

Minutes of the REC meeting held on 7-4-2023

The Research Ethics Committee (REC) zoom meeting was held on April 4, 2023. The following members of REC attended the meeting:

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|----------------------------------|------------------------------|
| 1. Prof. Dr. Saima Pervaiz Iqbal | Chairperson |
| 2. Prof. Dr. Munir Saleemi | Member |
| 3. Prof. Dr. Jamshed Akhtar | Member |
| 4. Prof. Dr. Amjad Mehboob | Member |
| 5. Dr. Farkhanda Ghafoor | Member |
| 6. Dr. Faiz Bashir | National Coordinator (NBC-R) |
| 7. Mr. Waryal Ali Daheri | L.D.C (NBC-R-Secretariat) |

The following projects reviewed / discussed:

NBC-946:

Title: **TENDENCY (The Fatty Liver, Cirrhosis an Liver Cancer Study).**

Principal Investigator: **Dr. Ahmad Karima Malik**
Department of hepatology, Pakistan Kidney and Liver Institute and
Research Centre. PKLI Avenue, DHA Phase 6
Lahore

Final REC Comments:

1. It is unclear why controls are being recruited from the UK and not from Pakistan. This makes no sense for a case-control study which should be matched by age, gender and ethnicity.
2. MTA needs to be attached.
3. What does self-funded (PKR 19,000/-) mean in the budget?
4. The informed consent form should provide more details about privacy and confidentiality of data.
5. What is the role of the local PI in terms of intellectual input?

COVID-136:

Title: **A Randomized, Blind, Active-controlled Phase I/II/III study to Investigate the Safety and Immunogenicity of Bivalent mRNA vaccine (RBMRNA-909) as a Booster dose in COVID-19 vaccine-experienced Healthy Adults.**

Principal Investigator: **Prof. Dr. M. Raza Shah T.I.**
Center for Bioequivalence studies and Clinical Research (CBSCR),
ICCBS, University of Karachi,
Karachi.

Final REC Comments:

1. We need complete documentation of the Co-PIs from other sites along with IRB approval letters.
2. What biospecimens and/or genetic material is being collected? It was not clear in the proposal. If samples are being sent abroad then MTA needs to be attached.
3. How is Dr. Iqbal Afridi, a psychiatrist involved in a vaccine trial? Has he such experience before?
4. Please provide constitution of the DSMB.
5. The current project cannot be approved with all three phases. We recommend that PI starts with Phase 1 trial and present the findings before moving onto Phase 2 and 3.

Next meeting:

The next zoom meeting will be held at 02:30 pm on May 2, 2023. The following projects will be reviewed:

1. NBC-932
2. NBC-934
3. NBC-936
4. NBC-938
5. NBC-939
6. NBC-940



Focal person NBC



Chairperson REC