

Minutes of the REC meeting held on 20-12-2022

The Research Ethics Committee (REC) zoom meeting was held on December 20, 2022. The following members of REC attended the meeting:

1. Prof. Dr. Saima Pervaiz Iqbal	Chairperson
2. Dr. Nighat Murad	Focal Person
3. Prof. Dr. Munir Saleemi	Member
4. Prof. Dr. Jamshed Akhtar	Member
5. Dr. Farkhanda Ghafoor	Member
6. Dr. Sualeha Siddiqui Sheikhani	Member
7. Prof. Amjad Mehboob	Member
8. Prof. Marie Andraes	Member
9. Prof. Dr. Nazli Hossain	Member
10. Dr. Faiza Bashir	National Coordinator
11. Mr. Khalid Mehmood	Assistant NBC
12. Mr. Waryal Ali Daheri	L.D.C.

The following projects reviewed / discussed:

NBC-881:

Title: Single oral dose of azithromycin 2 gm to prevent maternal peripartum infection and newborn sepsis in laboring women (A-PLUS Trial); Repurposing azithromycin as a neuro-protector; a neurodevelopmental follow-up secondary study (Azithromycin: Brain neuroprotection for Children) – ABC Study.

Principal Investigator: Dr. Siham Sundar Department of Community Health Sciences, Aga Khan University,

Comments:

1. Our prime concern is how can the PI in AKUH conduct this study in JPMC and JPMC only which is a public sector hospital? Is there any sort of capacity building for JPMC and its staff so that they can conduct future trials on their own and apply for foreign grants? It seems that a private sector organization is simply using JPMC as a trial site for patients without any moral responsibility towards uplift of a public sector hospital.
2. IRB of AKUH and JPMC needs to be attached.
3. Budget details to be provided in depth so that REC is aware of where the money is being spent. Detailed protocol to be sent as well.
4. Focal person from JPMC needs to be identified.
5. ICF translation to Urdu needs to be simplified and not given in "lughat" language. (Understandable by an eighth grader)
6. If a child is picked up with neuro developmental delay what mechanism exists to get that child checked up and referred for further management? Are pediatricians or child psychologists involved?
7. What adverse events are expected in this trial?
8. Will the dose of azithromycin have an effect on the microbiome of the fetus? Is azithromycin being given as it should be according to its pharmacokinetics?

NBC-882:

Title: Opioid Prescription And Usage After Surgery (OPERAS)

Principal Investigator: Prof. Peter Pockney Hunter Medical Research Institute, Newcastle, NSW, Australia
Dr. Adya Ejaz: United Medical College, Creek General Hospital, Korangi, Karachi

Final Comments:

1. Large number of steering committee members are medical students. This needs clarification as study is invasive using opioids and in multi centers. In what capacity they are part of it?
2. How local collaborators are identified? Are they experts in research / surgeons operating upon patients etc?
3. Duration of study was four months in 2022. This timeline is no more applicable.
4. Which of the opioids will be used, is not specified. In Pakistan drugs like morphine, pethidine, codeine etc are controlled drugs and are not available for use as such in postoperative period. Thus protocol appears to be quite non uniform. Choosing between various agents at the will of PI ??? or operating surgeon is not clear.
5. Informed consent is too superficial and sketchy.
6. It is also of interest for international collaborator that morphine and pethidine were routinely used in postoperative period some three decades ago but due to abuse and other issues it was disallowed and declared controlled drug. This information is missing in the text.

COVID-129:

Title: A qualitative study which explores the elements of COVID-19 vaccine hesitancy in pregnant women in a rural district of Pakistan.

Principal Investigator: Dr. Shiyam Sundar Department of Community Health Sciences, Aga Khan University, PO Box 3500, Stadium Road, Karachi.

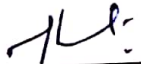
Final REC Comments:

1. The investigators must hold counseling sessions for hesitant subjects later in the study.
2. Budget lacks sufficient details and justifications
3. Consent form needs a mention of the information sharing with international collaborators and then seek the informed permission.
4. Timelines need revision.

Next meeting:

The next zoom meeting will be held at 03:00 pm on December 27, 2022. The following projects will be reviewed:

1. COVID-130
2. NBC-883
3. NBC-885
4. NBC-902



Focal person NBC



Chairperson REC

NBC-902:

Title: **National Survey on the Extent, Patterns and Trends of Drug Use in Pakistan 2022-23.**

Principal Investigator: Dr. Ayesha Sheraz,
National Institute of Population Studies (NIPS), NIH, Park Road,
Chank Shahzad, Islamabad

Final REC Comments:

1. Operational definitions of this project need clarity. What is included in the term "drug use"? Most questions are focused on alcohol but there may be others.
2. How will confidentiality be ensured in case someone does not wish to disclose his drug use in front of the household.
3. If 15 year olds are being included then an assent form will be required.

COVID-130:

Title: **A prospective, observational, multicentre, cohort study to follow-up patients with suspected or confirmed COVID-19 infection discharged alive from intensive care units across Pakistan.**

Principal Investigator: Dr Madiha Hashmi
South East Asian Research in Critical care Health, 199-E, Street 6,
Cavalry Grounds, Lahore Cantt, Pakistan

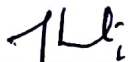
Final REC Comments:

1. Please identify focal persons and institutions from where data will be collected within Pakistan.
2. Is there an inbuilt process of facilitating any rehabilitation services if required by participants?
3. Is there a possibility of causing distress to the family if the participant has died and they have to relive the experiences?
4. Please confirm what is meant by "viral status" mentioned in Appendix 1.

Next meeting:

The next zoom meeting will be held at 03:00 pm on January 3, 2023. The following projects will be reviewed:

1. NBC-886
2. NBC-887
3. NBC-888
4. COVID-131



Focal person NBC



Chairperson REC