

**MINUTES OF THE MEETING OF RESEARCH ETHICS COMMITTEE (REC) OF
NATIONAL BIOETHICS COMMITTEE HELD ON NOVEMBER 25, 2010, AT
PMRC RESEARCH CENTRE, JPMC, KARACHI**

A meeting of the Research Ethics Committee of the National Bioethics Committee (NBC) was held on 25th November 2010 at PMRC Research Centre, Jinnah Post Graduate Medical Centre, Karachi. Professor Dr. Zulfiqar Ahmed Bhutta, Chaired the meeting.

The following members attended the meeting:

1. Prof. Zulfiqar A Bhutta, Prof. of Paediatrics & Child Health, the Aga Khan University, Karachi.
2. Dr. Maqbool H. Jaffery, Consultant Physician/ Cardiologist, Karachi Institute of Heart Diseases, Karachi
3. Prof. Aasim Ahmad, Chief Nephrologist, the Kidney Centre, Karachi.
4. Mr. Shaukat Ali Jawaid, Chief Editor, Pakistan Journal of Medical Sciences and Pulse International, Karachi
5. Dr Huma Qureshi, Executive Director, PMRC, Member / Secretary NBC

The following members could not attend the meeting due to their prior commitments:

1. Prof. Muhammad M. Amin, Dean, Shifa College of Medicine, Islamabad.
2. Prof. S. Haroon Ahmed, Director, Psycho Social Centre, Director, Psycho Social Centre, 11-13 Hilal-e-Ahmer House, Clifton, Karachi
3. Dr. Farid Khan, 68/1 Khyban-e-Mahafiz, Phase 6, DHA, Karachi

Dr Zulfiqar A Bhutta, Chairman REC, welcomed the participants of the meeting. Dr Huma Qureshi briefed the Members on the progress with regard to the decisions of the last NBC meeting. She presented the minutes of last NBC meeting held on 22nd May for approval. All members unanimously approved the Minutes.

Prior to proceeding with the project review by the committee, a policy discussion was held as to how to accelerate the implementation of decisions with regard to last NBC meeting. Following suggestions/decisions were made:

- A. National Bioethics Committee to be registered with international bodies such as US regulatory authority.
- B. Activation of Medical Ethics Sub-Committee of NBC. Dr Nadeem Akbar, Representative PMDC and Dr Maqbool Jaffery, Member NBC had previously consented to provide support for functionalization of this very important sub-committee. Chair REC strongly advised to expedite this process. If there is need to induct more academically qualified people from other organizations, they may be inducted as co-opted members. A Chair for this sub-committee also needs to be identified in the next NBC meeting.
- C. Physician-Pharma guidelines developed by the National Bioethics Committee under the leadership of Mr Shaukat Ali Jawaid may be put on the agenda of the next NBC meeting, for approval and endorsement by the Ministry of Health.
- D. Understanding the efforts that are required to take out a news letter (most members are busy with other commitments), it was decided that a website separate from the PMRC website

should be launched. Dr Anis Ahmed shall facilitate PMRC in developing an independent NBC website. A dedicated Webmaster should be employed for updating the website.

- E. Instead of developing a PC-I, it was suggested by the members that PMRC should apply for a grant from donor agencies like USAID. Professor Bhutta will explore the USAID funding.
- F. Provincial Bioethics Committees need to be established. Secretary NBC. A DO letter shall be written by the Federal Secretary Health to all provincial health Secretaries for establishment of provincial bioethics committees following the lines of national bioethics committee.
- G. The working of Clinical Research Organizations including Sea Horse Ltd and Metrics Research need shall be discussed in the next NBC meeting.
- H. Next meeting of NBC shall be held in the last week of December and Secretary Health will be requested to Chair the meeting.

A total of 03 old projects and 13 new projects previously circulated to REC members were reviewed by the group and following decisions/comments made:

1. Project-NBC-38: “Comparison of Microscopy and Rapid Diagnostic Test (RDT) for the Diagnosis of Malaria in Field Condition in Pakistan.”
 - Approved
2. Project-NBC-48: Pakistan TB Prevalence Survey 2010-2011
 - Approved
3. Project-NBC-50: Treatment supporters and their impact on treatment outcomes in routine TB programme conditions in district Rawalpindi, Pakistan.
 - Approved subject to ensuring that the doctors at the health facilities should obtain consent from the DOTS Facilitators prior to their being interviewed by the researcher. A line should be added in the consent form to verify if the consent of the supporter has been obtained.
4. Project-NBC-51: Rapid Nutritional Survey on Internally Displaced People in Flood Affected Areas 2010.
 - Approved
5. Project-NBC-52: Genetic, Phenotypic and Clinical Evaluation of Haemophilia A in Pakistan
 - It is unethical to give patient’s names to the researchers. The institute before giving the patients names must obtain the consent of the patients and only those who show willingness to get their tissues/blood tested should be processed.
 - Investigator should try to look if facilities to do the genotypic typing are available within Pakistan and if yes they should be done here only. If facilities are not available then only samples shall be sent abroad with assurance obtained from this institution that these samples will not be used for any other test other than the research objective for which they are being sent and that the samples would be destroyed once the research work is completed. This should be clearly written in the consent form also.

6. Project-NBC-53: Pakistan National Nutrition Survey, 2010-2011.
 - Approved
7. Project-NBC-63: Vitamin A supplementation coverage validation survey in Pakistan
 - Approved
8. Project-NBC-54: Role of Community-Based Savings Groups (CBSGs) in enabling greater utilization of Community Midwives in Chitral district of Pakistan
 - Date on the consent form is missing
 - Consent form in English has not been properly translated into Urdu
 - Add a line in the consent that “if you do not want to participate or want to quit any time during the study, you can do so”.
 - Participating group is not mentioned
 - Approved document from AKU ethics committee is not attached
 - Budget is too high and needs to be rationalized.
9. Project-NBC-55: “How far can I go? Social mobility of Community Midwives in Azad Kashmir”
 - Consent form is inadequate and most of the information on withdrawal and monetary support etc is missing. PI should use the format of NBC consent form
 - Date on the consent form is missing
 - The cost of consultancies in the budget is too high.
 - Budget is too much for such an activity and needs to be rationalized.
10. Project-NBC-56: Exploring Operational Barriers of CMWs Services in KPK.
 - Approved in principal
 - CMWs are not yet deployed in Mansehra and Kohat. What is the provision of deployment of CMWs in these districts in case they could not be deployed as perceived?
 - Consent should be as per NBC Format and date be mentioned in the consent.
11. Project-NBC-57: Identifying factors that enable community midwives to reduce the barriers to obstetric care in rural Pakistan.
 - In salaries the unit cost of Co-PI is too high. Some standardized formula should be devised to allow salaries/consultancy.
 - Are the consultancy costs consistent with the current standards of Pakistan or United Nations?
 - Consent should be as per NBC Format and date be mentioned in the consent.
12. Project-NBC-58: Are community midwives addressing the inequities in access to skilled birth attendance in Punjab, Pakistan?
 - A technically sound project.
 - PI should incorporate the ways and means on how the locals would be given feed back of the project observations?
 - Very heavy budget. Need to be rationalized.

- Note: one project which is covering two districts has a total budget of \$ 0.5 million, where as another project in 18 districts is costing only \$100,000. This disparity need to be carefully looked into and proper justification provided.
- Consent should be as per NBC Format and date be mentioned in the consent

13. Project-NBC-59: Are CMWs Accessible in Sindh and Punjab?”

- Approved.
- It’s a reasonable project in budget and size.

14. Project-NBC-60: Preference of Birthing Place: A mixed methods study of Communities, Households, Community Midwives & MNCH Program

- Title does not reflect that it is a national study.
- Sample design is not clear. Sample size of 1420 is not representative
- Results of only 02 FGDs cannot be generalized for the whole province
- Consent should be as per NBC Format and date be mentioned in the consent.

15. Project-NBC-61: Community mobilization through the Community Midwives (CMWs) – An initiative for community behavior change and mobilization

- Approved
- Consent form in Urdu not available

16. Project-NBC-62: Assessment of Community Participation in the Community Mid-Wives Program

- Consent should be as per NBC Format and date be mentioned in the consent.
- Very heavy budget. Need to be rationalized.

Meeting ended with the vote of thanks by the Chair