

**MINUTES OF THE RESEARCH ETHICS COMMITTEE MEETING HELD AT
AGA KAHN UNIVERSITY KARACHI ON 28TH May 2011**

A meeting of the Research Ethics Committee of NBC was held at AKU Karachi on 28th May 2011. The meeting was chaired by Professor Dr Zulfiqar Bhutta, Chaired the Meeting. The purpose of the meeting was to review and finalize the proposals received for ethical clearance. Following attended the meeting:

1. Professor Dr Zulfiqar A Bhutta, Chairman Research Ethics Committee, NBC
2. Professor Dr Haroon Ahmed, Member REC/NBC.
3. Dr Maqbool Jaffrey, Member REC/NBC.
4. Dr Huma Qureshi Member Secretary NBC.

A total of six projects were reviewed and discussed in depth and following comments were given:

1. NBC 52: Genetic, Phenotypic and Clinical Evaluation of Haemophilia A in Pakistan

1. Define age less than 18 years, as there might be issues in drawing large quantities of blood in very small children.
2. The consent form is inadequate and it should state what genetic tests shall be done and how long blood samples shall be stored
3. PI should send few completed forms for evaluation by ERC.

2. NBC 57: Identifying Factors that enable community midwives to reduce the barriers of obstetric care in rural Pakistan.

The budget is still too high. RAF should get the approved rates for consultation by UNICEF, WHO, UN and other donor agencies

3. NBC 64: World Maternal Antifibrinolytic Trial. Tranexamic acid for the treatment of postpartum haemorrhage: an international randomised, double blind placebo controlled trial

1. The project approval is only for the PI and not for other PI's who might take up the project on line
2. Consent script should be in Urdu and not Arabic and it should be in easy understandable language.
3. How will the PI change the placebo to drug, if the patient does not respond to placebo? This needs clarifications.
4. what happens if the condition of patient deteriorates, what safety nets have been placed for the patient, where would they be admitted and who shall pay for it?
5. The project needs to be written in future tense and PI should inform which site has been chosen as the study site.

4. **NBC 65: A Prospective Observational Study of the Clinical Performance of Femplant in Pakistan**

It is post marketing surveillance study and is **approved** provided following information is provided and incorporated in the text.

PI should identify what will happen if the patient develops complications like anemia, DVT, stroke infection at insertion site or perforation. Where would they be admitted and who shall pay for them.

Consent needs to be in Urdu script and simple understandable language should be used.

5. **NBC 67: Responsiveness of the Federal Health System to the Needs of 18-45 Year Old Adults with Physical Disabilities in Islamabad, Pakistan**

Project **approved** after the consent form script is done in Urdu

6. **NBC-68: Prison Psychiatry in Pakistan – A Prevalence Study of Psychiatric Morbidity in Karachi Central Prison prison/psychiatry**

Project **Approved** subject to clarification that who will give consent for these psychiatric cases

7. **NBC 69: Development of Entrepreneurial Skills Among Community Midwives in Pakistan**

7.1.1. Budget is too high to train 600 CMWs who are by and large not getting any compensation.

7.1.2. Need justification for payment to trainers

7.1.3. The program cost is around 5.7 million, research cost is 3.4 million while administrative cost is 17 million which is more than 50% of that of research and program. Administrative cost should not be over 20% of the total budget

7.1.4. The overall cost is too high for the potential benefit and the beneficiaries.

8. **NBC-70: Study on Post Abortion Care in Pakistan**

Project **Approved** with clear instructions that consent form needs to be signed and anonymity maintained