pattern surveillance.	
6. Server location is not disclosed. If data is stored outside Pakistan, applicable safeguards and cross-border data transfer agreements must be described.	
7. Data retention duration and destruction procedures are not mentioned anywhere in the application.	
8. Roche Pakistan is providing the Clarum software, valued at approximately US$2 million. As a pharmaceutical company with active commercial interests in MS treatments, Roche's sponsorship of a national MS registry constitutes a significant potential conflict of interest. A national MS registry could generate data of substantial commercial value for market analysis, treatment pattern surveillance, and promotional activities. No conflict-of-interest declaration is present in the application.	
9. The application indicates no support from relevant government departments. A national registry should carry government oversight at both provincial (DoH) and federal (MoNHSRC) levels rather than being solely sponsored by a pharmaceutical company. Government buy-in at both levels must be secured before the registry is permitted to	

proceed.
10. There is no discussion of long-term sustainability. The protocol does not address what happens to the registry when Roche's funding ends.
11. Community engagement and benefit sharing are declared 'not applicable.' For a national registry of MS patients, this determination is incorrect. These sections are fully applicable and must be completed in the resubmission.
12. Familiarity with clinical ethics or patient care does not equate to competence in research ethics. Without formal training, staff may fail to recognize subtle ethical issues such as therapeutic misconception, coercion, or improper data handling. All major international frameworks — CIOMS, WHO, and the Declaration of Helsinki — mandate appropriate research ethics training for all research team personnel. All members of the research team must complete CITI certification or an equivalent recognized program covering data safety and research ethics prior to commencement.
13. Multiple sections of the application are marked 'Not Applicable' or left blank despite being fully applicable to this study. These include: community engagement, benefit sharing, adverse events, data storage and sharing, and staff protection. All must be addressed in full.

Title: **Umbilical Cord Derived Stem Cells for the Treatment of Chronic Diabetic Wounds.**

Project #	PI Name & Address
NBCR-1398	**Dr. Azra Mahmood** Center of Excellance in Molecular Biology, University of Punjab Lahore

Final NBC-R Comments

1. There is no evidence provided that the stem cell processing laboratory holds ISO certification (e.g., ISO 15189 or ISO 13485), Good Laboratory Practice (GLP) accreditation, or Good Clinical Practice (GCP) compliance. For a first-in-human cell therapy trial, all cell processing, storage, quality control, and clinical activities must be conducted in a certified, auditable, and validated facility. Evidence of staff training, SOPs, quality assurance systems, and GCP-compliant documentation must be submitted before the study can proceed.
2. The protocol and NBC-R form contain contradictory information regarding umbilical cord transport conditions. One document state that cords will be transported refrigerated below 10°C, while another states transportation at room temperature (25°C). This discrepancy represents a major cold-chain and GLP compliance concern and must be resolved with a validated transport protocol.
3. The protocol specifies second-passage cells for the amniotic membrane construct but does not define the passage number for injected stem cells. All treatment groups must receive cells from a predefined, validated, and reproducible passage number with documented batch consistency and release criteria.
4. Group C involves curcumin-primed stem cells; however, the dose, solvent, formulation, exposure duration, and validation data are not provided. Statements such as "already optimized" without supporting experimental evidence, references, or SOPs are not acceptable under GLP standards.
5. The protocol lacks adequate laboratory-specific validation and release data demonstrating that Wharton's Jelly Stem Cells (WJSCs), primed WJSCs, and WJSC-amniotic membrane constructs can be manufactured reproducibly and safely for human use. Batch-level sterility, identity, viability, potency, genomic stability, transport validation, and quality-management data must be provided.
6. Detailed quality-control specifications and batch release criteria are absent. The investigators must provide testing procedures and acceptance criteria for sterility, endotoxin levels, mycoplasma testing, cell viability, immunophenotyping, genomic stability, and tumorigenicity/transformation potential prior to human administration.
7. The NBC-R form lists four collaborating institutions, whereas the protocol mentions only two. Roles and responsibilities of all participating sites are unclear, and no coordination or governance mechanism has been described. Institutional MOUs and governance arrangements between collaborating centers must be submitted.
8. Institutional ethics approval documentation from all participating centers has not been provided. Approval letters, submission evidence, or timelines from all collaborating institutions are required before review can proceed further.
9. The study setting is inadequately defined. It remains unclear whether participants will be enrolled and treated in Lahore, Islamabad, or both, and whether all participating centers possess adequate infrastructure, emergency support, biosafety measures, and trained personnel for administration of investigational cell therapy.
10. Sample size determination is inadequate. Although the NBC-R form mentions 40 participants (10 per group), no statistical justification or power calculation has been provided. Testing multiple experimental interventions with such a small sample size is unlikely to yield interpretable efficacy outcomes and may expose participants to risk without meaningful scientific value.
11. The protocol does not contain a statistical analysis plan. Detailed methodology for statistical testing, handling of missing data, interim analysis, dropouts, intent-to-treat analysis, and comparative analysis between treatment groups must be included.
12. The randomization process is insufficiently described. A clear, reproducible, and bias-minimizing allocation procedure must be detailed, including allocation concealment and implementation procedures.

13. Blinded wound evaluation is mentioned; however, procedures to ensure evaluator blinding and inter-rater reliability testing among blinded assessors have not been described and must be incorporated into the protocol.
14. The proposal appears inconsistent with the 2023 IWGDF recommendations, which conditionally support placental-derived products only as adjunctive therapy after failure of optimized standard care. The current study instead compares multiple experimental cell-based interventions without adequately demonstrating prior failure of optimized conventional wound management.
15. The definition of "standard of care" for the control group is unclear. Detailed information regarding wound cleaning procedures, dressings, antibiotics, off-loading strategies, debridement protocols, and other supportive measures must be provided. It should also be clarified whether controls will receive any sham injection or procedure.
16. The inclusion criterion "Suitable for Liposuction" appears unrelated to the proposed intervention and requires clarification or removal.
17. The protocol includes participants as young as 15 years without scientific or ethical justification for inclusion of minors. Procedures for guardian consent, participant assent, and additional protections for adolescents are absent and must be addressed.
18. Follow-up duration of 12 weeks/3 months is inadequate for a first-in-human stem-cell therapy study. Long-term surveillance plans for delayed adverse events such as abnormal tissue growth, immune reactions, ectopic differentiation, cell migration, or tumorigenesis must be incorporated, preferably extending to 6–12 months.
19. There is no independent Data Safety Monitoring Board (DSMB) information provided. A formal DSMB charter must be submitted, including names, qualifications, independence from the study team, stopping rules, adverse-event review mechanisms, and scheduled safety review meetings.
20. Regulatory approval status from the Drug Regulatory Authority of Pakistan has not been clarified. Evidence of approval, submission status, or regulatory pathway documentation for the investigational cell therapy product must be provided.
21. Donor screening procedures are inconsistent and incomplete. While HBV, HCV, and HIV testing are mentioned in one section, broader infectious screening (e.g., TORCH, herpes viruses) appears elsewhere without clarification. Comprehensive donor eligibility criteria, infectious disease screening, traceability mechanisms, and biospecimen tracking systems must be submitted.
22. The source and procurement procedures for amniotic membrane are inadequately described. The protocol must clarify donor source, consent procedures, infectious disease screening, and whether placentae/amniotic membranes originate from the same or different donors as the umbilical cords.
23. The duration and conditions of storage for umbilical cord-derived stem cells are not specified. Procedures for cryopreservation, labeling, monitoring, inventory control, and traceability must be documented.
24. Procedures for handling, storage, future use, and disposal of leftover biological material and unused stem cells are absent. Clear safeguards must be provided to ensure that biological materials will not be used beyond the scope of the approved study without additional approval and consent.
25. The premature discontinuation plan focuses primarily on investigator inconvenience rather than participant protection. The protocol must specify participant notification procedures, continuation of clinical care, handling of stored biological samples, and ongoing safety monitoring for participants who already received investigational cells.
26. The application incorrectly states that the investigational product is "non-immunogenic and non-contagious and does not pose any significant risk." This is scientifically inaccurate. Allogeneic MSCs may still induce immune or inflammatory responses, particularly in infected or inflamed tissue environments.
27. A comprehensive risk assessment is absent. The protocol and consent documents must clearly address foreseeable risks including infection, immune reactions, inflammatory responses, worsening ulceration, pain, bleeding, hospitalization, septicemia, amputation risk, abnormal tissue growth, unexpected differentiation, cell migration, and potential tumorigenesis, including acknowledgment that long-term risks remain incompletely

understood.
28. There is no contingency or escalation protocol for treatment failure or rapidly worsening diabetic wounds. A mandatory emergency management and referral protocol must be included, particularly given the risk of sepsis, hospitalization, or amputation in diabetic foot patients.
29. The protocol does not adequately distinguish between routine clinical care and research-specific procedures. Participants must be clearly informed which interventions are experimental and which constitute standard diabetic wound management.
30. Community engagement and benefit-sharing plans are absent. The protocol should address involvement of relevant diabetes patient groups or advocacy organizations, dissemination of study findings to participating communities, participant access to successful interventions after trial completion, and reimbursement or compensation for time and travel.
31. The budget and compensation arrangements are unclear. Participants may require repeated visits and prolonged follow-up without any reimbursement provisions. Clarification is required regarding free routine care versus research-related benefits in order to avoid therapeutic misconception.
32. The application states that investigators have "no conflict of interest," yet simultaneously discloses intent to pursue patents and commercialization. These statements are contradictory and must be reconciled through transparent conflict-of-interest disclosure and benefit-sharing mechanisms.
33. The informed consent document is written in a recruitment-oriented and benefit-focused manner rather than a balanced risk-based format. The language should be revised to clearly state that the intervention is experimental/investigational and not approved standard treatment for diabetic foot ulcers.
34. The consent form contains therapeutic/promotional language such as "stem cells have the potential to treat various diseases," which may create unrealistic expectations and therapeutic misconception. Such language should be removed or appropriately balanced with uncertainty and investigational status.
35. The consent form does not adequately explain study randomization, treatment allocation, multiple intervention arms, or that participants cannot choose their assigned treatment group.
36. Risks specific to manipulated stem-cell therapies are insufficiently explained in the consent form. The possibility of infection, immune reactions, worsening ulcers, bleeding, hospitalization, unexpected differentiation, distant cell migration, and unknown long-term effects must be clearly disclosed.
37. The consent form does not clearly explain what manipulations or laboratory processing procedures are performed on the cells before administration.
38. The consent form does not clearly explain alternative treatment options available outside the study, including access to conventional diabetic wound care.
39. The statement that the institution "will not be held responsible" for risks or harms associated with participation is ethically unacceptable and must be removed.
40. There is insufficient information regarding compensation and treatment for research-related injury or complications. Financial responsibility and participant support mechanisms must be clearly described.
41. Independent ERC/IRB contact information for participant complaints, concerns, or rights-related queries has not been provided and must be included in all consent documents.
42. The rationale for requiring contraception during the study and for six months afterward is not explained and should be scientifically justified within both the protocol and consent documents.
43. The consent form does not explain whether ulcer photographs may be used for publications, presentations, teaching, or research dissemination, nor does it describe associated confidentiality protections.

44. The patient information sheet and consent form do not adequately describe the study procedures, investigational nature of the therapy, or associated uncertainties and risks.
45. The Urdu version of the informed consent document has not been submitted and is mandatory.
46. Separate informed consent documentation for maternal umbilical cord donation is absent. A dedicated donor consent process must be established, including explanation of downstream research use, stem-cell derivation, and transplantation into unrelated recipients.
47. Donor information sheets and donor consent forms have not been provided and must be submitted.
48. The process for obtaining maternal consent is insufficiently described. The protocol must clarify who obtains consent, at what stage of pregnancy/delivery consent is sought, and how voluntariness will be ensured.
49. Publication timelines, authorship policies, data-sharing governance, and dissemination plans have not been described and should be incorporated into the protocol

Title: **Enhancing Health Systems to Strengthen Management of Possible Serious Bacterial Infections in Young Infants in Pakistan.**

Project #	PI Name & Address
NBCR-1404	**Dr. Zamir Hussain Suhag** Trust for Vaccines & Immunization, Suit # 301 Al Sehat Centre, 3rd Floor Near SIUT (Regent Plaza Hotel), Karachi.

Final NBC-R Comments
1. There is no Pakistan specific data.
2. The application states '≥80% identification and appropriate management' as the primary objective but does not specify the baseline rate against which this target will be measured. The baseline must be defined to allow meaningful evaluation of the intervention's impact.
3. The intervention relies on Medical Officers (MOs) as the central figure in guiding mothers regarding infant care. Given the 24/7 nature of the service, an adequate number of trained MOs will be required. Standard training protocols to ensure high-precision identification of emergency cases must be established. All deployed MOs should be at minimum bilingual in Urdu and Sindhi.
4. The application does not explicitly state that consent will be obtained from mothers or caregivers as the legally authorized representatives for infant participation. This must be clearly stated.
5. An explicit right-to-withdraw statement must be added to all consent forms.
6. A cooling-off period of at least 24 hours between initial approach and enrollment is recommended, particularly given the distress mothers may experience when a sick infant is being enrolled. LHWs are trusted community members, and the risk of inadvertent coercion or misunderstanding is real; this buffer is an important safeguard.
7. It is recommended that a Community Advisory Committee be established, comprising mothers, community leaders, Lady Health Workers (LHWs), and health facility representatives, meeting at least quarterly to provide feedback on implementation, acceptability, and any emerging concerns.
8. A plain-language summary of findings should be disseminated to participating communities through LHWs or community meetings, in both Urdu and Sindhi, upon study completion.
9. There is no provision for reimbursement of participant time or travel costs for survey participation. While not strictly required for minimal-risk research, NBC-R guidelines recommend that reimbursement for time and travel be considered and addressed.
10. Lady Health Workers involved in this study are already engaged in multiple tasks and in other research projects without additional financial compensation. Engaging them in further research activity without fair remuneration raises ethical concerns of equity and exploitation that must be addressed.

Minutes of the NBC-R meeting held on 19-05-2026

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on May 19th, 2026. The following members of NBC-R attended the meeting:

Sr.#	Group-II	
1.	Prof. Ejaz Ahmed Khan	Chair the Meeting
2.	Dr. Faiza Bashir	Focal Person NBC
3.	Prof. Saqib Mehmood	Member
4.	Prof. Shahid Mehmood Baig	Member
5.	Dr. Natasha Anwar	Member
6.	Mr. Mazhar Iqbal	National Coordinator
7.	Mr. Waryal Ali Daheri	LDC

The following projects reviewed / discussed:

Title: **Impact of Trout Fish, Cow Milk with Egg, Vitamin D Supplementation, and Dietary Education on Vitamin D Status, under nutrition, and Neurocognitive Outcomes among School Children in Pakistan: An Open-label Individually Randomized Controlled Trial.**

Project #	PI Name & Address
NBCR-1405	**Mr. Gul Nawaz Khan** Department of Paediatrics and Child Health The Aga Khan University Karachi
Final NBC-R Comments	
1. The rationale for conducting this study specifically in Ghizer District is not scientifically justified. The prevalence of Vitamin D deficiency has remained largely static for more than a decade and is distributed uniformly across Pakistan; neonatal Vitamin D levels reflect maternal patterns nationwide. The geographic specificity of this study requires a much stronger scientific justification.	
2. The study is described as an open-label RCT. While participant blinding may not be feasible for a food-based intervention, outcome assessor blinding for neurocognitive assessments should be incorporated to reduce measurement bias.	
3. Nutritional values per serving are not provided for any of the three intervention arms. The dose equivalence of Vitamin D across the three arms — trout fish once weekly; milk plus egg three times weekly; and weekly Vitamin D supplementation — is not calculated or justified. The risk of Vitamin D toxicity has not been acknowledged or addressed.	
4. The vitamin D supplementation regimen of 4000–6000 IU weekly is not adequately justified. Criteria for dose allocation by age, weight, or baseline Vitamin D level are absent. Compliance with international pediatric therapeutic dosing guidelines must be demonstrated.	
5. Neurocognitive assessment is limited to the Digit Span Test and Word List Recall, without justification or coverage of broader cognitive domains relevant to the study population.	
6. There are inconsistencies in study timelines across the protocol, consent and assent forms, and the Gantt chart, specifically regarding intervention duration, endline assessment, and follow-up periods. All timelines must be reconciled and made consistent before approval.	
7. The assent process is inadequately designed for children aged 6–12 years. A single assent form has been used across a wide developmental and literacy range. Best ethical practice under ICH E11, CIOMS guidelines, and Aga Khan University Ethics Review Committee standards requires separate age-appropriate assent processes, with verbal or pictorial assent for younger children. The proposal does not describe how verbal assent will be conducted or documented.	
8. Significant discrepancies exist between the protocol and the assent form regarding: intervention duration, Vitamin D dosage, blood sample volume, and timing of assessments. These must be reconciled and corrected.	

9. The assent and participant information sheet provides a Karachi-based contact number despite the study being conducted in Ghizer District. A locally accessible study contact must be provided.
10. The final approval or clearance letter from Aga Khan University Ethics Review Committee — which had previously requested resubmission — has not been attached and must be included.
11. The control arm of 'no additional meal' raises significant ethical and scientific concern in a food-insecure population. Children randomized to the control group receive no nutritional benefit despite possible Vitamin D deficiency or undernutrition.
12. Providing food to some children in a classroom setting while control arm children receive nothing poses a risk of psychological harm and stigmatization. This is a major ethical concern. At minimum, some form of equivalent food must be provided to all children during the same lunch period, regardless of allocation.
13. The risk of undue inducement has not been addressed. The provision of fish, milk, eggs, or supplements to food-insecure children may strongly and improperly influence participation decisions.
14. Emergency referral pathways are inadequately described, referring vaguely to 'nearby health facilities' without identifying specific referral centers, accessibility considerations, or realistic response mechanisms in a remote mountain district such as Ghizer.
15. Data confidentiality and participant privacy measures are inadequately described. The school-based setting makes confidentiality difficult to maintain, as teachers and peers may readily identify intervention group allocation. This practical loss of confidentiality is not acknowledged or mitigated in the protocol.
16. The follow-up assessment form asks respondents to compare participating children with 'other children of the same age,' but does not specify who will complete this form or which comparison group will be used.
17. No qualitative data collection tools — such as a Focus Group Discussion questionnaire — are attached despite mention of qualitative components in the proposal.

Title: **Nebulized Furosemide for the Treatment of Pulmonary Inflammation in Patients with Acute Hypoxemic Respiratory Failure – A Phase 3 study (FAST – 3).**

Project #	PI Name & Address
NBCR-1406	**Prof. Madiha Hashmi** Ziauddin University. 4/B Shahrah-e-Ghalib Rd, Block 6 Clifton, Karachi
Final NBC-R Comments	
1. The epidemiological justification is entirely based on Canadian data. No Pakistan-specific burden data on Acute Hypoxemic Respiratory Failure (AHRF) or ICU utilization are provided. Pakistan has a distinct and substantial burden of infectious and TB-related AHRF, a younger patient demographic, and different co-morbidity patterns. Local burden data is required.	
2. The anti-inflammatory effects of furosemide are stated as established facts ('potent inhibitor of IL-6 and TNF-α'), whereas clinical benefit remains the central unproven hypothesis of this trial. This language overstates certainty in an ethics application and must be corrected.	
3. The maximum sample size is never stated. While the Bayesian adaptive design does not require a fixed sample size, the maximum cap must be specified. Pakistan's expected contribution — number of patients, participating sites, and timeline — is completely absent and must be provided.	
4. The three participating sites (Ziauddin, South City, SIDH&RC) are listed but no description is provided of how eligibility criteria will be applied consistently across sites with potentially differing ICU capabilities, patient populations, and available equipment.	

5. The sulfonamide allergy exclusion criterion allows enrollment of patients with prior sulfonamide allergy if they have previously received furosemide without incident. This is a clinical judgment call that requires either experienced clinician input or a structured allergy assessment protocol, neither of which is described.
6. Tuberculosis is not mentioned as a cause of AHRF despite being a leading cause of respiratory failure in Pakistan. TB-related AHRF may respond differently to furosemide given its distinct pathophysiology, and this must be addressed.
7. The consent section consists of only two sentences and is entirely inadequate for a Phase 3 interventional drug trial enrolling critically ill, frequently unconscious, or sedated patients in Pakistani ICUs. A robust, detailed consent procedure must be developed.
8. The term 'substitute decision maker' is used without definition within the local legal and cultural context of Pakistan. This must be defined and operationalized.
9. Telephone consent for a Phase 3 interventional drug trial is ethically unacceptable. It must be replaced with a properly structured and documented surrogate consent procedure.
10. Consent forms and patient information sheets in local language (Urdu) are not provided and must be submitted.
11. Risks associated with the placebo arm (saline nebulization) are not addressed. All arms of an interventional trial require risk characterization.
12. A Data Transfer Agreement (DTA) is not attached and must be provided.
13. The proposal states fifteen-year record retention in accordance with Canadian regulations. It does not address whether this conflicts with Pakistani regulatory requirements, or how any such conflict will be resolved.
14. The clinical data form is not attached and must be included in the application.
15. No local Data Safety Monitoring Board (DSMB) composition, meeting frequency, stopping rules, or charter reference is provided. These are required for an interventional Phase 3 trial.
16. No Pakistan-specific Serious Adverse Event (SAE) reporting chain or timeline is described.

Title: **Enabling the Road to Zero Leprosy in Pakistan.**

Project #	PI Name & Address
NBCR-1409	**Dr. Kristien Cloots** Institute of Tropical Medicine, Nationalestraat 155, 2000 Antwerp, Belgium **Dr. Isabel Fernandes** Marie Adelaide Leprosy Centre (MALC) Mariam Manzil, Shahrah-e-Liaquat, Saddar, Karachi, Pakistan.

Final NBC-R Comments
1. The study involves geospatial mapping of leprosy cases; however, no evidence of prior approval from the **Survey of Pakistan** has been provided as required under **the Surveying and Mapping Act, 2014 (Section 7(b))**. Approval for collection, processing, and sharing of geospatial data must be obtained before commencement of the study.
2. The protocol lacks justification for selection of study sites across multiple geographic locations. A clear description of site selection criteria, coordination mechanisms, and procedures to ensure uniform implementation of SOPs across all sites is required.
3. There is no evidence of engagement with relevant local government structures, including district health offices and municipal authorities. Given the planned expansion of screening from households to communities, formal administrative coordination and governance mechanisms are necessary.
4. The consent process is insufficiently protective against therapeutic misconception. It must be explicitly stated in all participant information and consent forms that the study is diagnostic in nature only, that no therapeutic intervention is guaranteed, and that participation will not affect access to routine care.
5. The protocol includes retrospective genetic analysis of skin samples collected since 2021, but it is unclear whether prior informed consent covered such future use. The investigators must either obtain retrospective consent or provide a formally justified waiver for ethical review.
6. Consent for long-term storage and future use of biological samples for unrelated research is not adequately addressed. A separate, clearly defined consent component for biobanking and future research use is required in accordance with NBC-R standards.
7. Planned public deposition of genomic sequence data is not accompanied by explicit participant consent for open-access data sharing. This must be incorporated into the consent documentation, including explanation of risks of re-identification.
8. The retrospective component spanning 20 years is vulnerable to substantial recall and data incompleteness bias. The protocol does not describe statistical methods for handling missing or incomplete retrospective data and must include a dedicated analytic strategy.
9. Psychosocial harm associated with leprosy diagnosis and contact tracing, including stigma, discrimination, family rejection, and social exclusion, is not adequately addressed. A structured psychosocial support and referral system must be established.
10. Expansion of screening from household contacts to broader community/village-level screening increases risk of inadvertent disclosure of index cases. A confidentiality protection strategy to prevent identification and stigmatization of index patients must be implemented.
11. The protocol does not describe post-biopsy follow-up procedures. Duration and method of monitoring for biopsy-related complications must be clearly defined.
12. Several study objectives are contingent on additional funding not yet secured. Ethical approval should not be granted for partially defined research objectives unless they are either removed or formally subjected to future ethics amendment approval.
13. No provision is made for participant compensation, transport reimbursement, or support for biopsy-related visits. Given the invasive nature of procedures and socioeconomic vulnerability of participants, this is ethically inadequate.

14. Institutional Ethics Committee approval from Aga Khan University has not been clearly documented. All collaborating institutional ERC approvals must be submitted prior to approval.
15. There is insufficient planning for stigma mitigation associated with household visits, contact tracing, and visible field activities. A structured community sensitization and anti-stigma strategy must be implemented prior to field deployment.
16. Field staff training in stigma-sensitive communication, confidentiality protection during household visits, and management of community misinformation is not described and must be included.
17. The protocol does not address risks of social harm, discrimination, labeling, or family conflict arising from participation in leprosy screening activities.
18. There is no description of psychosocial referral pathways for participants experiencing stigma-related distress or social consequences.
19. Voluntariness of consent in household-based recruitment is not adequately protected. The protocol must describe how coercion within family structures will be minimized and how private, independent consent will be ensured.
20. Whole genome sequencing and strain typing with export of samples to Belgium raise concerns regarding data governance and sovereignty. The protocol must clarify: Ownership of genomic data; Access rights for Pakistani investigators; Data-sharing agreements; Duration of storage and conditions for destruction; Future use limitations.
21. It is unclear whether metadata accompanying genomic sequences (e.g., geographic, community-level identifiers) could allow re-identification. A clear de-identification and anonymization framework must be provided.
22. Consent forms do not clearly explain that only *Mycobacterium leprae* DNA will be analyzed and not human genomic material. This distinction must be explicitly stated.
23. Public deposition of genomic data requires explicit participant consent, including explanation of risks associated with open-access databases.
24. There is insufficient clarification regarding what will happen if geographically clustered "hotspots" are identified, including risk of community labeling or stigmatization as "leprosy villages." A public health communication strategy is required.
25. The role of public health authorities and engagement with district and national programs is not clearly defined. There is insufficient evidence of integration with existing leprosy control programs and local health systems.
26. Claims of capacity building and laboratory strengthening are not supported by a clear implementation plan, especially given existing expertise in bacterial WGS in Pakistan. The added value of training components should be clarified.
27. Community engagement activities, including awareness campaigns and educational interventions, are not described. A structured community education and engagement plan is required prior to initiation.
28. The role of post-exposure prophylaxis is unclear—whether it is part of the research intervention or a public health program. Its implementation framework, eligibility criteria, and equity of access must be clearly defined.
29. It is not specified how equitable access to prophylaxis will be ensured among contacts, or how refusal of prophylaxis will affect continued participation or access to care.
30. There is no clearly defined communication plan for dissemination of results to communities, health workers, or participants, including mitigation of potential misinformation or stigma following findings.
31. Overall, while the scientific objective of eliminating leprosy transmission is important and well-intentioned, the current protocol requires substantial strengthening in ethical safeguards related to stigma, confidentiality, community engagement, data governance, and participant protection before approval.

Title: **Trial: A Multicenter, Randomized, Controlled, Open-label, Phase III Study To Assess Efficacy and Safety Of Libevitug Injection in Participants With Chronic Hepatitis Delta virus infection (D-Clear Study).**

Project #	PI Name & Address
NBCR-1412	**Dr. Saeed Hamid** Department of Medicine Aga Khan University Karachi.

Final NBC-R Comments
1. Pakistan-specific HDV epidemiological and disease burden data are absent from the application. Local justification for participant recruitment and relevance to the Pakistani population must be provided.
2. The scientific rationale for inclusion of both 10 mg/kg and 20 mg/kg dosing arms in a Phase III study is not adequately explained. Dose-selection justification based on prior clinical or pharmacodynamic data should be provided.
3. The protocol does not clearly define whether the trial is being conducted exclusively in Pakistan or as a multinational study. All participating countries and sites must be clearly identified.
4. The delayed-treatment control arm raises significant ethical concerns. HDV is a progressive chronic liver disease, and participants randomized to observation-only for 48 weeks may experience fibrosis progression, hepatic deterioration, or irreversible liver damage during the waiting period.
5. The protocol does not adequately justify why delaying treatment for 48 weeks is ethically acceptable in participants with active HDV infection. Evidence supporting the safety of delayed treatment and expected progression risk during this period should be provided.
6. The protocol does not adequately justify why delaying treatment for 48 weeks is ethically acceptable in participants with active HDV infection. Evidence supporting the safety of delayed treatment and expected progression risk during this period should be provided. The protocol does not adequately justify why delaying treatment for 48 weeks is ethically acceptable in participants with active HDV infection. Evidence supporting the safety of delayed treatment and expected progression risk during this period should be provided.
7. The protocol should clarify whether participants in the control arm continue receiving standard HBV therapy and supportive management throughout the observation period.
8. The application states that there are “currently no approved effective treatments” in China or the United States; however, Bulevirtide has been approved in Europe for chronic HDV infection in compensated liver disease. The protocol and consent forms should accurately reflect the current international treatment landscape.
9. Given the existence of approved HDV therapies in some jurisdictions, the ethical justification for using a delayed-treatment control arm rather than an active-comparator or non-inferiority design requires clarification.
10. The eligibility criterion requiring participants to be “able to communicate well with the investigator” is vague. Language requirements and translated consent procedures for multilingual populations at participating sites should be clearly defined.
11. People who inject drugs, despite representing a high-risk HDV population in Pakistan, are excluded without adequate scientific or ethical justification. The implications of this exclusion for vulnerable populations should be addressed.
12. The protocol includes adolescent participants aged 12–17 years; however, parental consent procedures, adolescent assent procedures, and age-appropriate participant information materials are insufficiently described.
13. Separate parental consent forms and adolescent assent forms must be submitted. The protocol should clarify assent procedures, adolescent confidentiality protections, and withdrawal rights.
14. Additional clarification is required regarding reproductive counselling, pregnancy testing, contraception counselling, and management of pregnancy-related issues in adolescent participants.

15. The informed consent documents appear overly adult-focused and may not be sufficiently understandable for adolescents or participants with varying literacy levels. Simplified, culturally and linguistically appropriate versions should be provided.
16. Given the severity of HDV and limited treatment options locally, there is substantial risk of therapeutic misconception. The consent form should clearly explain the investigational nature of Libevitug; Uncertainty of benefit; Randomization procedures; Possibility of assignment to delayed treatment; Available alternative/supportive care options.
17. The informed consent documents should avoid language that may imply guaranteed treatment benefit or therapeutic certainty.
18. Contraception requirements for women of childbearing potential are included without adequate scientific explanation. The rationale for continued contraception after study completion should be clearly stated.
19. Pregnancy-testing schedules and management procedures for accidental pregnancy during the study are insufficiently described and should be clarified.
20. The protocol does not adequately address developmental, reproductive, psychiatric, or neurodevelopmental risks in adolescent participants receiving investigational biologic therapy.
21. The protocol demonstrates strong DSMB governance; however, local implementation procedures, meeting schedules, stopping rules, and Pakistan-specific oversight mechanisms should be clarified further.
22. No Pakistan-specific Serious Adverse Event (SAE) reporting chain is described. Reporting timelines, responsible authorities, and local escalation procedures should be specified.
23. The protocol references cytokine storm risk but does not clearly explain whether this is a theoretical or previously observed risk associated with Libevitug. Clarification regarding mechanism, monitoring, and mitigation strategies is required.
24. Emergency management procedures for severe infusion reactions or cytokine-release syndromes should be detailed, including ICU access, availability of tocilizumab or equivalent therapy, and emergency-response pathways.
25. The clinical significance and management of anti-drug antibodies (ADA) and neutralizing antibodies are insufficiently explained. Criteria for treatment discontinuation, monitoring, and long-term implications should be described.
26. The Hepatic Adjudication Committee is referenced but committee composition, independence, adjudication criteria, and timelines are not adequately described. A formal charter should be submitted.
27. The 24-week post-treatment follow-up period appears short for chronic HBV/HDV infection and investigational biologic therapy. Concerns remain regarding late virological relapse; ALT flares; HBV/HDV rebound; Resistance emergence; Delayed hepatic decompensation; Long-term durability of response.
28. Longer-term follow-up plans, relapse-management procedures, and post-study monitoring responsibilities should be clarified.
29. The post-study transition plan is vague. The protocol should clearly specify whether participants retain access to Libevitug after study completion; Availability of compassionate-use programs; continued sponsor support; post-study clinical management responsibilities.
30. The application does not adequately address whether Libevitug will be affordable or accessible to Pakistani participants after study completion. Clarification is needed regarding Expected pricing; Sponsor-supported access programs; Patient-assistance schemes; continued access for participants who benefit during the study.
31. If Pakistani participants are contributing to approval-generating evidence, a clear local benefit-sharing and access strategy should be provided, including potential improvements in local HDV diagnostic or treatment capacity.
32. The protocol indicates international transfer of biological samples and virological material but does not clearly specify: Which samples will leave Pakistan; Duration of storage; Future use plans; Ownership and governance of samples and genomic data.
33. Clarification is required regarding whether genomic analyses are limited to viral

sequencing or whether any human genomic analysis will also be performed.
34. Community engagement and benefit-sharing sections are incorrectly marked "Not applicable." HDV-positive populations in Pakistan frequently belong to vulnerable and marginalized groups, and community engagement obligations remain applicable.
35. A formal community-engagement and dissemination strategy involving relevant patient or hepatology groups should be developed.
36. The statement that the sponsor will cover "reasonable medical treatment costs" is ambiguous. The exact scope, limitations, and exclusions of sponsor responsibility for research-related injuries and complications must be explicitly defined.
37. Participant compensation and reimbursement arrangements are inadequately described. Clarification is required regarding travel reimbursement, visit compensation, and coverage of study-related costs.
38. Site-selection information and infrastructure details are insufficiently described. Documentation should be provided regarding, Participating centers; Investigator qualifications and GCP certification; Laboratory capacity; Emergency preparedness; Data-security infrastructure.
39. Institutional ethics approval letters from all participating sites must be submitted prior to study activation.
40. Sample-size justification and statistical power calculations require further clarification.
41. Recruitment procedures, participant referral pathways, and safeguards against undue influence should be more clearly described.
42. Data-management procedures, including e-CRF systems, audit trails, and data-validation mechanisms, require clarification.
43. The quality-of-life assessment tool referenced in the protocol should be specifically identified and evidence of validation in relevant populations should be provided.
44. Publication governance, authorship policy, dissemination procedures, and future data-sharing arrangements should be clarified.
45. The protocol does not adequately describe mechanisms for protection of research staff handling bloodborne viral infections and biologic infusions. Occupational safety procedures, needlestick-injury protocols, PPE requirements, HBV vaccination policies, and biosafety training should be incorporated.
46. The DSMB Charter, risk-management framework, predefined safety-monitoring procedures, and disease-specific clinical oversight mechanisms are comprehensive and represent significant strengths of the submission.
47. The protocol demonstrates strong alignment with international GCP standards, including centralized randomization, predefined endpoints, detailed safety assessments, and structured statistical methodology.
48. The inclusion of adolescents with separate stratification and avoidance of delayed-treatment controls within this subgroup demonstrates ethical consideration and thoughtful study design.
49. The budget documentation, safety-monitoring schedule, and disease-specific monitoring procedures are detailed and appropriately structured for a multicenter Phase III clinical trial.

Nazli Hussain

Chairperson

Minutes of the NBC-R meeting held on 02-06-2026

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on June 2nd, 2026. The following members of NBC-R attended the meeting:

Sr.#	Group-I	
1.	Prof. Nazli Hossain	Chairperson
2.	Prof. Ejaz Ahmed Khan (HSA)	Member
3.	Prof. Amjad Mehboob	Member
4.	Prof. Marie Andrades	Member
5.	Prof. Saira Afzal	Member
6.	Prof. Rameeza Kaleem	Member
7.	Mr. Mazhar Iqbal	National Coordinator
8.	Ms. Ayesha Abid	Assistant

The following projects reviewed / discussed:

Title: **Longitudinal Surveillance of Family Planning Uptake Indicators at Peri-Urban Communities in Karachi, Pakistan.**

Project #	PI Name & Address
NBCR-1407	**Dr Aamir Abbas** Vital Pakistan Trust 9th Floor, Al-Tijarah Centre, 32-1-A, Shahrah-e-Faisal Rd, Block-6, PECHS, Karachi.

Final NBC-R Comments

1. The protocol specifies an eligibility age range of 15–45 years. National law specifies a minimum marriageable age of 18 years. The eligibility criteria in the protocol and in the consent is inconsistent — the consent form references married women aged 19–45 while the protocol states 15–45 years. This discrepancy must be resolved.
2. The application proposes verbal informed consent without adequate justification. NBC-R guidelines specify that where written consent is waived, the individual administering consent must sign the consent record and an independent witness must be present and identified. The consent form does not conform to the NBC-R template; contact details of the Principal Investigator and the Institutional Review Board are absent.
3. The consent must outline participation in research-specific family planning questions from any pre-existing enrolment in routine surveillance activities. Participants must be explicitly assured that refusal to respond to research-specific questions will not affect their access to routine health services.
4. Female data collectors must be confirmed as the standard practice, in recognition of the cultural and social dynamics of the study population.
5. The protocol states that interviews will be conducted in private settings and data stored on password-protected devices, but provides no information on: (a) encryption standards for stored databases; (b) access log and audit trail protocols; (c) data transfer procedures between field devices and central servers; and (d) contingency procedures in the event of device loss or theft. A comprehensive Data Management Plan is required, covering physical and cloud storage, encryption standards, access control, retention timelines, destruction protocols, backup arrangements, and data-sharing agreements with all international partners including the Gates Foundation and the Aga Khan University. Compliance with applicable Pakistani data protection legislation and, where relevant, the GDPR must be confirmed.
6. The application identifies AKUH as a collaborating institution; however, no formal documentation substantiating this partnership has been appended. A signed agreement or letter of collaboration from AKUH is required. The absence of a co-investigator from

the collaborating institution is also noted and should be addressed.

7. The protocol states that no direct material benefits will be offered to participants. The Committee draws the applicant's attention to NBC-R guidelines (Page 13, point d), which permit and encourage reimbursement commensurate with participants' time and travel costs, particularly in the context of underserved communities. If compensation is not to be provided, substantive justification must be included. The total cumulative time burden per participant across 36 months and 12 quarterly visits must also be stated explicitly.
8. The questionnaire contains near-identical items (specifically Questions 6/7 and 13/14) that must be revised to eliminate redundancy. The presentation of a comprehensive list of contraceptive methods in a single question may be problematic for participants with limited familiarity with formal terminology; question framing should be simplified accordingly.
9. The target of interviewing more than 95% of eligible MWRAs per quarter is considered highly ambitious. A revised, statistically justified estimate and an attrition management plan are required. The statistical analysis plan as submitted is restricted to descriptive statistics. The Committee requires specification of: (a) confounder adjustment strategy; (b) planned subgroup analyses; (c) methods for handling missing data and attrition; and (d) statistical software to be employed.
10. The application refers to 'business intelligence dashboards' without adequate explanation. The purpose, audience, and governance of these dashboards must be described.
11. Contraceptive use is inherently a dyadic phenomenon. The exclusion of male partners from the study warrants explicit scientific justification, or the incorporation of partner-inclusive components where feasible.
12. The Committee requires clarification as to whether data collected prior to a participant's withdrawal will be retained or destroyed.
13. The NBC-R application identifies the relevant IRB; however, the institutional website does not disclose the IRB's composition. This information must be made available in accordance with transparency requirements.

Title: **Assessment and operationalization of breastfeeding support in conflict and humanitarian settings.**

Project #	PI Name & Address
NBCR-1408	**Dr. Jai Das** Department of Institute for Global Health and Development Aga Khan University Karachi

Final NBC-R Comments

1. The Committee acknowledges this as a well-designed study of considerable social and public health value, addressing a critical and under-researched domain at the intersection of humanitarian response and infant nutrition. The study population — mothers affected by the 2022 Pakistan floods — constitutes a multiply vulnerable group, and the Committee directs that proportionately heightened ethical safeguards be applied throughout.
2. The application proposes verbal informed consent for a population that includes survivors of a major natural disaster who may continue to experience residual psychological distress. Verbal consent alone is considered insufficient in this context.
3. Consent procedures must be trauma-informed in design and delivery. The applicant must ensure: (a) capacity assessment appropriate to the study context; (b) consent conducted in private settings free from community authority figures or family members; (c) materials available in the Sindhi language; and (d) explicit assurance to

participants that refusal or withdrawal will in no way affect their access to humanitarian assistance.

4. The protocol acknowledges the potential for emotional distress arising from interview participation, including distress triggered by recollection of flood-related trauma; however, no operational referral pathway has been specified. The Committee requires that the applicant identify named psychosocial support organizations by Taluka, describe warm versus cold referral procedures, and establish contingency arrangements for districts where formal services are unavailable. Data collectors must receive training in trauma-informed interview practices and management of acute distress responses.
5. The protocol does not mention any compensation or reimbursement for participants. Given that participants are economically vulnerable flood-affected individuals who may incur travel costs or lose caregiving time, the provision of modest reimbursement is required, or a robust justification for its absence must be provided.
6. The application states that community engagement will be facilitated through local health authorities, community leaders, and frontline workers. In humanitarian settings, such structures may inadequately represent the perspectives of women and caregivers. The applicant must describe how the engagement strategy will actively centre the voices of mothers and female community members, and mitigate hierarchical and gendered power dynamics in the recruitment process. A formal letter of support from the Sindh Department of Health or the relevant district health authority is recommended.
7. Confirmation is required that Focus Group Discussions (FGDs) will be gender-segregated and conducted in settings free from the influence of in-laws, spouses, or authority figures. Individual follow-up arrangements must be available for participants who are uncomfortable in a group format or who disclose distress during an FGD.
8. The application identifies SickKids (Toronto, Canada) as a collaborating institution but does not specify whether any data — including de-identified transcripts — will be shared with the Canadian team. If international data transfer is intended, a formal Data Transfer Agreement is required under the NBC-R checklist. If no data will leave Pakistan, this must be stated explicitly.
9. The policy on reporting violations of the WHO International Code of Marketing of Breast-milk Substitutes must be disclosed to participants and facilities at the outset of the study. The applicant must define the threshold for individual versus aggregate reporting and specify mechanisms by which participant confidentiality will be preserved.
10. The planned desk review of humanitarian programme reports may encompass references to identifiable individuals. The applicant must either obtain consent from such individuals or provide a waiver rationale consistent with NBC-R guidance on the use of existing records.
11. The retrospective nature of the study introduces potential for significant recall bias. The analytical framework must explicitly account for this limitation.
12. The application package appears to contain a document pertaining to an unrelated study **(Impact of Green Energy Use for Cooking and Heating on Indoor Air Pollution and Health Outcomes in Rural Communities of Pakistan)**. The applicant is requested to verify and correct the document assembly prior to resubmission.

Title: **Assessing Feasibility and Effectiveness of Swab-Based Near Point-of-Care (NPOC) TB Testing to Bridge Diagnostic Gaps at Primary and Secondary Health Care Facilities Serving Rural Populations in Pakistan.**

Project #	PI Name & Address
NBCR-1410	**Dr. Saman Ahmed** IRD Pakistan (Pvt.) Limited 4th Floor, Woodcraft Building, Plot 3 & 3-A, Sector 47, Korangi Creek Road, Karachi, Pakistan

Final NBC-R Comments

1. Verbal consent is considered insufficient for a study involving a novel diagnostic device not in standard clinical use. Participants have a right to documented evidence of consent for non-standard procedures. A formal mechanism for assessing participant comprehension must also be incorporated.
2. The application states that biological samples will be managed in accordance with standard clinical and laboratory protocols but provides no specifics. NBC-R requirements mandate disclosure of: (a) storage duration and conditions; (b) whether samples will be retained post-diagnosis for future research; (c) disposal mechanisms; and (d) whether participants are informed of and consent to potential sample retention, as required by NBC-R Page 12, point 9g.
3. No provision for participant reimbursement is mentioned, despite participants being drawn from rural communities with limited incomes and potentially significant travel costs. Compensation for community health workers undertaking study-related tasks must also be addressed.
4. The protocol does not specify: (a) the responsible party for communicating positive TB results to participants; (b) the mechanism for ensuring linkage to care; or (c) responsibility for the costs of confirmatory testing and treatment. NBC-R guidelines state that additional tests required by the study should be supported by the study budget.
5. The NPOC tongue-swab device is not fully described. The applicant must provide: (a) the specific test name and manufacturer; (b) applicable regulatory approvals including WHO prequalification status and DRAP approval; and (c) a statistical justification for the sample size of 7,200 participants, which is not provided.
6. The study design label — 'feasibility and implementation evaluation' — is inconsistent with the comparative analyses planned under Objectives 2 and 3.
7. The sample size justification is circular; no estimation of expected paired positives for the concordance analysis under Objective 3 has been provided, raising concerns that the study may be underpowered given low TB yield at primary care facilities.
8. No strategy for managing missing data or loss to follow-up has been described, despite the multi-step referral chains inherent in the study design and the expectation of substantial attrition.
9. The Intermediate Care and Diagnostic Centre (ICDK) and Primary Health Care (PHC) facilities are pooled within the intervention arm despite representing fundamentally different clinical contexts and TB prevalence rates. All primary analyses must be stratified by facility type. The inclusion of attendants and caregivers is not adequately justified; pooling individuals with low a priori TB probability with symptomatic care-seekers will dilute yield estimates unless analyses are stratified accordingly.
10. The protocol contains no provision for a data monitoring committee, interim review process, or pre-specified stopping rules. This is a significant omission given the deployment of an unevaluated diagnostic device where high false-negative rates could result in missed tuberculosis diagnoses. A formal safety monitoring framework must be established.
11. No Data Transfer Agreement with McGill University has been described. The institutional data protection policy applicable to the study must be specified, and the data governance section must address physical and cloud storage, encryption

standards, access control, retention timelines, and data destruction protocols.

12. Community engagement is currently limited to facility leadership and healthcare workers. Given the introduction of a novel diagnostic approach in rural Pakistan and the social stigma associated with tuberculosis, a standalone community awareness and trust-building strategy is required.
13. The budget narrative contains no figures, itemized costs, unit costs, or full-time equivalent disclosures. This is considered unfit for review, particularly as cost-effectiveness is a primary study objective. A fully itemized budget with micro-costing methodology must be submitted. The scope and value of in-kind cost-sharing from complementary programmatic activities must also be disclosed.
14. The following minor administrative issues require correction: (a) a version mismatch exists between the embedded flow diagram (v2.1, January 2026) and the protocol (v1.2, March 2026); (b) 'optimised routine diagnostic procedures' at control sites is undefined; (c) age group boundaries for pre-specified subgroup analyses have not been stated — adolescent yield (aged 10–17) should be designated a pre-specified equity outcome; and (d) no protocol deviation or amendment procedure has been described, which is required for GCP-aligned multi-site research.

Minutes of the NBC-R meeting held on 02-06-2026

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on June 2nd, 2026. The following members of NBC-R attended the meeting:

Sr.#	Group-II	
1.	Prof. Nazli Hossain	Chairperson
2.	Prof. Ejaz Ahmed Khan (HSA)	Vice Chairperson
3.	Prof. Saqib Mehmood	Member
4.	Prof. Shahid Mehmood Baig	Member
5.	Assistant Prof. Sarosh Saleem	Member
6.	Prof. Akhtar Sherin	Member
7.	Mr. Mazhar Iqbal	National Coordinator
8.	Ms. Ayesha Abid	Assistant

The following projects reviewed / discussed:

Title: **Trial: ACCESS Study: Achieving accessible control of Diabetes in Pakistani adults living with Diabesity through Semaglutide 1.0mg (Semagrix), A Multicenter Real-World Evidence Prospective Study.**

Project #	PI Name & Address
NBCR-1411	**Prof. Dr.Aziz ul Hasan Aamir** Peshawar General Hospital (PGH) Plot No. 6 A, Sector A2, Phase-V Hayatabad, Peshawar

Final NBC-R Comments

1. The Committee notes that a study involving a comparable intervention was conducted in 2022 at a collaborating institution. The applicant must explicitly articulate how the current study differentiates itself from prior research in terms of design, population, objectives, or expected contribution to knowledge.
2. The study is funded by a pharmaceutical entity. The applicant must provide a detailed description of the funder's role, including any rights of access to data, influence over study design or analysis, and rights regarding publication or dissemination of results. A conflict-of-interest management plan must be included.
3. The protocol does not define the Standard of Care for the management of type 2 diabetes with obesity (diabesity) within the Pakistani health system or at the participating institutions. This information is essential for assessing the comparative basis of the study. The criteria governing clinical decision-making regarding the initiation of Semaglutide — and the identity of the responsible clinician — must be specified.
4. The application's characterization of the study as involving minimal risk is not consistent with the nature of the intervention, which involves a pharmacological agent with a known adverse event profile. The risk-benefit section must be revised to accurately reflect and adequately mitigate the known risks and side effects of Semaglutide.
5. The potential for conflicts of interest arising from pharmaceutical funding must also be formally addressed.
6. The protocol does not provide a clear plan for the detection, documentation, recording, and reporting of adverse events (AEs), adverse drug reactions (ADRs), or serious adverse events (SAEs). The application must specify: (a) the procedure and responsible party for identifying and documenting AEs; (b) the methodology for attributing causality to the investigational product; (c) the reporting chain and timelines for SAE notification to the IRB and sponsor; and (d) the frequency of follow-up visits and laboratory investigations and who bears the associated costs.
7. The Urdu-language informed consent form has been reviewed and found to be inadequate. The document is not comprehensible to a lay reader and does not clearly convey information regarding follow-up visits, emergency procedures, or participant rights. The form must be substantially revised to meet NBC-R standards for readability, completeness, and non-coercive language

Title: **Why Are Women Not Online? A Qualitative Study Understanding Gender-Based Digital Exclusion Among Marginalized Women in Pakistan to Promote Digital Gender Inclusion..**

Project #	PI Name & Address
NBCR-1413	**Dr. Muhammad Asim** Department of Community Health Sciences Aga Khan University Karachi

Final NBC-R Comments

1. The term 'marginalized women' as used in the application requires a precise operational definition. The criteria by which participants will be classified as marginalized — whether by income, geography, educational attainment, or other indicators — must be stated explicitly.
2. The adequacy of the primary field site (Azam Basti) as a representative locus for the full spectrum of marginalized women in Pakistan requires further justification.
3. The application does not adequately address anticipated barriers to recruiting women who are, by definition, digitally excluded and potentially restricted in their mobility or autonomy.
4. A clear mitigation strategy must be articulated, including how the study will ensure that the very population of interest is not systematically excluded from participation.
5. The tools, guides, and language used for engagement with gatekeepers — including family members and community leaders — must be disclosed and submitted for review. Assurance is required that such materials are free from coercive framing and do not misrepresent the nature or purpose of the research to community intermediaries.
6. The application references an advisory committee but does not describe its composition, mandate, or operational role.
7. Given that the methodology oscillates between qualitative research and elements of Participatory Action Research (PAR), clarity is required on whether the advisory committee holds a consultative, deliberative, or co-investigative function. Informed consent from advisory committee members must be obtained and documented. If PAR elements are incorporated, actionable outputs — including engagement with technology developers, policymakers, or civil society — must be explicitly described.
8. Digital illiteracy among women in Pakistan is a well-documented phenomenon, with existing estimates indicating that approximately 43% of women lack basic digital literacy. The applicant must articulate with greater precision what new knowledge this study is expected to generate beyond existing evidence, and how findings will meaningfully advance policy or programmatic interventions.
9. The contribution and specific role of the international collaborating institution (Western University) must be described, including any implications for data sharing or intellectual property.

Title: **Trial:A Phase I/II Clinical Trial to Evaluate the Safety and Hemostatic Efficacy of OxyClot (ORC) Hemostatic Powder in Surgical Wound Management..**

Project #	PI Name & Address
NBCR-1414	**Dr. Sadia Salah Ud Din** Institute of Chemical Sciences, BZU, Multan Bahauddin Zakariya University, Multan.

Final NBC-R Comments

1. The investigational product, OxyClot (Oxidised Regenerated Cellulose — ORC), does not appear to hold current regulatory approval. No clinical investigation involving an unapproved agent may proceed in the absence of appropriate regulatory authorization.
2. The study involves the administration of an unapproved investigational haemostatic agent in a surgical context with the primary objective of establishing safety and efficacy. This constitutes a more-than-minimal risk study and must be classified and governed accordingly. The current application's risk characterization requires full revision. The Committee reiterates that administering an experimental agent to participants for the purpose of establishing its safety and efficacy is not, in itself, a direct benefit to those participants. The Standard of Care for surgical haemostasis at the participating institutions must be defined to enable a comparative risk-benefit assessment.
3. The protocol identifies the study setting as the "Department of General Surgery, Bahauddin Zakariya University Teaching Hospital, Multan." This description raises significant concerns regarding the authenticity and accuracy of the study site, as Bahauddin Zakariya University is not recognized as having a teaching hospital providing clinical surgical services.
4. The study involves surgical wound management; however, the study team does not include any orthopedic or general surgeons. The absence of qualified surgical expertise raises serious concerns regarding clinical governance of the trial and the management of adverse intraoperative or perioperative events. This deficiency must be rectified.
5. The types of surgical wounds to be included in the study must be defined. The absence of inclusion and exclusion criteria for wound type represents a fundamental gap in the protocol.
6. The data collection instrument as submitted is inadequate for a study with safety and efficacy objectives. No information is captured on confounders or independent variables that may influence haemostatic outcomes. The instrument must be comprehensively revised to enable valid inferential analysis.
7. The protocol states that all adverse events will be recorded and assessed for causality but does not identify the responsible party, the recording instrument, the reporting timeline, or the causality attribution methodology. These elements must be fully specified.
8. The application does not fully describe the role of the funding entity or its rights of access to study data and results. A complete disclosure of the funding arrangement, including contractual provisions governing data rights, publication, and conflict of interest management, is required.
9. The informed consent form has been reviewed and found to be inadequate, incomprehensible, and characterized by language biased in favour of participation. The form must be substantially rewritten to meet NBC-R standards, with particular attention to the balanced presentation of risks, participant rights, and voluntary participation.

Minutes of the NBC-R meeting held on 09-06-2026

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on June 9th, 2026. The following members of NBC-R attended the meeting:

Sr.#	Group-I	
1.	Prof. Nazli Hossain	Chairperson
2.	Prof. Ejaz Ahmed Khan (HSA)	Vice Chairperson
3.	Dr. Faiza Bashir	Focal Person NBC
4.	Prof. Marie Andrades	Member
5.	Prof. Amjad Mehboob	Member
6.	Assistant Prof. Sualeha Siddique Shekhani	Member
7.	Prof. Saira Afzal	Member
8.	Prof. Rameeza Kaleem	Member
9.	Dr. Farah Asif	Member
10.	Prof. Abubakar Ali Saad	Member
11.	Assistant Prof. Agha Riaz	Member
12.	Mr. Mazhar Iqbal	National Coordinator
13.	Ms. Ayesha Abid	Assistant

The following projects reviewed / discussed:

Title: **Clinical Evaluation of CelluPatch: An Innovative Silver-Loaded Sodium Carboxymethyl Cellulose (Na-CMC) Non-Woven Dressing for Acute and Chronic Wounds.**

Project #	PI Name & Address
NBCR-1415	**Saman Kainat** Institute of Chemical Sciences, BZU, Multan Bahauddin Zakariya University, Multan
Final NBC-R Comments	
1. As per NBC-R/DRAP requirements, the Principal Investigator must be a licensed clinician. Where regulatory or institutional norms require a non-clinician to serve as PI, a qualified clinician must be designated as Co-PI or Co-Investigator. This study appears to have been submitted without a clinician in the team; this must be rectified before any further review.	
2. The hypothesis mentions non-inferior cost-effectiveness. Clarify whether the locally developed dressing will be cost-effective compared to imported dressings, and provide the expected cost of CelluPatch to the patient.	
3. It appears that patient recruitment and trial activities have already started, as indicated by the submitted Gantt chart. If this is the case, the committee takes a serious view of this lapse, as research on human subjects must not commence before ethics approval.	
4. Study needs to mention potential confounders such as diabetes control, comorbidities, and concurrent medications, and describe how these will be controlled during the trial.	
5. Since there are two study sites with multiple physicians and nurses involved, the methodology must clearly describe the standardized training that will be provided to all site personnel for wound assessment and dressing application.	
6. Insurance coverage for participants in case of trial-related harm or complications must be arranged and clearly described in the protocol.	
7. The plan for patient management if the wound has not healed after 8 weeks must be specified. Ethically, participants should continue to receive free treatment for the wound beyond the trial period until healing is achieved.	

8. The mechanism for managing complications must be clearly described, including who will be responsible, what clinical resources are available, and how costs of complication management will be covered.

9. It must be clarified how osteomyelitis will be excluded at the time of enrollment, and how diabetes and other comorbidities will be monitored during the study period, including who will bear the cost.

10. The protocol must specify a clear Adverse Event and SAE reporting pathway, including timelines and reporting to the PI, site IRB, NBC-R, and DRAP as required under Pakistan medical device regulations.

11. Clarify whether CelluPatch or its comparator dressing will be labelled during the study, and whether participants will be blinded.

12. Clarify whether this product is manufactured by AB Medicals and whether it has been previously registered with DRAP; if yes, provide details.

13. The study is funded by the company that developed CelluPatch. A declared conflict of interest management plan must be included in the protocol to ensure scientific independence in study design, analysis, and reporting.

14. The sample size of 60 patients may be insufficient to detect uncommon adverse effects or safety concerns. A proper power calculation with statistical justification must be provided.

15. Written agreements (MoUs) with Nishtar Hospital and Civil Hospital are missing and must be submitted.

16. The following consent-related deficiencies must be addressed: (a) the consent form does not mention what type of blood tests will be conducted or how long samples will be kept; (b) the procedure for obtaining consent from illiterate participants is not clear — it is not stated whether the impartial witness will sign only the Urdu ICF or also a separate witness form; (c) patients with diabetic ulcers and burns are already in a vulnerable situation — the consent process must include explicit safeguards to ensure participation is entirely voluntary and free from any coercion or undue influence; (d) participants with low health literacy may not fully understand the risks and benefits — the consent form must be written in plain, simple language and comprehension must be assessed; (e) participants may incorrectly believe the new dressing is definitively superior to standard treatment even though this is unproven — the consent must clearly state the investigational nature of the product; (f) post-trial access to CelluPatch must be addressed in the consent form — it should be clearly stated whether participants will receive the dressing free of charge until their wound heals, and if not, why this is not feasible; (g) compensation for serious harm must be clearly described in the consent, including the process and responsible party; (h) the consent form must clearly inform participants that their data will be shared with the sponsor and regulators, and describe the confidentiality measures in place; (i) the study involves multiple hospital visits and dressing assessments — the burden of participation must be disclosed in the consent form; and (j) patent and commercial rights are expected to be retained by the company — participants must be informed of this, and any post-commercialization benefits for participants must be clearly stated.

17. The PI states that ethics training was obtained from the university's biosafety committee for animal handling. This is not adequate for research on human subjects. The PI and all key clinical staff must provide certificates from a recognized human research ethics training programme such as the CITI Program, NIH Protecting Human Research Participants, or a WHO/TDR-certified Good Clinical Practice course.

18. A plan for community engagement with diabetic patient support groups or burn survivor communities should be described. Additionally, used dressings are a biohazard — the protocol must confirm that the participating hospitals have incineration or other appropriate biomedical waste disposal facilities.

19. The travel reimbursement of PKR 500 per visit is inadequate given current travel costs. This must be reviewed and revised to reflect actual participant burden

Title: **Trial: A Single-Site Clinical Trial to Evaluate the Safety and Performance of SealRx®, a Surgical Adhesive for Wound Closure.**

Project #	PI Name & Address
NBCR-1416	**Dr. Fahmida Jabeen** Institute of Chemical Sciences Bahauddin Zakariya University, Multan

Final NBC-R Comments

1. As per NBC-R/DRAP requirements, the Principal Investigator must be a licensed clinician. Where regulatory or institutional norms require a non-clinician to serve as PI, a qualified clinician must be designated as Co-PI or Co-Investigator. This study appears to have been submitted without a clinician in the team; this must be rectified before any further review.
2. A detailed study protocol is required before approval can be considered. The current submission is too brief for substantive review.
3. The study objectives are listed without measurable endpoints, and the research question is not stated as a testable hypothesis. These must be explicitly defined.
4. No eligibility criteria, no data analysis plan, and no study timeline have been provided. All three must be included.
5. The sample size of 20–30 participants is stated without any power calculation or statistical justification. A formal sample size calculation must be provided.
6. Section 1.3 describes this as a non-randomized clinical trial with no control group. Without a comparison group (e.g., sutures or an existing surgical adhesive), it is impossible to determine whether SealRx® is superior, equivalent, or inferior to standard care. This violates the ethical principle of equipoise. Additionally, the study design is inconsistently described as non-randomized while also implying comparison with sutures — this inconsistency must be resolved and participants must be transparently informed of what treatment they will receive.
7. The standard of care for minor surgical wounds (e.g., Steristrips) must be clearly identified, and the operational definition of wounds suitable for SealRx® versus sutures must be specified.
8. The method of selecting participants for the intervention versus comparator group is not described.
9. It must be specified who will be evaluating outcomes, and how outcome assessors will be blinded if applicable.
10. The plan in case wound closure is suboptimal or fails with the investigational product must be described.
11. No independent Data Safety Monitoring Board (DSMB) or external safety oversight mechanism is described. In a first-in-human type surgical adhesive study, independent safety monitoring is necessary.
12. Predefined stopping rules for halting the study in the event of increased complications (such as infection, wound dehiscence, or allergic reactions) must be included.
13. Adverse event grading, reporting timelines, escalation pathway, and reporting to DRAP must all be clearly specified.
14. Insurance coverage for participants in case of trial-related complications must be arranged and described.
15. There is no justification for why Aga Khan University Hospital was specifically selected, or for this patient population.

16. The MoU between the study team and Aga Khan University Hospital for use as a clinical trial site is missing and must be submitted.

17. Pre-clinical safety data (animal studies or toxicity testing) must be provided to ethically justify introducing a new surgical adhesive in human subjects.

18. The commercial interest of AB Medicals / SOS Technologies in future licensing and manufacturing of SealRx® must be declared, and the protocol must demonstrate strong safeguards for scientific independence in study design, data analysis, and publication.

19. The roles of academic investigators and the industry partner must be clearly separated, particularly regarding data ownership, analysis rights, and publication rights.

20. Intellectual property rights are assigned to the industry partner. An institutional agreement and fair benefit-sharing framework must be established and documented.

21. Section 1.6 states that staff have ISO-based certifications and will comply with GCP training prior to trial initiation. ISO certification is not equivalent to human subjects research ethics training. The PI and all key staff must provide certificates from a recognized ethics training programme such as CITI, NIH PHRP, or a WHO/TDR-certified GCP course.

22. Community engagement is limited to educating doctors. A plan for engagement with patient communities must be described.

23. The following consent-related deficiencies must be addressed: (a) the consent form is very deficient and must be rewritten to be explanatory and meet NBC-R requirements; (b) there is no description of how comprehension of the consent form will be assessed; (c) no mention is made of an impartial witness for illiterate participants; (d) the consent must fully detail the range and severity of possible risks, including rare but serious outcomes; (e) post-trial access to SealRx® must be addressed in the consent, including under what terms it will be available; (f) the follow-up plan for participants after the trial must be described in the consent; and (g) the consent must clearly inform participants about the non-randomized design and what treatment they will receive.

Title: **Trial: Phase I/II Clinical Trial Evaluating the Safety, Tolerability, and Preliminary Efficacy of Locally Developed Iodinated Oil (Iodotrast®) for Transarterial Chemoembolization in Hepatocellular Carcinoma Patients.**

Project #	PI Name & Address
NBCR-1417	**Ms. Sabeen Iqbal** Institute of Chemical Sciences Bahauddin Zakariya University, Multan.

Final NBC-R Comments

1. As per NBC-R/DRAP requirements, the Principal Investigator must be a licensed clinician. Where regulatory or institutional norms require a non-clinician to serve as PI, a qualified clinician must be designated as Co-PI or Co-Investigator. Neither the PI nor the Co-PI appear to have clinical credentials. A chemistry department cannot conduct a Phase I/II cancer trial without a qualified clinical investigator (oncologist, interventional radiologist, or hepatologist) who will perform the TACE procedures, prescribe chemotherapy, manage complications, and provide overall medical oversight. This is a fundamental deficiency that must be resolved before any further review.
2. AKU is identified as the clinical trial site, but the site PI is not named and the written MoU for AKU's agreement to serve as a clinical site is missing. Both must be submitted.
3. The protocol is very brief and must be substantially expanded with full details of study methodology.
4. There is a contradiction in the protocol: Section 2.8 (Biological Material) states that no human biological material will be collected, while Section 1.3 mentions blood tests (CBC, LFTs, AFP). This contradiction must be resolved. If blood samples are to be drawn, detailed SOPs for collection, storage, and disposal must be provided.
5. Clarify whether this trial is registered in a recognized clinical trials registry (e.g., ClinicalTrials.gov or Pakistan's national registry). If not, registration must be completed prior to enrollment.
6. IRB approval from Aga Khan University Hospital must be obtained and submitted.
7. The transition criteria and stopping rules between Phase I (safety) and Phase II (efficacy) are not defined. These must be specified to ensure early participants are not exposed to unnecessary risk.
8. The proposed single-arm design with historical controls instead of a randomized comparator requires explicit ethical justification. Since Iodotrast® will be compared against historical data from imported lipiodol, the comparison may be biased due to changes in patient selection, supportive care, and imaging techniques over time. The committee requires justification for why a randomized controlled trial with lipiodol is not feasible.
9. The use of historical controls reduces scientific validity and raises fairness concerns regarding how outcomes are compared. A plan to mitigate this bias must be provided.
10. A Data Safety Monitoring Board (DSMB) has been mentioned, but the members, their independence, and their decision-making authority are not described. These details must be provided for an adequate safety oversight mechanism.
11. Predefined stopping rules for halting the study in case of serious adverse events such as liver failure or death must be included.
12. Serious risks such as liver failure and death are mentioned. A clear and proportionate risk-benefit justification for testing a new embolic material in humans must be provided.
13. No standard adverse event grading system or strict reporting timelines are specified. These must be defined, including reporting to DRAP as required under applicable regulations.

14. The source and quality control of sunflower oil (used in the product) must be described, including whether it is genetically engineered, and how consistent quality will be ensured across batches.

15. The method for checking the final product for impurities must be described.

16. The primary treating physician for enrolled patients and the site of patient recruitment must be clearly identified.

17. Insurance coverage for participants in case of trial-related complications must be arranged and described in the protocol.

18. Post-trial access to Iodotrast® and subsidized TACE must be addressed — will participants receive continued access after the trial, and under what conditions?

19. The study mixes clinical objectives with commercial and cost goals. These must be clearly separated so that patient benefit is distinguished from product development interests.

20. The study is funded by SOS/AB Medicals. The protocol must clearly describe how full scientific independence will be protected in study design, data analysis, and publication to prevent commercial influence.

21. An independent mechanism must be established to ensure that all results, including negative findings, will be published without sponsor influence.

22. The dissemination plan mentions only academic conferences and seminars. It must also include regulatory submission to DRAP and preparation of a lay summary for participants.

23. The plan for premature discontinuation must be described, including how participants will be notified, what follow-up care will be provided, and how their data will be handled.

24. The PI and all key staff must provide certificates from a recognized human research ethics training programme. The current team does not appear to have completed such training.

25. The exclusion criteria do not clearly protect borderline high-risk patients such as those with marginal liver function or frailty. These criteria must be strengthened.

26. Intellectual property rights are assigned to the industry partner. A fair institutional agreement and benefit-sharing framework must be documented.

27. The following consent-related deficiencies must be addressed: (a) the consent form must be entirely rewritten in plain layman's language that is comprehensible to patients with cancer; (b) the consent procedure section must include much greater detail on pre-procedure assessment, the specific blood tests to be taken, and what each procedure entails; (c) the consent must explicitly state that Iodotrast® is an experimental product under investigation, as compared to the standard approved embolic material (lipiodol), so that participants understand they may be receiving an unproven product; (d) the alternative treatment options available to patients must be clearly described in the consent form; (e) the consent must clearly state that this is an experimental study — participants must understand there is genuine uncertainty about whether Iodotrast® is equivalent or superior to standard treatment; (f) post-trial access to Iodotrast® must be addressed in the consent form; (g) compensation for serious harm must be explicitly described; and (h) the confidentiality of participant data, including what is shared with the sponsor, must be clearly stated.

Minutes of the NBC-R meeting held on 11-06-2026

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on June 11th, 2026. The following members of NBC-R attended the meeting:

Sr.#	Group-II	
1.	Prof. Nazli Hossain	Chairperson
2.	Prof. Saqib Mehmood	Member
3.	Prof. Shapper Mirza	Member
4.	Prof. Akhtar Sherin	Member
5.	Dr. Natasha Anwar	Member
6.	Mr. Mazhar Iqbal	National Coordinator
7.	Ms. Ayesha Abid	Assistant

The following projects reviewed / discussed:

Title: **Prevalence of Autism Spectrum Disorder Among Pakistani Children Aged 2–5: A National Study.**

Project #	PI Name & Address
NBCR-1418	**Dr. Shahnaz Ibrahim** The Aga Khan University Karachi

Final NBC-R Comments

1. Facility-based sampling (EPI centers, BHUs, urban diagnostic centers) targets a healthcare-seeking population, not the general population. This does not fit into prevalence study. Children with ASD in low-income/rural areas are less likely to attend due to lack of awareness, or geographic barriers, likely underestimating true prevalence.
2. Sindh is under-represented (24% of target population), covered only by urban Karachi centers; rural Sindh is excluded entirely.
3. Urdu-version tools (M-CHAT, SCQ) are used, but Pakistan has many regional languages (Pashto, Brahui, Sindhi). No mention of validation in these languages or how informal translation will be handled—a serious validity threat
4. The AIIMS Modified INCLEN-ASD is an Indian adaptation not validated for Pakistani cultural/linguistic contexts; its sensitivity/specificity in Pakistan is unknown.
5. Phase 2 diagnostic evaluation via teleclinic is problematic—ASD diagnosis requires direct behavioral observation. Remote assessment introduces measurement error and requires strong justification or an in-person only commitment.
6. No plan for inter-rater reliability despite a single PI conducting all multi-province Phase 2 assessments.
7. Electronic consent via RED Cap in low-literacy settings may be intimidating or misunderstood. Reading aloud is insufficient without assessing comprehension.
8. Consent process must be available in participants' primary languages (Balochistan participants may not speak Urdu)—not just verbally translated on the spot.
9. No assent process for children aged 4–5; omission should be explicitly justified.
10. Disclosing a positive screen carries real risks in high-stigma settings. Offering "resources and teletherapy" is insufficient; a culturally informed structured disclosure protocol is needed.
11. Prescription medications if needed" is medically inaccurate—ASD in ages 2–5 is not primarily pharmacotherapy-treated—and raises scope-of-practice concerns.
12. Adverse events section answered "NA"—unacceptable. Foreseeable events include caregiver distress, child distress during assessment, confidentiality breaches, and screen-positive children receiving no follow-up. A minimal protocol (e.g., caregiver distress referral pathway) is required.
13. Funding section says "NA" but Gates Foundation funding (via CoE-WCH) is mentioned elsewhere. The committee needs disclosure of whether ASD screening is piggy-backed on funded immunization research, whether Gates covers ASD costs, and who pays for Phase 2

diagnostic follow-up.

14. No community advisory processes, leader engagement, or co-design—despite working in marginalized communities.
15. Data retention period not specified
16. No service availability statement acknowledging limited ASD services in several provinces and what the study will do for families without local access.
17. Socioeconomic status (SES) measurement inadequate—only raw monthly income (no brackets, no asset-based measure). Cannot reliably assess prevalence across "diverse socioeconomic settings."
18. Dietary assessment insufficient—missing ultra-processed foods, snacks, sugar-sweetened beverages; does not meet minimum standards for nutrition-related analysis.
19. Vaccination question (singling out measles vaccine) directly evokes the debunked MMR-autism hypothesis and is potentially harmful.
20. Missing established ASD risk factors: advanced parental age at child's birth, maternal infections during pregnancy, prenatal medication exposure (e.g., valproate), breastfeeding history, previous pregnancy losses, household environmental exposures (pesticides, industrial areas).
21. Maternal substance use question (tobacco, naswar, gutka, paan, alcohol) is sensitive. In Pakistan, alcohol use is illegal and stigmatized—self-report will be highly unreliable and may cause distress or suspicion.

Title: **Real-World Efficacy, Safety, and Patient-Reported Outcomes of Tirzepatide in Adults with Type 2 Diabetes Mellitus, Obesity, and Prediabetes in Pakistan: A Multicenter Observational Study.**

Project #	PI Name & Address
NBCR-1421	**Prof. Dr. Abdul Basit** Indus Hospital & Health Network Indus Hospital, Korangi Crossing, Karachi, Pakistan

Final NBC-R Comments

1. The study only tests tirzepatide in one group of people, with no comparison group. This makes it hard to know if changes are truly from the drug.
2. The recruitment of treatment-naive patients who are subsequently prescribed the study drug, without provision of the medication by the research team, poses an ethical concern as it may impose an undue financial burden on participants and compromise the principles of equitable and non-exploitative research participation.
3. The study plans to look at three separate groups: people with diabetes, people with obesity, and people with prediabetes. The sample size is calculated of the T2DM but the number of obesity and prediabetic is considered as one group. This will create problem in final statistical analysis and results.
4. People with prediabetes will not be taking this drug as part of their routine care—it is not a standard treatment for their condition. This makes the study more like an experiment for them, which raises additional ethical concerns that have not been addressed.
5. Co-PI from other provinces and centers are not identified. Participant's numbers from each center are not given.
6. Ethics approval is documented for only two hospitals, even though the study is being done at many sites across the country.
7. The role of the Co-PI from Malaysia and another Malaysian researcher (Dr. Ong Siew Chin) is not clearly defined. Why are participants from Malaysia not included in the study when the proposal says that such study has not been done in Malaysia so far.
8. Different study papers give different lengths for the study—some say 24–26 weeks, some say Week 30, some say 6–7 months. The questionnaire also says "past 7 months " This lack of clarity raises doubts about whether the study plan is solid.
9. Twenty-four weeks is not long enough to see if the drug keeps working properly, how many people stop taking it, or to spot late side effects like pancreas or thyroid problems.
10. The study is funded by a BS Biosciences company, yet claims & quot no competing interests & quot; No safeguards are described to prevent bias.
11. The funding is described as coming from two sources: a university in Malaysia (academic

funding) and a BS Biosciences company. However, it is not clear how much each source is providing or what strings are attached.
12. It is unclear whether this study is a student project (MPhil or PhD) for someone based in Malaysia. If it is, this raises additional concerns about whether the student has the experience needed to run a large multi-center drug study across another country.
13. The NBCR-form mentions a mobile health tool called DiabTrend, but the main study plan does not.
14. Required eye exams and lab tests may not be paid for by the study, so costs could fall on participants. The budget does not include the cost of these tests.
15. The diabetes satisfaction questionnaire (DTSQc) asks about "the past 7 months, " but the study only runs for 24–26 weeks—this mismatch makes the answers less reliable.
16. Some references are numbered incorrectly or do not match between the text and the reference list.
17. No plan is described for people with low reading skills, for getting verbal consent, or for checking whether participants truly understood what they agreed to.
18. No independent safety monitoring board, no rules for when to stop the study, and no clear safety oversight are described.
19. The study does not provide insurance or compensation if a participant gets harmed by research procedures, even though some tests are done only for the study and not for routine care.
20. The section on side effects is not properly filled out. There is no clear plan for managing or referring participants who become distressed.
21. MMAS-8 (medication adherence across all cohorts) tool details are not given.
22. Required signatures from the lead researcher are missing on the NBCR form

Title: **Trial: A Double-blind, Randomized Clinical Study of the Pharmacokinetics, Safety and Immunogenicity of BCD-283-1 in Patients with Relapsed/Refractory Classical Hodgkin's Lymphoma.**

Project #	PI Name & Address
NBCR-1422	**Dr. Munira Borhany** Zia Uddin University Hospital, 4/B, Sharah-e-Ghalib, Block 6, Clifton, Karachi.

Final NBC-R Comments

1. Only Ziauddin Hospital, Karachi is listed, but the global trial needs 100+ patients. Given how strict the eligibility criteria are, it's unclear how many eligible patients exist locally.
2. Justification for doing the study in Pakistan is weak: Mostly general/copied language; doesn't explain why this site adds real value beyond patient access.
3. Up to 31 blood draws for PK testing, repeated CT/PET scans (7+over the study), possible biopsies, and 24-hour hospital stays for blood sampling. This burden isn't clearly described in the harms/benefits section.
4. Not stated whether Adcetris is normally available in Pakistan — important for understanding what patients gain/give up by joining.
5. Sponsor analyzes its own results: BIOCAD (maker of BCD-283) will perform the statistical analysis AND decide whether to extend the trial after interim results. This is a major conflict of interest with no independent oversight described.
6. "No competing interest" claim is incorrect
7. If patients respond well, what happens to their treatment after the study ends? Not addressed.
8. Funding amount is not yet decided
9. MTA is on Chughtai lab letterhead. It's not mentioned what is the role of this lab.

Minutes of the NBC-R meeting held on 16-06-2026

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on June 16th, 2026. The following members of NBC-R attended the meeting:

Sr.#	Group-I	
1.	Prof. Nazli Hossain	Chairperson
2.	Prof. Ejaz Ahmed Khan (HSA)	Vice Chairperson
3.	Prof. Marie Andrades	Member
4.	Prof. Amjad Mehboob	Member
5.	Assistant Prof. Sualeha Siddique Shekhani	Member
6.	Prof. Rameeza Kaleem	Member
7.	Dr. Faheem Ashraf Khan	Member
8.	Dr. Farah Asif	Member
9.	Mr. Mazhar Iqbal	National Coordinator
10.	Mr. Waryal Ali Daheri	LDC

The following projects reviewed / discussed:

Title: **Informed or Intuitive: Challenges and Opportunities in Decision-Makers' Use of Routine Health Data at Facility and District Levels in Tando Allahyar and Matiari.**

Project #	PI Name & Address
NBCR-1423	**Mr. Waqas Hameed** Department of Community Health Sciences Aga Khan University Karachi

Final NBC-R Comments

1. The participants are health administrators and senior officials whose responses may involve criticism of existing systems. Despite anonymization, a risk of professional or reputational harm remains, particularly in small districts where individual roles are readily identifiable. The protocol's assertion that there is "no risk involved" therefore underestimates the social and professional risks inherent in discussing organizational weaknesses; while the study may be regarded as low risk, it is not risk-free.
2. Interviews are to be conducted at participants' workplaces, which may constrain and raise concerns regarding privacy and confidentiality. Although no overtly sensitive information is sought, the potential for compromised privacy and confidentiality should be acknowledged and addressed.
3. Observation of dashboards, reports, and meeting records is proposed; however, the protocol does not specify the institutional permissions required or the safeguards by which sensitive organizational information will be protected.
4. The study is presented as a qualitative design, yet it incorporates a Likert-scale OBAT tool alongside qualitative methods. The protocol therefore describes a mixed-methods study rather than a purely qualitative one, and the rationale for integrating these approaches requires clearer justification.
5. The sampling strategy requires clarification: facilities are reportedly selected randomly while participants are selected purposively, and this combined approach is not adequately justified. Although the sample size is based on thematic saturation and prior studies, no explanation is provided as to how variation between the two districts will be adequately captured.
6. The exclusion of participants unable to communicate in English or Urdu may limit the representation of certain local perspectives.
7. Appointments of District Health Officers and data managers are frequently made on

political grounds, and the capacity of such individuals to interpret data may be limited; this raises concern regarding their understanding of the rationale and objectives of the research.

8. The key informant interviews comprise 22 questions, including sub-questions and open-ended items, and are likely to exceed 30 minutes. The consent form should be revised to extend the estimated duration from 30 to 45 minutes accordingly.
9. Concerns were raised regarding the budget, which appears disproportionate to the scope of work, with the majority of funds allocated to wages.
10. A broader concern was noted that a student's thesis should constitute her own work rather than being delegated to paid personnel.
11. Overall, the study is considered low risk but is also likely to be of limited impact.

Title: **To examine the relationship between dietary intake of vitamin D–rich foods and vitamin D deficiency among adult women in Lahore, Pakistan.**

Project #	PI Name & Address
NBCR-1424	**Zarmeena Ishtiaq** University of Wolverhampton, Wulfruna Street United Kingdom

Final NBC-R Comments

1. The supervisor for this project should be identified, as should the local Co-Principal Investigator, who is currently missing. Clarification is also required as to how a student based at a foreign university (University of Wolverhampton) will be permitted to conduct this study in Lahore.
2. Considerable research on this topic has already been conducted in Pakistan, and it is unclear what this project will add. It is well established, both scientifically and through an extensive body of local literature that the study population is highly deficient in vitamin D, and the reasons for this deficiency are well understood. The justification for granting access to this population is therefore questionable.
3. The methodology is not described, and the specific tests to be performed are not identified. The operational definition of non-invasive indicators of deficiency is not provided, and potential confounders and the means of controlling them are not addressed.
4. The proposed sample is inadequate. A pilot of 20 women is referenced, but the actual sample size and the method of participant selection are not specified. A sample of 20 participants is extremely small relative to Lahore's population of at least 15.5 million and is unlikely to yield meaningful or generalizable results; cross-sectional studies of this nature typically require a minimum of 350–400 participants. A formal sample size calculation is required.
5. The primary outcome, "risk of vitamin D deficiency," is based solely on self-reported symptoms and lifestyle factors without biochemical confirmation. Non-specific symptoms such as fatigue and muscle pain may lead to misclassification, and the exclusion of objective measures of vitamin D status may result in conclusions that overstate the findings.
6. Recruitment through clinics, markets, community centres, and social media may introduce selection bias and limit the representativeness of women in Lahore.
7. The proposed logistic regression analysis is not appropriate for such a small sample and may produce unreliable results.
8. Participants are asked about culturally sensitive matters, including clothing style, dietary habits, and socioeconomic status, yet the protocol does not describe how privacy will be ensured during interviews or online surveys. While no overtly sensitive information is requested, risks to privacy and confidentiality remain.
9. Data are to be stored on a cloud platform (OneDrive), but details regarding encryption, duration of storage, and access control are not provided. As data will be held by the University of Wolverhampton, a data transfer agreement is required.

10. The literature review is limited and relies heavily on older local studies, with little discussion of recent evidence or validated non-invasive screening tools.
11. The consent form does not conform to the standard format, lacks a patient information sheet, and requires revision.
12. Overall, the study is poorly written and requires a major rewrite and resubmission.
13. It was suggested that a form of exemption be established for studies posing no more than minimal risk, such as survey-based studies, so that these need not be reviewed by the full committee. It was further noted that, for such surveys, completion of the questionnaire may itself signal willingness to participate, potentially obviating a separate informed consent procedure

Title: **Evaluating The Impact of Flood on Maternal Health, Gestational Duration, and Pregnancy Outcome among Women of Lower Socioeconomic Status in Flood Affected Areas Of Sindh – A Retrospective Cohort Study.**

Project #	PI Name & Address
NBCR-1439	**Prof Dr Shahzad Ali Khan** Health Services Academy Chakshahzad Park Road Islamabad.

Final NBC-R Comments

1. There is a fundamental inconsistency regarding informed consent. The proposal describes the study as retrospective and indicates that no consent is required, yet Section 01 of the questionnaire refers to informed consent, and the protocol simultaneously mentions enrolling "consenting females" and obtaining an IRB waiver for retrospective data use. The consent form states that women may, if required, be contacted for a brief interview (20–30 minutes) to clarify pregnancy history, yet it appears that all women may in fact be questioned. As the study is described as retrospective, the rationale for including informed consent and emphasizing the voluntary nature of participation requires clarification.
2. The study design is internally inconsistent. Although labelled a retrospective cohort study, the questionnaire is oriented towards a cross-sectional survey, and the protocol additionally proposes hazard analysis, economic evaluation, and intervention development, which exceed the scope of a retrospective design. Clarification is required as to whether the research team will interview women at any stage or whether the study is purely data-driven, as the research requirements differ substantially between these approaches. The protocol is confusing in that it presents a detailed questionnaire for women while also stating that data will be extracted from files.
3. The feasibility of data retrieval is a major concern. At the time of the 2022 floods, approximately 750,000 women were recorded as pregnant. Many were displaced to makeshift camps in schools, colleges, and primary care centres, and numerous NGOs provided services during this period. Retrieving records from such settings is not feasible, and many women may never have returned to their original locations, as their lands remained inundated for many months. Consequently, enrolling all consenting women who were pregnant in 2022 is highly problematic, as many will have relocated and most will lack traceable addresses. For the same reasons, this study cannot be regarded as exempt, since most variables require information obtained directly from the previously pregnant women.
4. The study involves multiple vulnerable groups—pregnant women, women of low socioeconomic status, and disaster-affected communities—yet additional safeguards for these populations are not clearly described.
5. Patient and public involvement is weak. Healthcare facilities are proposed as stakeholders, but meaningful engagement with affected women and communities is limited.
6. The confidentiality plan is rudimentary and lacks detail regarding data linkage, storage duration, data destruction, and governance of the secondary use of hospital records. The mechanism for retrieving records is not described, and it is unclear how or why district health facilities would grant an external party access to their confidential files. Furthermore, it is unclear how the security of data collectors will be ensured, given that this is recorded as "NA" in the NBCR form.
7. Sample size justification is inadequate. Multiple estimates are presented without formal calculation or stated statistical assumptions. For Objective 1, the source of controls is not specified, and for Objective 4 (development of cost-effective interventions), the protocol notes that a smaller, focused group (e.g., 300 participants) may be adequate for piloting intervention strategies, yet the planned interventions themselves are not described.
8. Flood exposure is poorly defined, as the protocol does not specify how its severity, duration, or degree will be measured.
9. Key outcome measures, including preterm birth, neonatal mortality, stillbirth, and maternal morbidity, are not operationally defined. The questionnaire only partially

addresses the stated objectives.

10. The objective of developing interventions through a "hazard analysis approach" is insufficiently explained and appears overly ambitious for the proposed design. Concern was also raised regarding the nature of adverse events to be recorded four years after an event in which women lacked basic necessities, medical services, food, and sanitation, with sanitation failures contributing to deaths.
11. Several references are outdated or duplicated, and contemporary concepts such as climate justice, reproductive justice, and disaster ethics are not addressed.
12. The budget allocates substantial funds to fieldwork despite the predominantly retrospective nature of the study, raising concerns regarding the alignment between methodology and resource allocation.
13. Clarification is required regarding the involvement of a climate expert from Canada, who is also affiliated with the Ministry of Climate Change Pakistan as Co-PI, and whether data will be transferred to the Hospital for Sick Children (SickKids), Canada.
14. The proposed use of AI software raises significant concerns. The specific software, data protection guidelines, and governance mechanisms are not described. Given that potentially sensitive information may be entered, and that the data may have been collected at a time when analysis by AI was not anticipated, it must be clarified whether only anonymized data will be imported into the AI system.
15. It was noted that the ERC approval is almost one year old, which raises questions regarding the current status of the study.
16. It was queried why the study is being conducted in districts of Sindh rather than in flood-affected areas of Punjab.
17. While this retrospective cohort study could provide valuable information, there is significant concern that the underlying data may be of poor quality. As presented, the study raises concerns that it may be predatory in nature.

Minutes of the NBC-R meeting held on 23-06-2026

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on June 23rd, 2026. The following members of NBC-R attended the meeting:

Sr.#	Group-II	
1.	Prof. Nazli Hossain	Chairperson
2.	Prof. Ejaz Ahmed Khan	Vice Chairperson
3.	Prof. Saqib Mehmood	Member
4.	Prof. Shahid Mehmood Baig	Member
5.	Dr. Natasha Anwar	Member
6.	Prof. Akhtar Sherin	Member
7.	Mr. Mazhar Iqbal	National Coordinator

The following projects reviewed / discussed:

Title: **Trial: Comparing the Efficacy and Safety of Vericiguat with Standard Medical Treatment in Patients with Heart Failure and Reduced Ejection Fraction: Randomized, placebo-controlled, parallel-group, double-blind trial.**

Project #	PI Name & Address
NBCR-1425	**Dr. Ghazala Irfan** National Institute Cardiovacular Dieases Rafiqi (H.J. haheed Road, Karachi Cantonment, Karachi.

Final NBC-R Comments

1. Study design? At places PI writes placebo, and at places standard of care.
2. How can a heart failure patient receive placebo? Clarification that all patients will be receiving Standard of Care in addition to either placebo or the trial drug. Right?
3. Another question/clarification, is this trial registered?
4. The Primary Endpoint is explicitly defined as the change in the quality of life using the "Kansas City Cardiomyopathy Questionnaire (KCCQ-12)". Hospitalization and cardiovascular mortality are listed as Secondary Endpoints. They calculate the sample size using a primary outcome event defined as the "Composite of death from cardiovascular causes or first hospitalization for heart failure (35.5% vs 38.5%)". The primary endpoint should be decided. If it is the clinical composite (CV death/HF hospitalization), the endpoint section needs to be updated. If it is the KCCQ-12 score, the sample size calculation method is mathematically invalid for this study and must be recalculated based on expected changes in questionnaire scores.
5. The sample size calculation is based on the composite outcome of cardiovascular death or first hospitalization for heart failure. However, the protocol lists Quality of Life (KCCQ-12) as the primary endpoint and cardiovascular outcomes as secondary endpoints. Clarification is required regarding the true primary endpoint and whether the sample size calculation is appropriate for that endpoint.
6. Has the KCCQ-12 been translated by the researchers? Can it be converted into comprehensible language? The proposal needs clarification on methodology; how will it be executed? There is no mention of follow up of patients? How will they be followed to assess the effect of drug?
7. How many follow-ups will be required of the study participants, and is there any compensation for their commute and time for follow-up?
8. The investigators should provide details for rescue treatment options, emergency unblinding procedures, and withdrawal criteria.
9. Section 2.5 in NBC form says that "the study will provide education on heart failure management, including lifestyle advice and symptoms monitoring to participants and families" while the study protocol or objectives do not show anything of that sort in the

plan.

10. The protocol says a total study timeline of 12 months. However, the Informed Consent states that the sponsor will only provide the medications for 6 months.
11. What is the total duration of the study?
12. The protocol states a study duration of 12 months. Elsewhere, it refers to a median follow-up of approximately 6 months and participant evaluations only up to month 6.
13. How will be adverse events monitored, provision of support for the study participants in event of AE. The protocol in Safety Outcomes states that there will be a "clinical events committee, who will be on this committee? Who will be on the "steering committee" or the clinical data and safety monitoring board (DSMB)? Event adjudication committee (EAC)?
14. How will the adverse events be recorded and by whom?
15. What is the plan for sharing the adverse events with the IRBs?
16. Clarify DSMB membership, independence, review frequency, reporting mechanisms, and stopping criteria.
17. Apart from drug, what other benefits will be there for patients? Will they be given free investigations, echo?
18. The harms of these medicines have been very humbly described. And receiving the trial drug or its "potential" benefits cannot be counted as a direct benefit to the research participant.
19. The researchers state in the NBC form that the Harms/risks are minimal. That is not true.
20. This is a "more than minimal risk" study and should be treated like that.
21. There should be a balanced presentation of potential benefits and known risks.
22. What is the post-study plan for the availability of the drug to the research participants, IF found helpful?
23. Section K (Contact Person) on Page 2 of the Informed Consent Form leaves fields such as the Doctor's Name and Telephone/Contact Numbers entirely blank. The trial participants must have an immediate way to reach the research team in the event of an adverse reaction or injury.
24. How much time will be given to the research participants to read and sign the informed consent? Will they be asked to do that while they are visiting an outpatient clinic or when they are admitted? How do the researchers ensure that they know and understand all the risks and benefits involved in this research?
25. The informed consent is inadequate. Does not actually inform the patients of risks involved and how they will be managed. The second part especially the trial drug related implies all the responsibility of finding and understanding side effects etc on the research participants
26. When in reality, this should be the job of researchers to give them all the information to be able to make an informed" decision.
27. The IC also does not guide them on how and where to report the side effects.
28. According to IC: Will any injury while being a study participant be catered to by NICVD?
29. IC: I don't see that the patients are being told that they might be receiving a placebo.
30. In IC and everywhere else, "potential" benefits of the drug are highlighted as the "benefits of the study" how can this be true when half of the patients will be receiving a placebo?
31. While the consent form contains the required elements of informed consent, it is lengthy, densely formatted, and highly technical in language. The document appears to be written more like a protocol than a participant information sheet. Consider

restructuring the consent form around participant-focused questions: Why is the study being done? Why have I been invited? What will happen to me? What are the risks and benefits? What alternatives do I have?

32. Consider adding a brief "Information" section at the beginning summarizing the purpose of the study, procedures, risks, benefits, alternatives, and voluntary nature of participation.
33. The bilingual English–Urdu format is appreciated; however, improvements in layout, readability, and simplification of technical language would enhance participant understanding, not sure if currently the average heart failure patient attending NICVD can reasonably read, understand, and use the information to make an informed decision.
34. The section about compensation requires more details and should specify arrangements for management and reimbursement of research-related injury. It is not sufficient to state that care will be provided, will there be a limit, what will be covered and what will not be covered. Insurance or indemnity arrangements should be described.
35. What is the role of funding pharma company? Will they have access to the participants' data?
36. There needs to be a clarification of the sponsor role in study design, conduct, data analysis, publication, drug supply, placebo supply, and data ownership. Appropriate conflict-of-interest management should be described.
37. Body fluids and tissues may be sampled – no details of what and how. Not mentioned in the protocol. Need to know if additional samples will be collected what will they be used for and how long will they be stored
38. There is no information regarding data storage, security, access controls, retention, and destruction/anonymization.
39. The funding document only outlines personal, direct, and indirect costs. A comprehensive breakdown of all funding is required. The budget is too vague. Please clarify whether the study medication, placebo, laboratory investigations, DSMB activities, and endpoint adjudication processes are covered within the submitted budget or provided through separate institutional or sponsor support.

Title: **Trial: Trientine tetrahydrochloride Administered once a day for the first line treatment of Wilson's disease patients.**

Project #	PI Name & Address
NBCR-1426	**Prof. Huma Arshad Cheema** Children Hospital, University of Child Health Sciences, Kasur Rd, Nishtar Town, Lahore

Final NBC-R Comments

1. The main protocol has been provided but there is no site-specific protocol outlining how the study will be operated at the different sites.
2. The protocol includes clinical assessments that may influence eligibility, determination of disease worsening, treatment continuation, and treatment failure. Please clarify: if the investigators have prior experience using the proposed assessment tools; if study-specific training or certification will be provided before enrollment begins; how consistency between participating sites will be ensured; if assessment manuals, training materials, or competency evaluations are available.
3. Please provide confirmation that the DSMB has been formally constituted and provide the final DSMB membership, as the submitted Charter identifies the DSMB Chair as "TBC."
4. The DSMB Charter describes DSMB review of cumulative safety data, deaths, SAEs and SUSARs; however, the pathway by which site-level safety events are escalated from

investigators to the Sponsor and subsequently to the DSMB is not fully described.

5. Genetic testing will be conducted, however no counselling or access to counselling services has been mentioned.
6. The investigators have done well to make available age-specific consent and assent documents. However, the adult and parent information sheets are lengthy and contain substantial regulatory and technical information that may affect participant comprehension. It would be advisable to simplify the document and cover purpose of the study, procedures, risks, benefits, alternatives, sample transfer arrangements, and voluntary nature of participation to facilitate informed decision-making.
7. The consent form states that samples may be provided to "third parties" for testing, research use, and storage on behalf of the sponsor and its collaborators. Further clarification is required for the following: which organizations may receive participant samples; whether samples will be transferred to Labcorp Singapore or other named laboratories; whether any additional third-party collaborators may receive samples.
8. It would be a good idea to revise the consent form to provide participants with more specific information regarding the destination and purpose of sample transfers. The consent form does not explicitly tell participants that samples will be exported to Singapore and retained for up to 5 years.
9. Does "research use" mean only research described in this protocol, or does it include future unspecified research
10. The submission includes a certificate of insurance indicating that study participants are covered under the applicable insurance policy. However, the certificate alone does not provide sufficient detail regarding the scope and applicability of coverage. Can the investigators confirm that the policy covers research-related injury arising from participation in this study, including participants enrolled at all participating sites in Pakistan and pediatric participants where applicable. Given that this is an international multicenter clinical trial, a policy summary or relevant policy provisions should be provided for review to allow assessment of the extent of coverage, exclusions, compensation arrangements, and applicability across participating sites.
11. Please describe whether the study includes any plans for local capacity strengthening, technology transfer, training, or collaboration that may enhance future diagnostic and clinical care for Wilson disease in Pakistan.
12. Could the investigators provide details regarding post-trial access arrangements? Specifically, if TETA 4HCl demonstrates clinical benefit, please indicate whether mechanisms are anticipated to support continued access for participants following study completion, and whether there are plans for future availability, registration, affordability, or access to relevant diagnostic testing within Pakistan.

Title: **Bridging Science and Society: Identifying Community Levers and Co-Designing Metabolic Disorders Prevention Strategies in Karachi, Pakistan.**

Project #	PI Name & Address
NBCR-1427	**Ms. Samina Akhtar** Department of Medicine Aga Khan University Karachi.

Final NBC-R Comments

1. NBC form has been submitted without the required signatures of the PI and Supervisor/Chairman.
2. The project timeline is inconsistent with the May 2026 NBC submission date, as planning, ethical approval, and parts of data collection were scheduled for 2025 in Gantt chart.
3. Registration of the scoping review protocol (e.g., OSF or PROSPERO) is not addressed and

should be considered to improve transparency and reproducibility.

4. How do the researchers plan to recruit the patients (from Children hospital)?
5. NBC need clarification about the study design. Is it a randomized controlled trial? Will one group be receiving standard of care, and the other will receive SOC + Trial drug?
6. The protocol inconsistently uses the terms “thematic saturation” and “theoretical saturation”, which represent different qualitative methodologies. Terminology should align with the stated analytical framework.
7. The statement that interviews may continue until “the point of saturation” is methodologically unclear, as saturation is generally assessed across interviews rather than within a single interview. This wording should be reconsidered; it is a technical term and may also not be truly understood by participants
8. The protocol should explain how the mapping exercise will be adapted for participants with low literacy.
9. Selection criteria for workshop participants, particularly the “2–3 most engaged community members” forming the Core Design Team, are not specified.
10. The process for selecting the final “one or two most promising strategies” lacks predefined criteria and should incorporate a transparent decision-making framework (e.g., feasibility scoring, stakeholder voting, or consensus methods) to minimize researcher bias.
11. Too many follow-ups, visits, labs, etc and no compensation?
12. The protocol states that the study will be conducted in "urban informal settlements and rural catchment areas of Karachi"; however, the specific communities, neighborhoods, or catchment areas have not been identified. Could the investigator please provide details of: the proposed study sites; the rationale for their selection; how diversity of socioeconomic, cultural, and demographic contexts will be represented; the recruitment strategy for each site.
13. The proposal aims to identify community levers influencing metabolic health across Karachi; however, the planned qualitative sample is relatively small and drawn from selected stakeholder groups and communities. The investigators are requested to clarify how the proposed sample will adequately capture the diversity of Karachi’s socioeconomic, cultural, and environmental contexts and support conclusions at a city-wide level. Consideration should be given to framing the study as an exploratory assessment of selected communities within Karachi, with findings intended to inform the development of contextually relevant prevention strategies rather than represent the experiences and perspectives of Karachi as a whole.
14. Gender representation is inadequately addressed despite identifying gender-related barriers to physical activity. The protocol should include a clear gender-equity strategy and specify recruitment of women community members, female frontline workers, and female influencers to ensure adequate representation.
15. The study contains limited exploration of gender-related influences on health behaviors, including women's mobility, household decision-making, cultural norms around physical activity, and access to community resources.
16. The study focuses primarily on individual knowledge, motivation, and behavior. Greater attention may be needed to structural determinants such as food affordability, employment, transportation, urban design, food marketing, and access to healthy food so as not to only see behavior in isolation but within the context that defines it.
17. Several questions may inadvertently frame NCD prevention as an individual responsibility rather than exploring broader social, economic, and environmental influences on health.
18. Questions exploring causes of diabetes, obesity, and hypertension may generate stigmatizing or discriminatory explanations regarding particular groups or communities. Guidance for interviewers on managing such discussions should be considered.
19. Several questions in the questionnaire may elicit information about identifiable

individuals who are not study participants (e.g., family members, teachers, faith leaders, community influencers). Clarification is required regarding how such information will be anonymized and managed during transcription, analysis, and reporting.

20. Participants are asked to comment on the behaviors and influence of other individuals and groups. The protocol should clarify how such indirect information will be interpreted and reported.
21. Section 2.2 is inadequate. The researchers must clearly if the study has any benefits i) directly to research participants, ii) to the community, and, iii) to society/science in general.
22. The risk mitigation strategies must also include, in addition to titration or discontinuation of the drug, how they will manage the side effects, for example, if a patient has hypersensitivity, how/where/when/by whom will those symptoms be managed.
23. Important thing to remember is that these patients have no other therapies available once the traditional therapy fails. There is a huge risk of therapeutic misconception or false hope among the patients/families.
24. Discussions regarding barriers to health, poverty, illness, or lack of community resources may generate frustration or emotional discomfort. The protocol should describe how interviewers will respond if participants become distressed during interviews.
25. The consent form states that no risks or discomforts are anticipated. While physical risks are minimal, participants may experience psychological discomfort, concerns regarding confidentiality, or unease when discussing personal health behaviours, community challenges, institutional weaknesses, or policy gaps. The risk statement should be revised accordingly.
26. The consent process for co-design workshop participants is not described and should include participant information, consent for participation, consent for audio recording, and consent for use of workshop-generated data.
27. Although interviews are stated to be audio-recorded, explicit consent for audio recording is not separately addressed in the consent form and should be included as a distinct component of informed consent.
28. What happens if someone agrees to participate in the study but does not agree to be recorded?
29. The assent and consent forms are too long and overwhelming. What is the plan of researchers to ensure that the research participants understand this?
30. What will the researchers do if the patient, who is a child, does not know these many details about her illness or prognosis? Will they still be asked to read the whole document?
31. What is the researchers' plan if the parents agree but the child refuses, or if parents refuse but the child wants to participate in the study?
32. If interviews are conducted in participants' homes the protocol should describe measures to ensure privacy and confidentiality where family members or others may be present and influence responses.
33. Why the school needs to know all the details about Wilsons and the research.
34. That's up to the patient and their parents to decide how much info they would like to share with the school/teachers. Isn't just a letter that the child is receiving treatment or is a part of research related to his treatment, enough?
35. Although participant names are listed as optional, the combination of job role, organization, years of experience, and responses may make individual policymakers, programme managers, NGO representatives, and public health experts readily identifiable. The protocol should clarify how confidentiality and anonymity will be maintained in reporting.
36. Participants may provide critical views regarding government programmes, institutional performance, funding decisions, policy gaps, or inter-organizational coordination. The protocol should describe measures to protect participants from potential professional or reputational consequences arising from disclosure of such opinions.

37. Questions relating to programme effectiveness, coordination, policy implementation, and funding gaps may elicit information that participants consider sensitive or not publicly available. Clarification is needed regarding how such information will be handled and reported.
38. Interviews with policymakers, programme managers, and senior officials may involve hierarchical or institutional pressures. The protocol should clarify how voluntary participation will be ensured and how potential conflicts of interest will be managed.
39. What is the plan to report SAEs to IRBs?
40. The sponsors will have access and will store all the data and samples. This is a little discomforting. The section 2.8 suggests that the samples will be kept and may be used by the sponsors for any future research. This is very concerning. What is being done to ensure that the research participants are protected, have the exact knowledge and will not be disadvantaged if any information from future research implies their or their relatives' wellbeing?
41. The protocol should clarify whether data will be shared with international collaborators and whether any participant-level data will be transferred outside Pakistan. Given funding through the Gates Foundation, the committee should verify whether any data-sharing, reporting, Data Transfer Agreement (DTA), or Data Use Agreement (DUA) requirements exist.
42. If AI-assisted tools will be used for coding or qualitative data processing, the specific tools and data-processing environment (local or cloud-based) should be identified to address data privacy and sovereignty concerns.
43. The confidentiality section requires additional detail regarding: who will have access to recordings and transcripts; whether transcription will be performed by study staff or third parties; data storage arrangements; duration of retention of recordings and transcripts; and procedures for destruction of recordings.
44. The consent form does not indicate whether de-identified data or transcripts may be shared with collaborators, funders, or used in future research. If such data sharing is planned, participants should be informed.
45. The form states that no financial compensation will be provided. Clarification may be helpful regarding whether transportation or other reasonable participant expenses will be reimbursed.
46. The study is described as co-designing prevention strategies, but participants are not told what happens after the interview. Will they be invited to workshops? Will they have any role in reviewing or shaping the interventions? The consent form presents participation as a one-off interview, whereas the project title suggests a more participatory process.
47. For a Gates Foundation-funded project focusing on community engagement and co-design, there is surprisingly little mention of community feedback, dissemination of results, and stakeholder engagement after data collection.
48. Given the involvement of policymakers, programme managers, NGOs, and public health experts, consideration should be given to how study findings will be shared with participating stakeholders and whether opportunities for feedback on findings will be provided.
49. Contact information for the relevant Ethics Review Committee should be included to allow participants to raise concerns regarding their rights as research participants or to submit complaints independent of the research team.
50. The budget allocates funds for IDI and KII participant incentives, whereas the consent form states that no financial incentive will be provided. The budget includes costs for air travel to Islamabad and hotel accommodation, whereas the study activities are proposed to be conducted in Karachi. The protocol does not explain the purpose of these travel-related expenses or how they are directly linked to study implementation.

Minutes of the NBC-R meeting held on 30-06-2026

The National Bioethics Committee for Research (NBC-R) zoom meeting was held on June 30th, 2026. The following members of NBC-R attended the meeting:

Sr.#	Group-I	
1.	Prof. Nazli Hossain	Chairperson
2.	Prof. Marie Andrades	Member
3.	Prof. Amjad Mehboob	Member
4.	Prof. Saira Afzal	Member
5.	Assistant Prof. Agha Ria	Member
6.	Dr. Faheem Ashraf Khan	Member
7.	Dr. Farah Asif	Member
8.	Mr. Mazhar Iqbal	National Coordinator
9.	Ms. Ayesha Abid	Assistant

The following projects reviewed / discussed:

Title: **Genomic and Environmental Drivers of Extensively Drug-Resistant Salmonella typhi Transmission in Pakistan.**

Project #	PI Name & Address
NBCR-1428	**Brad Spiller** Cardiff University (CU) Main Hospital Building, Floor 6th, University Hospital of Wales, Heath Park, Cardiff, CF14 4XN Country of PI Institute/Organization: United Kingdom **Prof. Dr. Rabaab Zahra** Quaid-i-Azam University (QAU) Department of Microbiology, QAU.

Final NBC-R Comments

1. PI is based at Cardiff University in the UK. The application correctly identifies a local Co-PI and site investigators, which is a step in the right direction. However, for a study so deeply rooted in the Pakistani context, a local principal investigator is strongly recommended as a matter of ethical and equitable partnership.
2. Application does not provide a specific sample size or a formal power calculation for the number of clinical isolates or environmental water samples to be collected. A vague statement like "will depend on availability and feasibility" is insufficient for ethical review. The sample size should be scientifically justified.
3. The eligibility criteria for participants are not clearly defined. The application mentions "selected close contacts or individuals with recurrent infection" and "patients... presenting to participating healthcare facilities." The specific criteria for enrollment must be defined.
4. Plan for benefit-sharing is very general ("improved disease control, safer water interventions"). For an international study, a more concrete plan for local capacity building, technology transfer, or co-authorship for local researchers is expected as part of an equitable partnership.
5. Plan for community engagement is limited to "collaboration with local clinicians, hospital leadership, and public health authorities." This does not clearly describe how the general community will be informed or engaged, which is an ethical requirement for research involving environmental and public health issues.
6. The informed consent form needs to be revised. Kindly add IRB and Researcher contact numbers. For patients in KPK, Pashto translation may be warranted. Add witness name and signatures as mentioned in the proposal, "For illiterate participants, consent will be read aloud and witnessed.
7. IRB of Cardiff university and Quaid e Azam University needed
8. **Retrospectives** stored blood samples (study will utilise archived blood culture isolates).

Prospective by collecting samples from various local water sources (sewage, clean drinking water and flood water samples), and where ethically approved, stool samples may be collected from individuals with recurrent infections and/or close contacts to investigate potential asymptomatic carriage. **Government permission needed to export water, sewerage samples.**

9. Study says (DNA will be extracted locally). Which institute will extract DNA not specified?? It is presumed to be KTH, QU, and BKMC?? Or just QU.
10. Consent form is very vague and not made according to NBCR guidelines. Was consent taken for the archived samples? For prospective stool samples the consent form is not appropriate. How long will the samples be stored for? Will they only be used for Typhoid testing?? How will data be anonymized using AI?
11. If we are diagnosing carriers, will they be treated for eradication of carrier state???
12. MTA needed

Title: **Fungal Cell Wall Targeting Immunotherapies: A New Approach for the Treatment of Drug-Resistant Invasive Fungal Infections.**

Project #	PI Name & Address
NBCR-1429	**Prof Dr Carol Munro** Institute of Medical Sciences, University of Aberdeen, UK University Office, King's College, Regent Walk, Aberdeen, AB24 3FX, UK.

Final NBC-R Comments

1. This is a laboratory-based study using clinical isolates. The application correctly identifies that direct participant or community engagement (and thus informed consent) is not applicable for the basic research work. However, this triggers an important question that must be addressed: How were the clinical isolates obtained originally? A waiver of consent for the use of these isolates in this study requires a clear justification from the original study or clinical source. This justification or clarity must be provided.
2. For an international collaboration, a more concrete plan for local capacity building, technology transfer, or co-authorship for local researchers is expected as part of an equitable partnership. The application's statement that "findings may contribute to future development" is too vague.

Title: **Trial: An open-label, randomized, single-dose, two-treatment, two-period, two-sequence, crossover bioequivalence study of ITAGLIP PLUS XR (Sitagliptin-Metformin Extended-Release) 50/500 mg tablet (Test) versus JANUMET XR (Sitagliptin-Metformin Extended-Release) 50/500 mg tablet (Reference) under fasting and fed conditions in healthy adult participants..**

Project #	PI Name & Address
NBCR-1430	**Dr. Sadia Asim** Institute of Biological, Biochemical & Pharmaceutical Sciences (IBBPS) Dow University of Health Sciences, (DUHS) Ojha Campus, Karachi, Pakistan.

Final NBC-R Comments

1. The most pressing issue is the conflict between the proposed study design and Pakistan's Bio-study Rules.
2. DRAP rules ought to be considered for such investigations. Moreover, DRAP's approval is required for study site approval also.
3. Enrolling only healthy male participants is a well-established practice in BE studies, but it is a significant ethical limitation. By excluding females, the application fails to adequately plan for a future product that will be used by both genders. The justification is weak and does not fully satisfy the ethical imperative for fair participant selection.
4. Provision of a standard breakfast in the 'fasting arm' sounds like a protocol violation. Giving food 4 hours post-dose violates the standard required fasting period for BE studies

under fasting conditions and will compromise the study's results and regulatory acceptability. Check the protocol again.
5. The application contains minor typographical errors, such as an inconsistency in the sample size calculation justification between the main text and the structured abstract.
6. The application states "N/A" for conflict of interest, but the Principal Investigator is also the Director of IBBPS. This is a potential institutional conflict that should be declared.
7. How is ITAGLIP XR cost effective versus standard drug?
8. The consent form needs to use layman terms. The patient be pricked 16 times for blood collection. Needs to be specifically mentioned and method of blood collection needs to be mentioned in ICF

Title: **Trial: An open-label, randomized, single-dose, two-treatment, two-period, two-sequence crossover bioequivalence study of ITAGLIP PLUS XR (Sitagliptin-Metformin Extended-Release) 100/1000 mg tablet (Test) versus JANUMET XR (Sitagliptin-Metformin Extended-Release) 100/ 1000 mg tablet (Reference) under fasting and fed conditions in healthy adult participants...**

Project #	PI Name & Address
NBCR-1431	**Dr. Sadia Asim** Institute of Biological, Biochemical & Pharmaceutical Sciences (IBBPS) Dow University of Health Sciences, (DUHS) Ojha Campus, Karachi, Pakistan.

Final NBC-R Comments

1. This is a nearly identical application to the previous one for a higher strength of the same drug combination. While the format is correct and the required sections are mostly complete, the core ethical and scientific deficiencies are same.
2. The most pressing issue is the conflict between the proposed study design and Pakistan's Bio-study Rules. DRAP rules ought to be considered for such investigations. Moreover, DRAP's approval is required for study site approval also.
3. The application provides no justification for why women of childbearing potential are excluded. This is a significant ethical oversight and a violation of the principle of fair and equitable participant selection.
4. Provision of a standard breakfast in the 'fasting arm' sounds like a protocol violation. Giving food 4 hours post-dose violates the standard required fasting period for BE studies under fasting conditions and will compromise the study's results and regulatory acceptability. Check the protocol again.
5. The provided sample size justification is copied from the 50/500 mg study and uses the same parameters (CV=13.31%, Mean ratio=93.42). This is unlikely to be accurate for the 100/1000 mg formulation and raises concerns about the validity of the statistical power calculation for this specific study.
6. The application states "N/A" for conflict of interest, but the Principal Investigator is also the Director of IBBPS. This is a potential institutional conflict that should be declared
7. How is ITAGLIP XR cost effective versus standard drug?
8. The consent form needs to use layman terms. The patient be pricked 16 times for blood collection. Needs to be specifically mentioned and method of blood collection needs to be mentioned in ICF

Title: **Evaluation of appropriate practice for VTE prophylaxis in surgical patients in Pakistan – A pharmacoepidemiologic study.**

Project #	PI Name & Address
NBCR-1444	**Prof. Dr. Muhammad Waris Farooka** National Hospital & Medical Center Street 123, Sector L DHA Phase 1, Lahore.

Final NBC-R Comments

1. PI has not signed the application himself; whereas NBC-R requires the application to be signed and stamped by the PI themselves. This is a procedural requirement.
2. Inclusion criteria state "Surgical patients who are undergoing any major elective or

emergency surgery..." but the definition of "major" surgery is not provided. This is a significant ambiguity that could lead to inconsistent enrollment across the six sites. A clear, operational definition is required.

3. Protocol states, "All eligible participants will be enrolled only after obtaining written informed consent." In the context of surgical patients who may be in a state of anxiety or stress pre-operatively, obtaining consent "sufficiently before the start of the study" is a challenge. The applicant must describe the specific timing and process for obtaining consent to ensure it is truly informed and voluntary, and not under duress.
4. The primary data for the study is retrospective/prospective data collection from patient records and VTE prophylaxis practices. A waiver of consent for the retrospective component (or portions of it) may be appropriate to avoid selection bias. The application does not address this, which is a standard consideration for such pharmacoepidemiology studies.
5. References in protocol very old except for the guidelines. One of the latest relevant references (Venous thromboembolism in hospitalized medical patients: incidence, risk factors, and prevention gaps in a resource-limited setting. KJMS January March 2026, Volume 19, No. 1) not mentioned
6. The consent form is for patients (needs to be in layman language). Doctors consent form missing (what is the sample size for KAP of doctors?)
7. Poorly written protocol very confusing. Study design is flawed. IT does not match the objectives of the study.
8. The main objective (To evaluate the adherence of current clinical practice for venous thromboembolism (VTE) prophylaxis in surgical patients in Pakistan to international guidelines) CAN BE DONE THROUGH RETROSPECTIVE REVIEW OF CHARTS. **Secondary Objectiv**e: To explore healthcare providers knowledge, perceptions and barriers regarding venous thromboembolism (VTE) risk assessment and prophylaxis
9. This pharmacoepidemiology study will assess the time-based incidence of VTE events over a 30-day follow-up period. (THAT IS NOT THE OBJECTIVES)

Nazli Hussain

Chairperson