

**DRAFT MINUTES OF THE RESEARCH ETHICS COMMITTEE MEETING
HELD AT PMRC RESEARCH CENTRE, JINNAH POSTGRADUATE MEDICAL
CENTRE, KARACHI ON 05 April 2012**

A meeting of the Research Ethics Committee of NBC was held at PMRC Research Centre, Jinnah Postgraduate Medical Centre, Karachi on 05 April 2012. In the absence of Professor Dr Zulfiqar Bhutta, Chairman REC who was not able to attend due to some important prior commitment, the meeting was chaired by Prof. Dr Aasim Ahmad. The purpose of the meeting was to review and finalize the proposals received for ethical clearance. Following attended the meeting:

1. Professor Dr Aasim Ahmad
2. Professor Dr Anis Ahmed
3. Professor Dr Haroon Ahmed
4. Mr Shaukat Ali Jawaid
5. Dr Huma Qureshi Member Secretary NBC.

Following members could not attend the meeting due to prior commitments:

1. Dr Maqbool Jaffrey
2. Prof. Dr. Muhammad Amin

After recitation from Holy Quran, the Chair welcomed all participants who came to attend this important meeting. The Executive Director PMRC/Member Secretary NBC, Dr Huma Qureshi briefed the members on the objectives of the meeting. She gave overview for the status of the projects presented to NBC for review and ethical clearance.

Agenda wise discussion is as follows:

Agenda 1: Actions taken on the decision of the last REC Meeting held on 24th November 2012.

Dr Huma then presented the minutes of the last REC meeting held on 24th November 2011, and informed the house regarding the actions taken on the decisions of the last REC which is summarized in the table below:

Sr.No	Decisions of the Last REC Meeting	Actions Taken
1.	<p>Expedited review should NOT be done as a routine to get quicker clearance but it should be tagged to the urgency which should be identified by the Principal Investigator and agreed by the Chair REC.</p> <p>Funding agency should decide which projects (not more than 2 projects) require expedited review and apply accordingly giving full justification.</p>	RAF was informed accordingly

2a	Non availability of full budget details and suggested that projects without budget details should not be accepted or processed next time. For RAF projects a letter should be sent to them for justification of budget (not to criticize) but for clarification.	Letter sent to RAF and in response they sent detailed budgets along with justification
2b	It was also suggested to ask the British Council or the Department from where PI were drawing their salaries to match it with the % of time they were spending in the research as in some cases the calculation of their salaries was very high	Draft Letter may be approved by the REC before it is sent to British Council
3.	3--4 REC meeting should be held annually	Three meetings will be held annually as per following schedule: April, August and December. This is the first meeting as per schedule

The members were satisfied with the actions taken; however, for agenda item 2 b, they reviewed and edited the draft letter. It was decided to send the letter to Prof Dr Aasim Ahmed for approval before being dispatched to the British Council.

Decision: REC edits should be incorporated in the draft letter should be finalized and sent to Dr Aasim Ahmed, before being dispatched to the British Council.

Agenda Item-2: Update on the status of projects submitted for review and ethical clearance of NBC:

Dr Huma briefed the members on the status of the projects submitted for ethical review which is as follows:

Total Projects received:	94
Approved:	66
Not approved:	02
In process	09
Withdrawn by PI	08
Non response	08
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The members suggested that for the non-responsive projects, a letter should be written to the principal Investigators, that their project review has been abandoned due to the non-response and that if they are still interested for the ethical review they need to re-apply.

Decision: A letter should be written to the principal Investigators of the non-responding projects, clearly mentioning that their project review has been abandoned due to the non-response and that if they are still interested for the ethical review they need to re-apply.

Agenda Item 3: Minutes of the Last NBC

Dr Huma Qureshi informed the members that the minutes of the last NBC were approved by all the members except one whose suggestion/changes would be incorporated but milder language. She also informed that the same member had complained that the names of the NBC members were not updated on the website. Dr Huma informed the REC that the website was checked on the next day of the meeting and it was found updated except that the names of the Patron and Chair, as these can only be uploaded after the approval is received from the Cabinet Division. The REC members reviewed the minutes again and made necessary corrections.

Decision: PMRC will circulate the corrected/revised minutes to the Chair and Members of the NBC and then upload them on the Website.

Agenda Item 4: Review of the project proposals submitted for ethical clearance of NBC

Project Title	REC Decision
NBC-85: Immunogenicity of Combined Bivalent OPV and IPV Vaccines at 9 - 12 months of Age Compared to bOPV alone in Malnourished and Non-Malnourished Pakistani Infants.	Project approved subject to the submission of detailed budget
NBC-86:	Withdrawn by the PI
NBC-87: Assessing Retention and Motivation of Public Health Care Providers (particularly Female Providers) in Rural Pakistan	<ul style="list-style-type: none"> • The results of the project will not be different than what is already known about this issue, so the study is not likely to bring new information. • Budget is huge. • Total cost = Rs 31,744,559 • Project cost= Rs 16,040,430 (50%) • Rest is on salaries of staff and consultancies. • If we calculate per person cost, it comes to Rs 130,000/person/month. • This budget would need to be justified
NBC-88: Care Plus: Community-based delivery of MNCH care in conflict affected areas	<ul style="list-style-type: none"> • Urdu Questionnaire missing and is need for review. • The information that will come out of the

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	<p>study does not rationalize with the budget.</p> <ul style="list-style-type: none"> • Budget cost is = Rs. 66,942,484/ • Actual project cost is =Rs 3,752,000 (5.6%) • Rest of the budget is for salaries, per diem and travel and accommodation • A total amount of Rs 2,706,664 (i.e. 4%) is on account of bank borrowing. Why is bank borrowing being done as some money is given upon approval to start the project? This amount is huge and very difficult to accept. • In addition to electricity, gas and other utilities there is a 10% management/administrative cost, which needs clarification and justification.
NBC-89: Delivering enhanced CVD-hypertension care through private health facilities in Pakistan	<ul style="list-style-type: none"> • Who will bear the cost of drugs that are prescribed by the doctor? Project or patient • How will you ensure that same drug has been purchased (branded vs non branded) • Clearly mention in the consent what do they mean by “slightly different procedures” i.e. more visits, more blood tests or more drugs and how much more. • Approved subject to the above clarification
NBC-90: Enhanced Diabetes-CVD Management through Primary Health Care in Pakistan	<ul style="list-style-type: none"> • In the consent it should be clearly mentioned that the participants will have no financial gain and also there is no clinical advantage. • Approved subject to above
NBC-91: Reduction of Low Birth Weight &Maternal Anemia in Umerkot and Tharparker	<ul style="list-style-type: none"> • Clearance would be given on submission of detailed budget
NBC-92: Meeting Birth Spacing Needs of the Underserved in Punjab Districts	<ul style="list-style-type: none"> • The methodology is totally unclear as to what PI wants to do and how. • No details of interventions are given. • Questionnaire has many unnecessary questions not relevant to project if there is a sound scientific reason then we need that otherwise this wastes time of the participants. Budget is too high and about 60% is spent on monitoring and evaluation; this needs proper justification
NBC-93: Effectiveness and feasibility of hospital and community-based delivery of care for multi-drug resistant tuberculosis (MDR-TB) in Pakistan: A randomized controlled trial.	<ul style="list-style-type: none"> • Project is technically sound but budget is too high. • As treatment is being provided by the DOTs and patients are either admitted or sent home so what is the budget for- needs

	rationalization.
NBC-94: Pharmacokinetic evaluation of Amoxicillin/clavulanic acid and antacid interaction.	<ul style="list-style-type: none"> • To avoid bias in selection of controls the students should be informed to join the study using a general notice board ensuring voluntary participation. If this is not possible then the students should be selected from other departments. • Pharmacy students should not be included as their consent may not reflect their free will (induced or coerced). • Consent form should clearly state the number of pricks that the student will get. • The total volume of blood drawn is 70 ml while in consent it is written as 5-10 ml. • Also mention time frame that the student will have to come during and after study • The study will not bring any new information as these pharmacokinetics have already been studied while drugs were produced.

Towards the end following suggestions were made:

1. Mr Shaukat Ali should write an article on AID given to Pakistan for research and its implications.
2. Physician Pharma guidelines need to be widely disseminated
3. It was also discussed that both funding agency and cabinet division should be informed about the worry of members regarding the unjustified and apparently huge RAF budget

The meeting ended with vote of thanks from the Chair.