DRAFT MINUTES OF THE RESEARCH ETHICS COMMITTEE MEETING HELD AT PMRC RESEARCH CENTRE, JINNAH POSTGRADUATE MEDICAL CENTRE, KARACHI
25th November 2013

A meeting of the Research Ethics Committee (REC) of NBC was held at PMRC Research Centre, Jinnah Postgraduate Medical Centre, Karachi on **25th November** 2013. The purpose of the meeting was to review and finalize the proposals received for ethical clearance.

Following members attended the meeting:

1. Professor Dr. Aasim Ahmed
2. Dr. Asmatullah
3. Dr Farid Khan
4. Mr Shaukat Ali Jawaid
5. Dr Huma Qureshi Member Secretary NBC
6. Dr Muhammad Arif Munir PMRC

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

1. Dr Zulfiquar Bhutta
2. Dr Maqbool Jaffrey
3. Prof. Dr. Muhammad Amin
4. Prof S. Haroon Ahmed

The meeting started with recitation of Holy Quran. The Executive Director PMRC/Member Secretary NBC, Dr Huma Qureshi welcomed all participants who came to attend the meeting and briefed the members on the projects presented to NBC for review and ethical clearance.

Following agenda items were discussed:

Agenda Item-1: Update on the status of projects submitted for review and ethical clearance of NBC:

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

Total Projects received:	**107**
In process:	14
Not approved:	04

Agenda Item 2: Review of the project proposals submitted for ethical clearance of NBC

Project Title	REC Decision
NBC-128: Saving Mothers and Newborns in Communities: Strengthening Community Midwives to provide high quality essential newborn and maternal care in Balochistan, Pakistan in a financially sustainable manner	**Not approved in its present form clarifications needed from the investigator.** 1. Study involves provision of loans to research participants and that too on interest basis& transaction fee it does not seem ethical? What if someone is unable to return the loan. 2. What would be the conditions for giving loans and are community midwives (CMW s) in rural areas of Balochistan competent enough to understand the term and conditions of the loan. 3. As a third party (Microfinance Instit, Tameer microfinance) is involved in giving loans so who will be responsible in case CMW s are not capable of paying the loan amount? 4. Policies of Tameer bank should be given in detail? 5. Justification for using Design Quasi experimental in 2 districts (Quetta/Gawadar) while pre and post strategy in Kech? 6. An overseas telephone number is given for an inquiry related to the study in consent; at least one local representative (understanding local language) should be designated for queries? As language barrier and time difference could contribute to impossibility for contacting the person. 7. Consent form for CMW s should be clearly describing, the exact role of CHWs in the study as there is no mention of CHW s training and loan scheme (interest rate and other conditions) in the form. 8. Budget justification is needed? Please elaborate on personal cost? 9. Right to withdraw from the study is not mentioned in the consent form? 10. Was consent seeked from University of Alberta for 4 years duration of the project? 11. No consent form has been attached for Exit interviews with patients.
NBC-129: Malaria Indicator Survey in 38 Global Fund Round-10 & 7 districts	**Approved after clarification from investigator** 1. Clarification of budget is needed? 2. NBC form question 4 (b) has to be answered (mention time duration for questionare, consent for blood testing where ever applicable. 3. Consent form for blood testing should be provided by the investigator? Consent form need to include what blood test will be done in the project and whether the sample will be used in Pakistan or will they be sent abroad? 4. Estimated time for filling questionare in households. 5. Save the children name should not be mentioned in the consent.
NBC-130: Development and validation of fidelity criteria for explaining variation in cluster randomised studies of complex interventions.	**Approved after changes by the investigator** 1. Title is not clear the caption should be changed to that what is given in the York University form?

	(**Explaining variation in cluster randomised studies to inform complex interventions for smoking cessation**) 2. What is a control cluster? Explanation is needed 3. Video tapes should be password protected for confidentiality of participants in case they are lost for some reason e.g. during transportation.
NBC-131: Exploring factors improving the acceptability and feasibility of contraception messaging and counseling among community-based marketing workers enrolled in MSI's outreach programme: A mixed methods research project using Participatory ethnographic evaluation research (PEER) in Layyah/Muzaffargarh/Khanewal, Punjab, Pakistan	**Approved after clarification from investigator** 1. Clarification of legal age is required? As according to Pakistani law legal age is 18 years for both males and females if less then assent form is also required. 2. While non-participant observation technique is being employed in Field marketing worker's(FMW's) case but Urdu consent form or FMW is not clear in describing that clearly or has few spelling mistakes?
NBC-132: Exploring factors or perceptions among married men and women of child-bearing age on the use of fertility control during early marriage years in Pakistan: A Participatory Ethnographic Evaluation Research (PEER) method among young married men (aged 18-35 years) and women of reproductive age (16-25 years) in Khairpur/Qambar Shahdad Kot, Sindh, Pakistan.	**Approved after clarification from investigator** 1. PEER researchers will be chosen from the same community where study is to be conducted but as the research involves discussion on a culturally sensitive issue, there are chances that during interviews PEER researcher may identify the third person about whom interviewer is talking which may result in harm or stigmatization to that third person. In order to maintain confidentiality it is suggested that an unknown translator/ PEER researcher from similar background (acquainted with local language and tradition) but not from the same community is a better option. 2. Why is this written in the consent form 'By inviting you to take part in a study commissioned by MSS' it should say that it is being done by MSS or it is commissioned to another party? **3.** It is mentioned in the consent form that improvement from study will be achieved but through a observational study this is not a possibility hence this statement should be removed?
NBC-133: An integrated toolkit to save newborn lives in Pakistan	**Previous issues are answered in the revised proposal.** 1. AKU ERC document is needed. When is it likely that this trail will be registered in Clinicaltrails.gov? 2. It is presumed that LHW have a role in home deliveries because if not then this exercise is futile. 3. Are there any traditional birth attendants if yes why are they not involved? 4. If LHW as mentioned in the intervention arm on Page 10 under bullet 13) "In the existing LHW program, LHWs are meant to visit all births within 24 hours of delivery, however, in practice this does not always happen. LHW will thus be provided with a **small inconvenience allowance so that the first post-delivery visit to the home occurs within the first 24 hours after delivery**. At this visit, teaching regarding use of the kit contents will be reiterated". It would be fair and also scientifically valid to give the same allowance in the control arm too (this would make the LHV visit more likely and the actual intervention "tool kit" to be assessed.

	5. In the 'control arm' clusters that will get 'Standard care' I need to know what is that the LHV suppose to have with her-does she have any disinfectant? Umbilical cord clamp? Etc. If these are supposed to be there but are not there (because of monetary or other reason) then they should be provided.
NBC-134 Attending mental health clinic services in a district hospital in a conflict affected region of Pakistan: Who, why, and for what condition?	**Approved after clarification from investigator** 6. Retrospective review data exemption criteria should be clearly detailed out through a formal letter? 7. Actual study duration to collect data is not mentioned? 8. There are 15 co investigator in the project please elaborate their role clearly?
NBC-135: Understanding the evolving reproductive health policy context in Pakistan	**Approved after clarification from investigator** 1. No Major Issues 2. Submit Consent form for LHWs
NBC 136: Pilot Study to Assess The Feasibility For Testing The Made-in And Made-for Methodology For Estimating The MMR In Pakistan	**Approved after clarification from investigator** 1. Consent form of informants (LHWs & LHS) are missing. 2. On Page 6 of protocol activity,4 Lady health supervisor(LHS) supposed to conduct interview about verbal autopsy but in budget 10 social scientist have claimed incentive to do the same work. 3. On Section B of questionare why nationality and ethinicity of diseased is asked .Is there a scientific explanation for this? 4. In section: F questions related to accidental death like gun shot, burn, stab, suicide is asked; justification might be needed for detailed inquiry in this heading. 5. Native workers are conducting the interview it may leave respondents vulnerable to exploitation in future. 6. During the interview duration (30 minutes) for verbal autopsy questions, some useful health information like dangers of smoking e.t.c should be communicated. 7. In section F / accidental death data will not be used? Clarification is needed
NBC-137 : Burden of non communicable diseases in Pakistan	**Approved after clarification from investigator** 1. Title is slightly confusing? As all aspects of non communicable disease is not being covered under this heading. 2. Suggested title? **Survey of risk factors of non-communicable disease in Pakistan** 3. ERC commented to include blood tests and tag a parallel study with that of parent study for fulfillment of title Burden of non communicable disease in Pakistan.
NBC-138: The CLIP (community level intervention of pre-eclampsia) cluster randomized controlled trial	**Approved after clarification from investigator** 1. What part of CLIP is the investigator looking at? clarification needed 2. Don't use CLIP intervention but elaborate on the fact that whether, Is standard practice being followed? **3.** Training of control cluster should be emphasized

	in the project. 4. Consent of Lady Health worker not included? 5. Budget of the project is needed?

Agenda item 3: any other matter.

Dr Asim and Dr Fareed commented that an overview of total projects submitted should be made available for all members to be onboard.

Another project was discussed by Dr Huma regarding, **HBV Mutant** study which was earlier approved by NBC and the query was that since the study was not completed in the given time duration an extension of study was requested by the investigators and issue at hand was of sample destruction as a reminder was sent to the investigator for destruction of samples at maximum 5 years duration.
Dr Asim commented that if the investigators provided enough scientific evidence that cases of HBV Mutants, are relatively hard to find and stored samples can be helpful then they may be given permission.

The committee agreed that there should be MOU (agreement of understanding) for legal binding while sending samples outside of Pakistan and this issue should be discussed in the NBC meeting .
Representation of Punjab in NBC was also discussed.

The meeting ended with a vote of thanks.