

NATIONAL BIOETHICS COMMITTEE
DRAFT MINUTES OF THE ETHICS RESEARCH COMMITTEE MEETING
27/09/2014

Meeting of the Research Ethics Committee (REC) of **NATIONAL BIOETHICS COMMITTEE** was held at PMRC Research Centre, JPMC, Karachi on 27th September 2014. Professor Dr. Aasim Ahmad, Chair of the REC chaired the meeting along with following members

1. Dr. Aasim Ahmed (Chair REC)
2. Dr. Huma Qureshi (Member/Secretary)
3. Prof. Asmatullah (Member)
4. Dr. Muneer Saleemi (Member)
5. Dr. Aamir Mustafa Jafarey (Member)
6. Dr. Muhammad Arif Munir(Focal Person for NBC))
7. Ms. Safia Bibi (Co-opted Member)
8. Ms. Taranum Ruba Siddiqui (Co-opted Member)
9. Dr. Waqauruddin Ahmed (Observer)

The meeting started with the Tilawat-e-Quran followed by the introduction of participants and welcome note by Dr. Aasim Ahmed.

Agenda Item-1: Update on Projects received and approved by REC

Dr Huma Qureshi presented an update on the total number of projects received and reviewed by REC, and their outcome in terms of approved, not approved or closed.

Dr. Aamir Jafarey raised a point that discussion and learning of participants lacks if reviews are virtual. Dr. Aasim responded that there are advantages and disadvantages of virtual review. Due to financial and time constraint it is not possible for members to meet so frequently hence reviews are usually done virtually but we meet quarterly. He recommended that all members should copy their comments to all members and not just the chair or the secretariat so that everyone knows other's comments. Dr Aasim also asked the secretariat to provide the time taken from submission to approval of each project.

Dr. Aamir put forward the idea for a web portal where every reviewer could put their comment so as to enable all members to know everyone’s comments. This may contribute to healthy discussion and learning of members. Dr. Aasim appreciated the idea but said that these have their own limitations and we should share comments on email.

Decision: The secretariat will provide the time taken from submission of the project to its approval in the next meeting. All members should send their comments to all REC members.

Agenda Item-2: Collated review comments on the projects

2.1. Collated review: Dr. Aasim Ahmed presented the collated comments given by NBC members on NBC 155, NBC 158, NBC 160, and NBC 161.

The Comments are as shown in the table below:

Project Title	Collated comments
<p>NBC-155: Phase III(b) Clinical Trial for Use of Buprenorphine for Treatment and Detoxification of Injectable Drug Users in Pakistan</p>	<ol style="list-style-type: none"> 1. Psychiatric/psychological evaluators will be required may be throughout the study therefore it is recommended that someone be included. 2. If individuals are found to be hepatitis B or C or HIV positive will they be offered treatment? Where? 3. Is this drug registered for use in Pakistan or it would be brought for trial only? 4. What is its likely cost? 5. If it is not available in Pakistan, has the investigator done any prior negotiations with the company to make it available on priority or a cheaper rate (for the country that undertook the trial) whenever it is available. 6. Will it be available in Pakistan at differential price? 7. Will all women be tested for pregnancy even unmarried?

	<ol style="list-style-type: none"> 8. What if unmarried woman is found pregnant, as is common in this high risk group? 9. Why are pregnant women excluded? Is this drug more harmful than the I/V drug? 10. Could there be a social issue with women visiting the centre so often? 11. Will male permission be required for women participants? 12. Why is video recording done? Is observation not enough 13. For cases who require long term treatment, will the drug will be made available, how? especially if it is not registered?
<p>NBC-158: IRADA: Improving Reproductive Health through Awareness, Decision and Action”</p>	<ol style="list-style-type: none"> 1. What is the device? (Implant, oral drug or IUD) Is this new? 2. Questioner is long and will take at least one and a half hour to two hours so this needs change. 3. Maintaining privacy for 2-hr especially in women may be difficult, how will it be ensure. 4. As this is research study therefore family planning devices should be provided free. 5. The control group should get some family planning advice as a minimum benefit to be in the study. 6. There is confusion in total number of participants 200,000? Our calculation is that there are 4 groups of 20,000 to 30,000 making max total 120,000. 7. Ethical clearance has been obtained from "Pakistan medical research committee". This needs correction.

	8. Are there any post trial benefits to this community?
NBC-160: Vaccine Reminder and Indicator (VIR) Band Community Effectiveness Trial	<ol style="list-style-type: none"> 1. Consent form for the control groups is missing. 2. Consent form needs to be in much simpler language. 3. Community engagement/ participation should be there and health messages about vaccination, breast feeding nutrition should be incorporated. 4. Will this community get any post trial benefits (reduced prices/free etc). 5. Is there engagement of procurement or use of this devise in EPI in future with the Govt. ? 6. The safety and efficacy of the devise has to checked by some other authority and not by ethical clearance board 7. The devise has not been sent or shown to bioethics board though it is written?
NBC-161: Improving Maternity Care in rural Sindh Pakistan, RE-defining the roles of community health workers	<ol style="list-style-type: none"> 1. In Q-8, travel cost to community health workers is being given as they are visiting house to house and collecting data of women who had delivered in the project period, so this cost should be shown in budget. 2. Are they bringing the women who agree to participate or CHWs are collecting the data in the household? 3. There is a strong possibility of a biased sample as CHWs will bring only those women who are their happy clients! 4. Confidentiality is very important in this case as the information given by participants should not be shared with the CHW especially if it is a negative feedback. 5. FGD will be time consuming, is there a provision to ensure privacy? 6. In the consent form there is no mention of ‘travel cost’. 7. Q-8 ERC form it is mentioned ‘no compensation and then written ‘as per govt rule” this statement is contradictory.

	<p>8. Why should the researcher bear the cost in case of 'distress'. It is noble but it would be more appropriate to make prior arrangement in 'public health' facility.</p> <p>9. Budget should ideally include stationary, photocopy and other costs too.</p> <p>10. Q 12 location not marked.</p> <p>11. There is discrepancy of in the year for taking pregnancy. In Q-3, survey part it is written as 2013 and in Q-7 it is written as 2014</p>
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Agenda Item-3: Members contribution to review

Dr. Huma Qureshi mentioned that communication between REC members and the chair or secretariat is very weak. There is a need for all members to proactively respond and react to the reviews, timings of meeting, agenda and booking for travel etc. They should acknowledge the receipt of e-mails we are sure that they have received it. Dr Aasim also agreed to this and requested that as we are very few members (6-7) in the ERC so everyone should review the proposals and send comments.

Dr. Aamir Jafarey proposed that we should co opt members from other Provinces too who have the background of reviewing proposal for ethics. Dr Aasim said that as most of the members are from Karachi therefore, to save time and money for travel and accommodation we hold meetings in Karachi but we shall try to move or tag these with the NBC meeting if possible and If finances allow

Decision: Members should become proactive in all NBC activities and acknowledge emails immediately. More co opted members may be identified and inducted and tasked to do virtual review.

Agenda item-4: Review criteria: Should we change the criteria of review – Expedited/Routine

Members were informed that there are very few projects which are received as routine projects while most projects are sent for expedited review.

Dr. Aamir Jafarey suggested that we should have Co-opted members to review the projects, they could be from other cities too, but. Dr. Aasim asked members to recommend names of those persons who have the potential to carry out ethical review so that we may co- opt them. It was agreed that since there are not many projects to review therefore, we may continue to take the expedited projects even if there are no reasons to expedite it. When we run short of time then we can be choosy.

Dr. Huma Qureshi also raised the query whether Case reports should be sent for ethical review, to which Dr. Aasim responded that authors of case reports should apply for exemption. Members agreed that that as exemption criteria for NBC is not there therefore these may be drafted, finalized and placed online.

Decision: REC will continue with the expedited review for projects. Exemption from REC on case reports and other studies need to be developed

Agenda Item-5: Calendar for REC Meetings

Dr Amir suggested that we should try to hold the REC meetings at other cities also to provide learning opportunity to others. All members agreed and decided that next REC meeting will be held quarterly, on last Saturdays, therefore next meeting is to be held on Saturday, 27thDecember,2014. However, as a meeting of NBC is also scheduled in Quetta in the month of November, therefore if we get a space in the NBC meeting in Quetta then we shall hold the next REC meeting in Quetta and cancel the December meeting otherwise we shall continue with the December meeting.

Decision: Secretariat will inform the members if REC meeting could be held with NBC in Nov.