A meeting of the National Bioethics Committee (NBC) was held on 08 June 2015 at Centre of Biomedical Ethics and Culture (CBEC), Sindh Institute of Urology and Transplant (SIUT), Karachi. In the absence of the Secretary, Ministry of NHSRC, Dr. Aasim Ahmad, Chairperson Research Ethics Committee (REC) and Member NBC was asked to chair the meeting.

Following Members attended the meeting:

1. Prof. Dr. Farhat Moazam, Professor & Chairperson, Centre of Biomedical Ethics and Culture, Sindh Institute of Urology and transplant, Karachi.
2. Prof. Dr. Aasim Ahmad, Dean and Chief Nephrologists, Kidney Centre, Karachi
3. Dr. Aamir Mustafa Jafarey, Associate Professor Centre of Biomedical Ethics and Culture, Sindh Institute of Urology and Transplantation, Karachi.
4. Prof. Dr Munir Akhtar Saleemi, Professor of Social and Preventive Pediatrics, University of Health Sciences, Lahore
8. Dr. Farooq Azam Jan, Director General Health Services, Health Department, Government of Baluchistan, Quetta.
9. Dr. Abdul Majeed Akhtar, Representative Nominee, Director General Health, Health Department, Government of Punjab, DG Office, 6 Cooper Road, Lahore.
10. Dr Saleem Memon (Representative) Director General Health Services, Health Department, Government of Sindh, Hyderabad.
11. Dr. Khawaja Tahir Aziz, Representative Director General Health Services, Health Department, Government of AJ&K, Muzaffarabad.
12. Sahibzada Muhammad Khalid (Representative DGHS FATA)
13. Dr. Farah Qadar, Head of Department Behavioral Sciences, Fatima Jinnah Women University, Rawalpindi.
14. Prof. Dr. Asmatullah, Associate Professor (IRI), International Islamic University, Shah Faisal Mosque, Islamabad. P.O Box 1035, GPO, Islamabad.
15. Prof. Dr. Abdul Razzaq Sabir, Vice Chancellor, University of Turbat (Baluchistan), Makran Division, Baluchistan.
16. Dr. Ambreen Munir, Associate Professor of Surgery, Liaquat University of Medical and Health Sciences, Jamshoro/Hyderabad.

17. Dr Farkhanda Ghafoor, Principal Research Officer, PMRC Research Centre NHRC, Lahore.

18. Dr. Salman Ahmed Tipu, Vice Dean, ISRA University, Islamabad.

19. Dr Saima Pervez Iqbal, Associate Professor, Community Medicine, Shifa College of Medicine, Islamabad.

20. Dr. Muhammad Arif Munir Representative Member Secretary NBC/Focal point NBC Secretariat, Pakistan Medical Research Council, off Constitution Avenue, Sector G-5/2, Islamabad.

Following Members could not attend the meeting due to their prior commitments:

1. President, Supreme Court Bar Association, Supreme Court Building, Islamabad.
2. Director General Health Services, Health Department, Government of Khyber Pakhtunkhwa.
3. Prof. Dr Hafizullah, Vice Chancellor, Khyber Medical University, Peshawar (Representative PM&DC).
4. Dr. Tariq Mehmood Mian, President, Pakistan Association of Family Physicians.
6. Dr. Huma Qureshi
7. Dr. Farid Khan, 68/1 Khyban-e-Mahafiz, Phase 6, DHA, Karachi.
8. Prof. Dr Zafar Hayat, Khyber University Head of Department Medicine. Khyber Teaching Hospital, Peshawar
9. Dr. Mahjabeen Khan, Assistant Professor, Research and Development, Dow University of Health Sciences, Karachi
10. Dr Jamshed Akhtar

The meeting started with recitation from the Holy Quran by Prof. Asmatullah, Associate Professor, Islamic International University, Islamabad. Dr. Aasim Ahmad informed the members about the sad demise of Dr. Aamir Jafarey mother and the house offered Fatiha for the departed soul.

Dr. Aasim Ahmad, Chairman NBC then requested Dr. Anwar Naqvi, to say few words as a representative of the host institution. Dr Anwar expressed his appreciations and congratulated CBEC/SIUT for hosting NBC meeting and thanked the NBC for providing SIUT with the opportunity.
Meeting formally started with the introduction of the participants including the 4 newly elected NBC members. Dr. Aasim Ahmad and Dr Farhat Moazam expressed their pleasure on the presence of NBC members, especially the provincial representatives in the meeting.

The Chair then requested Dr. Muhammad Arif Munir to extend welcome note to the participants on behalf of Dr. Huma Qureshi, Member Secretary NBC. Dr. Munir welcomed the NBC Members and thanked them for taking time out from their busy schedules and coming all the way to attend the meeting. He expressed special thanks to the Secretary Health and Population Welfare Department, Gilgit-Baltistan for attending the meeting. Dr Muhammad Arif Munir also thanked Dr. Farhat Moazam and CBEC for their hospitality.

After the introduction of the members, the Chair asked the Member/Secretary NBC to start the proceedings of the meeting.

Agenda item 1: Approval of minutes of the last NBC meeting held on 02 March 2015.

Dr Muhammad Arif Munir informed the house that minutes were circulated to all members and all corrections that were suggested have been incorporated. The members were requested to approve the minutes.

Decision: Minutes were approved.

Agenda item 2: Briefing on NBC activities

Due to the presence of four newly elected members, Dr. Arif Munir gave a briefing about the National Bioethics Committee, its aims and objectives, composition and functions of its sub committee’s i.e. Health Care Ethics Committee (HCEC) and the Research Ethics Committee (REC). Following this he updated the members on the current status and steps taken by the Provinces towards establishment of Provincial Bioethics Committees. He said that each provincial representative will share the progress made regarding the establishment of PBC.

Dr. Arif Munir, updated the members on the decisions of the last NBC meeting held in Muzaffarabad, AJK on 02 March 2015 and the actions taken thereof. He informed that the health department, government of Sindh has established their Provincial Bioethics Committee. The Chair appreciated the step taken by the DG Health Sindh and the efforts put in by Dr Saleem Memon, Additional Director Health and focal person/representative of DGH Sind in materializing the establishment of PBC. Dr. Farhat Moazam said that notification letter for PBCs establishment should be sent to NBC secretariat.
In the last meeting, it was decided that Dr Khawaja Tahir Aziz will discuss with CPSP, regarding development of guidelines on medical ethics for postgraduate medical/dental students by NBC. Dr Tahir Aziz informed that he has written a letter to President CPSP, suggesting that Bioethics Education should be incorporated in postgraduate training of CPSP but his response is awaited. Maj. Gen (Retd.) Salman Ali (Representative CPSP) requested NBC may also develop guidelines for researchers on “Clinical Ethics” for CPSP, which was agreed by all once a formal request is received from CPSP.

Dr. Khawaja Tahir Aziz informed that he received the minutes of the last NBC late, to which Dr. Arif Munir responded that minutes were circulated to all NBC Members well in time including President CPSP who is also an Ex-officio Member and his permanent representative Maj Gen. (Retd.) Salman Ali. However, Dr Tahir Aziz got missed inadvertently as he was sent as a representative of CPSP in AJK only.

It was also discussed that PBC and Regional Bioethics Committee should nominate one permanent member for NBC and informs the NBC accordingly. Dr. Arif Munir mentioned that DGs have already nominated their focal persons/Representatives for the tenure of NBC (e.g. Dr Saleem Memon from Sindh and Dr Abdul Majeed Akhtar from Punjab) who are also members of PBCs, so a separate member for PBC may not be required. Dr. Aasim Ahmad and others agreed to the suggestion, but Dr. Farhat Moazam was of the opinion that one representative from PBC should be there.

Decisions:

1. Maj. Gen (Retd.) Salman Ali will inform the NBC about the decision of President CPSP regarding the development of guidelines on medical ethics for postgraduate medical/dental students by NBC

2. Dr Saleem Memon will send a copy of the notification of PBC Sindh to the NBC Secretariat

Agenda item 3: Report on selection process of 5 new members

Dr. Aasim Ahmad appraised the members about the selection process adopted for recruitment of five new NBC members and mentioned that these criteria will be incorporated in the TORs. He informed that the NBC Secretariat sent out letters to almost all medical colleges and universities and research institutions of the country, inviting nominations of relevant faculty members for NBC Membership. Last date for receiving nominations was 30th April 2015. A total
of 57 CVs were received till closing date. Summary template was then developed from the CVs received and sent out to all NBC Members on 6th May 2015. Members had to choose 5 persons with 1st one being the most preferred. The last date for sending the ranked list was 10th May 2015. In response only 5 members sent their preferences. The deadline was therefore extended for another 04 days. Finally 11 members sent their preference list. Ranked list was then weighed as under: 1st = 5 numbers, 2nd = 4 numbers, 3rd = 3, 4th = 2 and 5th = 1. The final list of top five elected members was automatically generated. Result was announced on 18th May 2015 and elected members were informed and also invited to attend the NBC Meeting on 8th June and the subsequent Ethics Workshop on 09-10 June at CBEC Karachi.

**Decision:**

Selection criteria adopted for recruitment of new NBC members will be incorporated in the TORs

**Agenda item 4: Difference of opinion Re. Voting Rights: Discussion and Resolution for Future**

The Chair informed the house that in the revised ToRs it has been mentioned that only Members would have the right to vote for the selection of new NBC Members. In this regard concerns have been raised by various members, therefore, it was decided to present this issue in today’s meeting and get the opinion of the house. The Members were then asked to share their views.

Dr. Abdul Majeed (Representative DGHS Punjab) said that NBC is government body so to make NBC sustainable, ex-officio members should have more rights than other members. Depriving the rights of government members who are working for the government body is unheard of and will convert it into an NGO. Maj. Gen (Retd). Khalid Naveed said that if ex-officio members are not given voting rights then they will lose interest in NBC activities and even the government may stop its funding. On behalf of Dr. Huma Qureshi, Dr. Arif Munir asked the chair to give reasons why Ex-officio should not have a right for voting Dr. Abdul Razak Sabir informed that all universities, assembly and syndicate give ex-officio members the right to vote so why create a disparity in NBC. Dr. Farooq Azam, Director General Health Services, Balochistan, also showed his concern on the matter and said that it is not fair to deprive ex-officials with their right as it is a government body and not a private NGO, and the government is funding it while government officials are working for its sustainability and progress. Maj. Gen
(Retd). Salman Ali also said that why are we creating a voter and non-voter community within NBC, it is a body to check bioethical issues where every member has to contribute and work and leave to make space for new members. Dr. Khawaja Tahir Aziz said that being a government body, NBC’s decisions can only be implemented through efforts of ex-officio members, so how can you use them for implementing the decision and yet not give them voting rights. Dr. Sahibzada Muhammad Khalid said that NBC is an advisory body, and PMRC and DGs have to make it sustainable. He said that in the Provinces, all administrative powers are with DGs and they have the authority to implement the decisions and check compliance, so the authority should have all rights in electing new members.

Dr. Farhat Moazam said that universal standards are that ex-officials are non-voting members but that does not mean they are less important, it only shows that they represent their institute and they are not actually elected members, and the role they play is their duty. Voting rights are given to elected members. We do not have any control on ex officio and their representatives. She pointed out that only 5 ex-officio members voted this time and that too after they were given the extension in the deadline, to this Maj Gen (Retd). Dr. Abdul Khaliq Naveed informed that only 6-members voted from the non-ex-officio category so this doesn’t mean that ex-officio members are not interested. Dr Farhat Moazam clarified that the purpose is not to belittle ex-officials or to throw them out but if collective wisdom of NBC concludes that the right should be given to ex-officio then this may be incorporated in revised NBC TORs.

Dr. Aasim Ahmad clarified that that for the selection of five new members, everybody including ex-officio members did vote however he also believed that the universal norm is that ex-officios do not vote but to settle the issue, the Chair asked the members to show hands who are in favor that Ex-officio Members should have the right to vote and majority voted for this.

Decision:

It was decided by the majority vote that Ex-officio Members would have the voting right and that the revised NBC ToRs will be updated accordingly

Agenda item 5: Briefing on the Research Ethics Sub-Committee of NBC

Dr. Aasim Ahmad gave details on the progress of Research Ethics Committee (REC) including total projects received, approved and revised in last 7-years. He explained the process of research projects evaluation and its review. Dr Aasim further informed that project review form (REC Application Form) and guidance document have also been revised and updated. He also
pointed out that previously we had two categories of review; routine review (12 weeks) and expedited review (6 weeks), but in the revised ToRs there is only one type of review for all projects and all shall be reviewed in 08 weeks.

Dr. Aasim Ahmad mentioned that feedback from ERC members on research proposals is not good and usually three members (Dr. Aasim, Dr. Amir Jafarey and Dr. Huma) are giving feedback or observations on the research proposals while, all others either do not send comments or say they have no observations. He urged that all members should actively review the projects and submit their comments, as even one comment will add to the review.

He further mentioned that projects are usually very bulky and a lot of time is required to go through them so, there is a need to devise ways to do a rapid but comprehensive review. He requested the newly elected NBC members to join the next REC meetings so that they can train themselves in the review process and be part of the REC.

Dr. Saima Pervez raised a query that her institute (Shifa international) received a letter from NBC that projects should be sent to NBC for ethical review and clearance along with project processing fee. She informed that many a times Shifa International receives foreign funding for their research studies and these studies are approved by their IRB, so, do they still need to get NBC clearance. Dr. Asim Ahmed clarified that NBC approval is required in 3 conditions (1) Projects that are to be conducted in 2 or more provinces of Pakistan. (2) Projects that are to be done all over the country. (3) Projects that are internationally funded. NBC is the only gazette notified body of Pakistan and all above type of projects need to be sent to NBC for approval irrespective of their approval from IRB. He informed that a notification by the Director General, Ministry of Health has already been issued in this regard to almost all medical institutions and universities in the country.

Dr Farah Qadir suggested that NBC should have its news letter, that should be circulated to all institutions for creating awareness regarding NBC. Dr. Amir Jafery raised concern that many institutions in the country do not know if there is any NBC, therefore it needs to be more visible. Prof. Dr. Munir A Saleemi suggested that NBC Secretariat should send repeated reminders to all institutions to comply with the instructions of the Ministry of Health and send above mentioned category of projects for review and clearance to NBC. Dr. Farhat Moazam supported the suggestion made by Dr Munir A Saleemi and said that reminders should be sent to institutes and it’s their moral obligation to send all above types of projects to NBC. She however clarified that NBC does not review institutional funded projects which are being done within that institute.
Maj Gen (Retd). Dr. Abdul Khaliq Naveed showed concern that Higher Education Commission (HEC) funds projects worth billion of rupees but there is no member from HEC on NBC. It was decided that a representative from HEC should be added as Ex-officio member,

**Decision:**

1. Secretariat should send reminders to various institutions in the country to send their following category projects for NBC clearance. (1) Projects that are to be conducted in 2 or more provinces of Pakistan. (2) Projects that are to be done in all Provinces, all over the country. (3) Projects that are internationally funded.

2. NBC Secretariat should invite Higher Education Commission to join as ex-officio member.

3. Four newly elected members (Dr Farkhanda, Dr Saima, Dr Ambreen Munir, Dr Salman Ahmed Tipu) agreed to be the members of Research Ethics Committee and to participate in the project review process.

**Agenda item 6: Briefing on Health Care Ethics Sub-committee (HCEC) of NBC**

Dr Farhat Moazam, Chair Health Care Ethics Committee (HCEC), presented progress report on HCEC activities and provided some general information to new members. She informed that HCEC focuses on ethics education – through ethics workshops for PBCs and national institutions. Dr Moazam stated that HCEC has developed guidelines for introducing ethics in the curriculum of undergraduate dental and medical students and has also developed a handbook after an intensive exercise of 2.5 years to help introduce ethics in the undergraduate curriculum through PMDC.

Dr Moazam pointed out that despite repeated reminders; the representative of PMDC does not regularly show up in the HCEC meetings. She said that although guidelines and booklet are ready and have been sent to PMDC but there is no response from PMDC as yet. She mentioned that Dr Hafizullah had promised to present these to their committee but again there is no response from Dr. Hafizullah except that the document has been sent to relevant people. Maj Gen (Retd.) Abdul Khalid Naveed informed that the issue is under process in PMDC and this can be minuted in this meeting.
Agenda item 7: Progress on Provincial Bioethics Committees (PBCs).

Dr. Muhammad Arif Munir informed the house that as per decision of the last NBC meeting, Dr Farooq Azam Jan, DGHS Balochistan will follow with Secretary Health regarding notification of the provincial PBC Balochistan and likewise it was also decided that PBC Sindh has to be notified and will include Members from outside Karachi also.

The chair then invited each provincial representative to provide a progress report.

7.1. Progress on PBC-Punjab

Progress on PBC-Punjab was presented by Dr. Abdul Majeed Akhtar (representative of DGHS Punjab). He informed that in the existing list of the members, they also included a Member from World Health Organization. The subcommittees (REC and HCEC) have been formed and each has 6-members from various disciplines. The 1st meeting is planned after Ramadan i.e. August/Sept. Regarding ToRs of PBC; he said that NBC-TORs will be adopted. He further informed that PBC website is also being developed and that he will inform NBC about its progress. Dr. Farhat Moazam said that HCEC in PBC should work towards education in clinical ethics and suggested that there are many fellows and diploma holders in ethics in Punjab and these persons can be taken as members of Punjab HCEC. Dr. Abdul Majeed agreed to this suggestion.

7.2. Progress on PBC-Baluchistan

Progress for PBC-Baluchistan was presented by Dr. Farooq Azam Jan. He told NBC members that they have not yet been able to formulate PBC due to frequent changes in the bureaucracy. However, he mentioned that sitting secretary is now taking interest in the matter and he has given suggestions to incorporate members from Atomic Energy Commission. Dr Abdul Razak Sabir said that there is a need to add people from Khuzdar, Sibi and Loralai also in the Provincial Bioethics Committee. He suggested that Deans of the Social Sciences Departments of the Universities can be included as members of PBC.

Dr. Farooq Azam informed that PBC membership from very far flung areas within Balochistan may be excluded as it will be difficult for the Provincial committee to manage their TA/DAs for meetings. Dr. Amir Jafery responded that Balochistan might not have funds right now for which they should get this money from their development budget but with the passage of time they could generate funds through ERC project review fees. Dr. Farhat Moazam suggested Dr
Farooq Azam to coordinate with Dr Huma Qureshi, Member Secretary NBC to discuss the issues of funding.

Dr Farooq Ahmed Jan however, ensured that he will try to resolve the issue of the establishment/notification of PBC within this week and shall report to NBC accordingly. Dr. Farhat Moazam said that NBC can offer technical help to train people from Quetta on bioethics, to which Dr Farooq agreed.

Decision:

1. Dr Farooq Azam Jan will follow with Secretary Health regarding notification of the provincial PBC and inform the NBC Secretariat.

2. For funding to conduct provincial bioethics committee meetings the provincial health department should fund them their own budget but for the time being. Dr Farooq Azam may discuss this with Dr Huma Qureshi, Member Secretary NBC.

3. Dr Farooq will send a request for training in bioethics to NBC Secretariat and this activity shall be funded through NBC/PMRC

7.3. Progress on PBC-Sindh

Progress for PBC-Sindh was presented by Dr. Muhammad Saleem Memon. He informed the members that PBC-Sindh has been constituted but they want to add some members with medico legal background to handle the issues of clinical and research ethics. Dr. Farhat Moazam informed the members that the size of PBC is entirely up to the province but all committees should try to have members who have bioethics background, and to this Dr. Asim Ahmed also agreed. Regarding the TORS, Dr Saleem Memon said that they have adopted the NBC ToRs. Dr. Memon requested for a training workshop on bioethics in LUMHS with the support from NBC, to for which he will send a written request.

Decision:

1. Dr Saleem Memon will send a written request to NBC Secretariat regarding holding a workshop in LUHMS.

2. PBC Sindh to have maximum members who have been trained in bioethics to ease its working
3. Dr Saleem Memon will draft the ToRs of PBC Sindh in line with the ToRs of NBC and share with the NBC Secretariat

7.4. Progress on PBC AJK: The representative of Director General Health, AJK, Dr. Khawaja Tahir Aziz, informed the house that due to the retirement of Dr Mukhtar, meetings of the Regional and Institutional Bioethics Committees have not yet been held. He however, ensured the house that he will discuss the matter with the DGHS, AJK and will hold meetings and share the minutes with NBC. He also requested NBC to hold another Clinical Ethics Workshop in AJK, which was agreed to subject to receipt of a written request from AJK.

Decision:

1. Dr Khawaja Tahir Aziz will hold the meetings of Regional and Institutional Bioethics Committees and share the schedule with NBC Secretariat.

2. He will send a written request for holding a clinical ethics workshop in AJK

7.5. Progress on PBC- KPK
Due to the absence of Khyber Puktoonkhwa representatives there was no PBC progress report from the province.

7.6. Progress on PBC-Gilgit-Baltistan
Progress on the matter of PBC-Gilgit/Baltistan was presented by Mr. Rasheed Ali, Secretary Health and Population Welfare Department. He told NBC members that in Gilgit-Baltistan there is no medical university or tertiary care hospital. He also informed the house that there is very little research being done and that too is done by the CPSP fellows. He stated that there is no Director General in the region but the focal person is the Director Administration who looks after the policies of the province and this person will be the focal person for NBC. Mr Rasheed Ali however, showed his willingness to work with NBC and to develop regional bioethics committee. Due to such a fragile health system in GB, the members suggested that at this stage Regional Bioethics Committee is not required but GB should start educating and sensitizing healthcare workers regarding bioethics education in secondary health care facilities. Dr. Rasheed Ali agreed to this and requested NBC to hold workshop in Gilgit-Baltistan, which was agreed provided a formal request to NBC is sent.
Decision:

1. Gilgit-Baltistan should start educating and sensitizing healthcare workers regarding bioethics education at secondary health care level

2. Secretary GB will send a written request to NBC for holding a capacity building workshop in ethics in Gilgit-Baltistan.

Agenda item 8: Progress on development of Guidelines on storage and transportation of biological material within the country and abroad

Dr. Aasim presented progress regarding the guidelines on storage and transportation of export of human biological material. He informed the house that he along with 2 co-opted members (Safia Bibi and Taranum Ruba Siddiqui) has developed a review type document on this issue and they can work further on it to develop a comprehensive set of guidelines. He invited NBC members to join them in this task. Dr Moazam appreciated the efforts of the group but suggested that the draft needs to be modified in the light of comments from NBC. She proposed formulation of a committee from among NBC Members (in addition to Ms Safia and Tarranum Ruba) to work with Dr Aasim Ahmad in refining the guidelines. Prof. Saleemi and five new members volunteered to join the group.

Dr. Muhammad Arif Munir informed the house that that Government is very serious towards the development of these guidelines and that PMRC has already been approached by the representatives from Foreign Office, conveying the urgency of the issue.

Decision:

A committee comprising of the following Members is formulated to work with Dr Aasim Ahmad on the development of guidelines on “Storage and Transport of Human Biological Material”:

1. Dr Munir A Saleemi
2. Dr Saima Pervez Iqbal
3. Dr. Farkhanda Ghafoor
4. Dr. Ambreen Munir
5. Dr. Salman Ahmed Tipu
6. Dr Jamshaid Akhtar

Agenda item 9: Any Other Business

Dr. Aamir Jafarey informed the members that he is selected as a non-voting member of the World Congress on Bioethics (WCB) steering committee and. He also informed that Dr. Farhat
Moazam represented Pakistan in the last WCB at Mexico. Dr. Aamir mentioned that WCB has sent him a survey form to identify themes for the next Global Summit for Ethics to be held in 2016. He said that he has forwarded the same to NBC Secretariat for circulation to all Members. He requested the Members to fill the “Form” and send it to WCB.

Dr. Amir Jafery raised the point that there should be some credit hours for the participants and facilitators of bioethics workshops that NBC holds. Maj. Gen. (Retd.) Abdul Khalid Naveed informed the house that RIPHAH University is accredited to give CMEs and he offered to affiliate NBC with this university to assign CMEs to NBC workshops.

**Decision:**

NBC Secretariat will circulate to all NBC Members the survey form received from the World Congress on Bioethics to identify themes for the next Global Summit for Ethics to be held in 2016.

NBC should explore other public and private universities that can credit CME’s, meanwhile NBC may also write a letter to RIPHAH University to find out how to do it.

**Agenda Item 10: Next NBC Meeting**

It was decided that the next NBC meeting will be held in Islamabad in the last week of September (preferably on 30th September 2015)

The meeting ended with a vote of thanks by Dr. Aasim Ahmad, Chair NBC.

Dr Aasim Ahmad
Chairperson REC/Chair NBC
03 April 2014

Secretary
Ministry of NHSR&C