

**NATIONAL BIOETHICS COMMITTEE
RESEARCH ETHICS COMMITTEE MEETING**

JUNE 28, 2014

PMRC Research Centre, Jinnah Postgraduate Medical Centre, Karachi

MINUTES OF THE MEETING

A meeting of the Research Ethics Committee (REC) was held under the Chairpersonship of prof. Dr Aasim Ahmad on 18th June 014 at PMRC Research Centre, JPMC Karachi. The agenda of the meeting was to review the projects received for ethical review and clearance by REC and other to discuss other issues related to Research Ethics committee.

Following participated in the meeting:

Participants of the meeting:

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| 1. Dr. Aasim Ahmed | Chairperson |
| 2. Dr. Huma Qureshi | Member/Secretary |
| 3. Prof. Munir Saleemi: | Member |
| 4. Dr. Asmatullah: | Member |
| 5. Dr. Arif Muhammad Munir | Co-opted Member/Focal point REC |
| 6. Dr. Waqauruddin Ahmed: | Co-opted Member |
| 7. Ms. Safia Bibi | Co-opted Member |
| 8. Ms. Taranum Ruba Siddiqui | Co-opted Member |

The meeting started at 9:00 am with the recitation of holy Quran. After the introduction of the members, Professor Aasim, Chair REC welcomed the new members and highlighted the role of NBC, its scope, subcommittees and working in order to take the new NBC members on board. The Chair also informed the members that he has developed updated REC Frame work and Application Forms and the TORs of the committee in line with the international standards. He then shared the forms with the members. The members commended the efforts of Professor Aasim Ahmad on undertaking this very important and long needed task and agreed to provide their feed back to the Chair in a week time.

During discussions Prof Dr Munir Saleemi, asked about the role of NBC on experimental studied being carried out on animal models by the students. The Chair responded to the member that animal studies do not come under the domain of NBC. We deal with the human subjects only. However, for animals there are separate ethics committee e.g. at Aga Khan University Karachi, and University of veterinary Sciences, Lahore. Dr. Huma Qureshi informed the new members

that review of NBC projects is on volunteer basis and reviewers are not paid any honoraria or that except for TA/DAs.

Dr. Huma Qureshi briefed the members on the working of the National Bioethics Committee and Research Ethics Committee. She spelled out in detail the review process of the research projects submitted for ethical clearance. Dr Huma also updated the members on the status of the research projects submitted by various national and international institutions for review to REC of NBC.

Dr. Aasim Ahmed suggested that studies to which responses are not received from researchers should be labeled as abandoned and not as “not approved”

Review of research proposals:

Projects	REC Comments/Decisions
<p>NBC 151: Assessment of Hygiene Behaviors and Exposure to Fecal Bacteria among Infants and Young Children in Rural Pakistan for the Development of Improved Water, Sanitation and Hygiene (WASH) Interventions.</p>	<ol style="list-style-type: none"> 1. Which are the study sites? 2. Has the University of Cornell’s ERC/IRB reviewed this research? 3. Questioner in Urdu is also necessary as to limit inter researcher variance. 4. Age range needs to be clearer [zero-six months the next range should be from seventh month (not six) and so on or age range should be in days]. 5. Q 16 in the ERC form cannot be N/A as any situation will have some ethical challenges. Needs some reflection. 6. Observation of child and care giver <ol style="list-style-type: none"> a. It does not seem fair/ethical to observe a child putting contaminated (biologically harmful) material in the mouth? Consider stopping it and record it ‘nearly put in mouth but stopped’ or give scientific justification why this cannot be done b. Who will visit households and be the ‘observer’? Will he/she have training (what type and by whom). c. ‘Observation’ will be both of child & care-giver; will it be possible for one person to observe both? d. Six hours of observation may be daunting for the house hold will it affect their daily chores? Do they need some compensation for their time? 7. Benefits: <ol style="list-style-type: none"> a. As mentioned that there may not be any direct benefit of this study, however indirect benefit as part of reciprocity can be achieved at minimum giving the household advise about cleanness, hygiene, hand

	<p>washing etc at the end of observation.</p> <ul style="list-style-type: none"> b. "... Improved WASH interventions based on the study findings, may be implemented in the community at large, in the future. {Q.15 (B) pg. 9/15 NBC form}" has any effort to engage the policy makers or community leader for implementation made? c. There should be some methods to at least tell the participating households about the research findings. May be in simple local language with a thank you by post. d. Does time of preparing food and time of consumption need to be recorded? As delay may be as harmful as other things being observed? <p>8. As accuracy is key in any research and therefore collecting samples in a 'cooler' is vague, as there are many types, how much ice etc. Is there a desired temperature? Or methodology of storage defined?</p> <p>9. In these rural areas will permission from community head/leader or the head of household be required?</p> <p>10. Who will give the consent? Mother/father/caregiver any or all?</p> <p>11. Consent in Urdu/regional language is mandatory.</p>
<p><u>NBC 152:</u></p> <p>A Survey to evaluate the consumption, buying practices, cost effectiveness and willingness to pay for packaged food items in two districts of Pakistan.</p>	<p>The protocol should be sent to NBC members for their comments.</p>
<p><u>NBC 153:</u></p> <p>Genetic polymorphisms in diabetes</p>	<ul style="list-style-type: none"> 1) Researcher should send complete research protocol required for review for NBC to reach any decision and not only the part of methodology that need to be done in UK. 2) Previous consent form that was used while doing sample collection should also be sent to NBC. 3) NBC does not review protocols after the study has already been conducted. Dr. Aasim volunteered that he would write a comprehensive response or comments for this protocol.

OTHER ITEMS

1. Dr. Aasim Ahmed shared the framework for submission of protocols for ethical approval that he developed for MSF. NBC members applauded Dr. Aasim Ahmed's and his team's effort in designing such a concise and comprehensive frame work for the application form for ethical approval. Dr. Aasim Ahmed mentioned that this framework will soon be published and NBC may also adopt this framework.
2. Dr. Aasim Ahmed also shared the TORs he developed for NBC-ERC. There was a discussion among members on quorum requirement; Dr. Munir Saleemi suggested that we should have at least 50% attendance for quorum in case the total number of members is below 10.
3. Dr. Aasim Ahmed mentioned that he'll circulate these TORs to all NBC members via email and welcomed any recommendations to further make things defined and clear for NBC members. He added that NBC TORs and member's profile should also be on website. He further mentioned that exemption policy or criteria is not mentioned in TORs, he discussed two options for that either NBC should issue exemption after review of proposals or criteria should be published on website and researcher should decide if his/her study is exempted.
4. There was a discussion on the letter received from RAF for ethical exemption for replicating an already approved study by NBC. Dr. Aasim Ahmed responded that since NBC currently does not have any policy for exemption so NBC requires reviewing all studies and granting approval or disapproval as appropriate. It was decided that RAF will submit a new protocol fulfilling all requirements of the REC along with the findings of the previous proposal that they piloted in Chakwal. Any change in the new proposal will be also highlighted. Dr. Arif Munir raised a query regarding the fee for ethical approval in such cases to which Dr. Aasim Ahmed responded that a concession may be granted in such case as appropriate.
5. Regarding the PBC- Sindh, Dr. Huma Qureshi mentioned that Dr. Suresh, Special Secretary, Health Department, Government of Sindh may serve as a resource person for formulation of PBC-Sindh and requested Dr. Aasim Ahmed to contact him and discuss the matter with him.
6. Dr. Aasim Ahmed also briefed members about the PBC-Punjab meeting held in Lahore on June 18, 2014.

Meeting ended with the concluding remarks by Dr. Aasim Ahmed.